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(5) Hepatitis A vaccines (Item XIII of the Table) are included on the Table as of December 1, 2004.

(6) Trivalent influenza vaccines (Included in item XIV of the Table) are included on the Table as of July 1, 2005. All other seasonal influenza vaccines (Item XIV of the Table) are included on the Table as of November 12, 2013.

(7) Meningococcal vaccines and human papillomavirus vaccines (Items XV and XVI of the Table) are included on the Table as of February 1, 2007.

(8) Other new vaccines (Item XVII of the Table) will be included in the Table as of the effective date of a tax enacted to provide funds for compensation paid with respect to such vaccines. An amendment to this section will be published in the FEDERAL REGISTER to announce the effective date of such a tax.

[82 FR 6299, Jan. 19, 2017, as amended at 86 FR 68427, Dec. 2, 2021]

PART 110—COUNTERMEASURES INJURY COMPENSATION PROGRAM

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AUTHORITY: 42 U.S.C. 247d–6e.

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Subpart A—General Provisions

§ 110.1 Purpose.

This part implements the Public Readiness and Emergency Preparedness Act (PREP Act), which amended the Public Health Service Act (herein after ''PHS Act'' or ''the Act'') by including section 319F–3, and section 319F–4 entitled ''Covered Countermeasure Process.'' Section 319F–4 of the PHS Act directs the Secretary of Health and Human Services, following issuance of a declaration under section 319F–3(b), to establish procedures for the Countermeasures Injury Compensation Program (herein after ''CICP'' or ''the Program'') to provide medical and lost employment income benefits to certain individuals who sustained a covered injury as the direct result of the administration or use of a covered countermeasure consistent with a declaration issued pursuant to section 319F–3(b), or in the good faith belief that administration or use of the covered countermeasure was consistent with a declaration. Also, if the Secretary determines that an individual died as a direct result of a covered injury, the Act provides for certain survivors of that individual to receive death benefits.

§ 110.2 Summary of available benefits.

(a) The Act authorizes three forms of benefits to, or on behalf of, requesters determined to be eligible by the Secretary:

(1) Payment or reimbursement for reasonable and necessary medical services and items to diagnose or treat a covered injury, or to diagnose, treat, or prevent its health complications, as described in § 110.31.

(2) Lost employment income incurred as a result of a covered injury, as described in § 110.32.

(3) Death benefits to certain survivors if the Secretary determines that the death of the injured countermeasure recipient was the direct result of a covered injury, as described in § 110.33.

(b) In general, the benefits paid under the Program, are secondary to any obligation of any third-party payer to provide or pay for such benefits. The benefits available under the CICP usually will be paid only after the requester has in good faith attempted to obtain all other available coverage from all third-party payers with an obligation to pay for or provide such benefits (*e.g.*, medical insurance for medical services or items, workers' compensation program(s) for lost employment income). However, as provided in § 110.84, the Secretary has the discretion to pay benefits under this Program before a potential third-party payer makes a determination on the availability of similar benefits and has the right to later pursue a claim against any third-party payer with a legal or contractual obligation to pay for, or provide, such benefits.

§ 110.3 Definitions.

This section defines certain words and phrases found throughout this part.

(a) *Act* or *PHS Act* means the Public Health Service Act, as amended.

(b) *Alternative calculation* means the calculation used in § 110.82(c) of this part for the death benefit available to dependents younger than 18 years old at the time of payment.

(c) *Approval* means a decision by the Secretary or her designee that the requester is eligible for benefits under the Program.

(d) *Benefits* means payments and/or compensation for reasonable and necessary medical expenses or provision of services described in § 110.31, lost employment income described in § 110.32, and/or payment to certain survivors of death benefits described in § 110.33.

(e)(1) *Child* means any natural, illegitimate, adopted, posthumous child, or stepchild of a deceased injured countermeasure recipient who, at the time of the countermeasure recipient's death is:

(i) 18 years of age or younger; or

(ii) Between 19 and 22 years of age and a full-time student; or

(iii) Incapable of self-support due to a physical or mental disability.

(2) *Posthumous child* means a child born after the death of the parent.

(3) *Stepchild* means a child of an injured countermeasure recipient's spouse but who is not the child of the injured countermeasure recipient. For a stepchild to be eligible for survivor death benefits under the Program, the stepchild's parent must have been married to the injured countermeasure recipient at the time of that injured countermeasure recipient's death, and the stepchild must have been supported by the injured countermeasure recipient.

(f) *Covered Countermeasure* means the term that is defined in section 319F–3(i)(1) of the PHS Act and described in a declaration issued under section 319F–3(b) of the PHS Act (42 U.S.C. 247d–6d(i)(I), (b)). To be a covered countermeasure for purposes of this part, the countermeasure must have been administered or used pursuant to the terms of a declaration, or in a good faith belief of such; and

(1) Administered or used within a State (as defined in §110.3(bb)), or otherwise in the territory of the United States; or

(2) Administered to, or used by, otherwise eligible individuals—

(i) At American embassies or military installations abroad (such as military bases, ships, and camps); or

(ii) At North Atlantic Treaty Organization (NATO) installations (subject to the NATO Status Agreement) where American servicemen and servicewomen are stationed.

(g) *Covered Injury* means death, or a serious injury as described in §110.3(z), and determined by the Secretary in accordance with §110.20 of this part to be:

(1) An injury meeting the requirements of a Covered Countermeasures Injury Table, which is presumed to be the direct result of the administration or use of a covered countermeasure unless the Secretary determines there is another more likely cause; or

(2) An injury (or its health complications) that is the direct result of the administration or use of a covered countermeasure. This includes serious aggravation caused by a covered countermeasure of a pre-existing condition.

(h) *Declaration* means a recommendation issued by the Secretary under section 319F–3(b) of the PHS Act (42 U.S.C. 247d–6d(b)), for the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures, following her determination that a specific disease, condition, or threat represents a public health emergency or a credible risk of a future public health emergency.

(i) *Dependent* means, for purposes of lost employment income benefits, a person whom the Internal Revenue Service would consider to be the injured countermeasure recipient's dependent at the time the covered injury was sustained. For purposes of survivor death benefits, *dependent* means a person whom the Internal Revenue Service would consider to be the deceased injured countermeasure recipient's dependent at the time the covered injury was sustained, and who is younger than the age of 18 at the time of filing the Request Form.

(j) *Disapproval* means a decision by the Secretary that the individual requesting benefits is not eligible to receive benefits under the Program for the specified injury that is the basis of the Request for Benefits.

(k) *Effective period of the declaration* means the time span specified in a declaration, or as amended by the Secretary.

(l) *Federal Employees' Compensation Act (FECA) Program* means the workers' compensation benefits program for civilian officers and employees of the Federal Government established under 5 U.S.C. 8101 *et seq.* as amended, and implemented by the United States Department of Labor in regulations codified at 20 CFR part 10, as amended.

(m) *Healthcare provider* means an individual licensed, certified, or registered by an appropriate authority and who is qualified and authorized to

provide health care services, such as diagnosing and treating physical or mental health conditions, prescribing medications, and providing primary and/or specialty care.

(n) *Injured countermeasure recipient* means an individual:

(1) Who, with respect to administration or use of a covered countermeasure pursuant to a Secretarial declaration:

(i) Meets the specifications of the pertinent declaration; or

(ii) Is administered or uses a covered countermeasure in a good faith belief that he or she is in a category described by paragraph (1)(i) of this definition; and

(2) Sustained a covered injury as defined in § 110.3(g).

(3) If a covered countermeasure is administered to, or used by, a pregnant woman in accordance with paragraphs (1)(i) or (1)(ii) of this definition, any child from that pregnancy who survives birth is an injured countermeasure recipient if the child is born with, or later sustains, a covered injury (as defined in section 110.3(g)) as the direct result of the covered countermeasure's administration to, or use by, the mother during her pregnancy.

(o) *Lacks legal capacity* means legally incompetent to receive payment(s) of benefits, as determined under applicable law.

(p) *Medical records* means documentation associated with primary care, hospital in-patient and out-patient care, specialty consultations, and diagnostic testing and results.

(q) *Payer of last resort* means that the Program pays benefits secondary to all other public and private third-party payers who have an obligation to pay for such benefits.

(r) *Program* means the Countermeasures Injury Compensation Program (CICP).

(s) *PREP Act* means the *Public Readiness and Emergency Preparedness Act*, codified as sections 319F–3 and 319F–4 of the PHS Act (42 U.S.C. 247d–6d, 42 U.S.C. 247d–6e).

(t) *Public Safety Officers' Benefits (PSOB) Program* means the Program established under Subpart 1 of part L of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796 *et seq.*), as amended, and implemented by the United States Department of Justice in regulations codified at 28 CFR part 32, as amended.

(u) *Representative* (legal or personal) means someone other than the person for whom Program benefits are sought, and who is authorized to file the Request Package on the requester's behalf pursuant to § 110.44.

(v) *Requester* means an injured countermeasure recipient, or survivor, or the estate of a deceased injured countermeasure recipient (through the executor or administrator of the estate) who files a Request Package for Program benefits, or on whose behalf a Request Package is filed, under this part.

(w) *Request Form or Request for Benefits Form* means the document designated by the Secretary for applying for Program benefits under this part.

(x) *Request Package* means the Request Form, all documentation submitted by, or on behalf of, the requester, and all documentation obtained by the Secretary as authorized by, or on behalf of, the requester for determinations of Program eligibility and benefits under this part.

(y) *Secretary* means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority conferred on the Secretary under the PREP Act has been delegated.

(z) *Serious injury* means serious physical injury. Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

(aa) *Standard calculation* means the calculation used in § 110.82(b) of this part for the death benefit available to all eligible survivors (other than surviving dependents younger than the age of 18 who do not fit the definition of ''child'' under § 110.3(e)).

(bb) *State* means any State of the United States of America, the District of Columbia, United States territories, commonwealths, and possessions, the Republic of the Marshall Islands, the Republic of Palau, and the Federated States of Micronesia.

(cc) *Survivor* means a person meeting the requirements of §110.11 with respect to a deceased injured countermeasure recipient who died as a direct result of a covered injury.

(dd) *Table* or *Table of Injuries* means a Table of Covered Countermeasure Injuries to be included under Subpart K of this part, including the definitions and requirements set out therein.

(ee) *Third-party payer* means the United States (other than for payments of benefits under this Program) or any other third party, including but not limited to, any State or local governmental entity, private insurance carrier, or employer, any public or private entity with a legal or contractual obligation to pay for or provide benefits. The Program is the payer of last resort.

[75 FR 63675, Oct. 15, 2010, as amended at 76 FR 62308, Oct. 7, 2011]

Subpart B—Persons Eligible To Receive Benefits

§110.10 Eligible requesters.

(a) The following requesters may, as determined by the Secretary, be eligible to receive benefits from this Program:

(1) Injured countermeasure recipients, as described in §110.3(n);

(2) Survivors, as described in §110.3(cc) and §110.11; or

(3) Estates of deceased injured countermeasure recipients through individuals authorized to act on behalf of the deceased injured countermeasure recipient's estate under applicable State law (*i.e.*, executors or administrators).

(b) If a countermeasure recipient dies, his or her survivor(s) and/or the executor or administrator of his or her estate may file a new Request Package (or Request Package(s)) or amend a previously filed Request Package. A new Request Package may be filed whether or not a Request Package was previously submitted by, or on behalf of, the deceased injured countermeasure recipient, but must be filed within the filing deadlines described in §110.42. Amendments to previously filed Request Packages and the filing deadlines for such amendments are described in §110.46.

(c) The benefits available to different categories of requesters are described in §110.30.

§110.11 Survivors.

(a) *Survivors of injured countermeasure recipients who died as the direct result of a covered injury.* If the Secretary determines that an injured countermeasure recipient died as the direct result of a covered injury (or injuries), his or her survivor(s) may be eligible for death benefits.

(b) *Survivors who may be eligible to receive benefits and the order of priority for benefits.* (1) The Act uses the same categories of survivors and order of priority for benefits as established and defined by the PSOB Program, except as provided in paragraphs (b)(3), (4), and (5) of this section.

(2) The PSOB Program's categories of survivors (known in the PSOB Program as beneficiaries) and order of priority for receipt of death benefits are detailed under subpart 1 of part L of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796 *et seq.*), as amended, as implemented in 28 CFR part 32.

(3) In the PSOB Program, the person who is survived must have satisfied the eligibility requirements for a deceased public safety officer, whereas the person who is survived under this Program must be a deceased injured countermeasure recipient who would otherwise have been eligible under this part.

(4) Unlike the PSOB Program, if there are no survivors eligible to receive death benefits under the PSOB Program (as set forth in paragraph (b)(2) of this section), the legal guardian of a deceased minor who was a countermeasure recipient may be eligible as a survivor under this Program. Such legal guardianship must be determined by a court of competent jurisdiction under applicable State law.

(5) A surviving dependent younger than the age of 18 whose legal guardian opts to receive a death benefit under

the alternative calculation on the dependent's behalf will have the same priority as surviving eligible children under the PSOB Program (consistent with paragraph (b)(2) of this section) even if the dependent is not the surviving eligible child of the deceased countermeasure recipient for purposes of the PSOB Program. However, such a dependent may only be eligible to receive benefits under the alternative death benefits calculation, described in §110.82(c), and is not eligible to receive death benefits under the standard calculation described in §110.82(b). Death benefits paid under the alternative calculation will be paid to the dependents' legal guardian(s) on behalf of all such dependents.

(6) Any change in the order of priority of survivors or of the eligible category of survivors under the PSOB Program shall apply to requesters seeking death benefits under this Program on the effective date of the change, even prior to any corresponding amendment to this part. Such changes will apply to Request Packages pending with the Program on the effective date of the change, as well as to Requests filed after that date.

Subpart C—Covered Injuries

§ 110.20 How to establish a covered injury.

(a) *General.* Only serious injuries, as described in §110.3(z), or deaths are covered under the Program. In order to be eligible for benefits under the Program, a requester must submit documentation showing that a covered injury, as described in §110.3(g), was sustained as the direct result of the administration or use of a covered countermeasure pursuant to the terms of a declaration under section 319F–3(b) of the PHS Act (including administration or use during the effective period of the declaration) *or* as the direct result of the administration or use of a covered countermeasure in a good faith belief that it was administered or used pursuant to the terms of a declaration (including administration or use during the effective period of the declaration). A requester can establish that a covered injury was sustained by demonstrating to the Secretary that a Table injury occurred, as described in paragraph (c) of this section. In the alternative, a requester can establish that an injury was actually caused by a covered countermeasure, as described in paragraph (d) of this section. The Secretary may obtain the opinions of qualified medical experts in making determinations concerning covered injuries.

(b) *Table injuries.* A Table lists and explains injuries that, based on compelling, reliable, valid, medical and scientific evidence, are presumed to be caused by a covered countermeasure, and the time periods in which the onset (*i.e.*, first sign or symptom) of these injuries must occur after administration or use of the covered countermeasures. If an injury occurred within the listed time periods, and at the level of severity required, there is a rebuttable presumption that the covered countermeasure was the cause of the injury. A Table is accompanied by Qualifications and Aids to Interpretation which provide an explanation of the injuries listed on a Table. A requester may establish that a covered injury occurred by demonstrating that the countermeasure recipient sustained an injury listed on a Table, within the time interval defined by the Table's Definitions and Requirements. In such circumstances, the requester need not demonstrate the cause of the injury because the Secretary will presume, only for purposes of making determinations under this Subpart, that the injury was the direct result of the administration or use of a covered countermeasure. Even if the Table requirements are satisfied, however, an injury will not be considered a covered injury if the Secretary determines, based on her review of the evidence, that a source other than the countermeasure more likely caused the injury. In such circumstances, the Table presumption of causation will be rebutted.

(c) *Injuries for which causation must be shown (non-Table injuries).* If an injury is not included on a Table or if the injury does not meet the requirements set out for an injury that is listed on a Table (*e.g.*, the first sign or symptom of the injury did not occur within the time interval specified on the Table), the requester must demonstrate that

the injury occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. Temporal association between receipt of the countermeasure and onset of the injury is not sufficient by itself to prove that the countermeasure caused the injury.

(d) *Injuries resulting from the underlying condition for which the countermeasure was administered or used.* An injury sustained as the direct result of the covered condition or disease for which the countermeasure was administered or used, and not as the direct result of the administration or use of the covered countermeasure, is not a covered injury (*e.g.*, if the covered countermeasure is ineffective in treating or preventing the underlying condition or disease).

Subpart D—Available Benefits

§ 110.30 Benefits available to different categories of requesters under this Program.

(a) *Benefits available to injured countermeasure recipients.* A requester who is an injured countermeasure recipient may be eligible to receive either medical benefits or benefits for lost employment income, or both.

(b) *Benefits available to survivors.* A requester who is an eligible survivor of a deceased injured countermeasure recipient may be eligible to receive a death benefit if the death was caused by the covered injury or its health complications.

(c) *Benefits available to estates of deceased injured countermeasure recipients.* The estate of an otherwise eligible deceased injured countermeasure recipient may be eligible to receive medical benefits or benefits for lost employment income, or both, if such benefits were accrued during the deceased countermeasure recipient's lifetime, or at the time of death, as a result of a covered injury or its health complications, but have not yet been paid in full by the Program. Such medical benefits and benefits for lost employment income may be available regardless of the cause of death. The estate of the deceased injured countermeasure recipient may not receive a death benefit. Death benefits are only available to certain survivors.

§ 110.31 Medical benefits.

(a) Injured countermeasure recipients may receive payments or reimbursements for medical services and items that the Secretary determines to be reasonable and necessary to diagnose or treat a covered injury, or to diagnose, treat, or prevent the health complications of a covered injury. The Secretary may pay for such medical services and items in an effort to cure, counteract, or minimize the effects of any covered injury, or any health complication of a covered injury, or to give relief, reduce the degree or the period of disability, or aid in lessening the amount of benefits to a requester (*e.g.*, a surgical procedure that lessens the amount of time and expense for the treatment of a covered injury). The Secretary may make such payments or reimbursements if reasonable and necessary medical services and items have already been provided or if they are likely to be needed in the future. In making determinations about which medical services and items are reasonable and necessary, the Secretary may consider whether those medical services and items were prescribed or recommended by a healthcare provider, and may consider whether the applicable service or item is within the standard of care for that condition.

(b) To receive medical benefits for the health complications of a covered injury, a requester must demonstrate that the complications are the direct result of the covered injury. Examples of health complications include, but are not limited to, ill-effects that stem from the covered injury, an adverse reaction to a prescribed medication or as a result of a diagnostic test used in connection with a covered injury, or a complication of a surgical procedure used to treat a covered injury.

(c) The calculation of medical benefits available under this Program is described in §110.80. Although there are no caps on medical benefits, the Secretary may limit payments to the

amounts that she determines are reasonable for services and items considered reasonable and necessary. All payment or reimbursement for medical services and items is secondary to any obligation of any third-party payer to pay for or provide such services or items to the requester. As provided in §110.84, the Secretary retains the right to recover medical benefits paid by the Program to requesters if third-party payers are obligated to provide those benefits. Requesters are expected to make good faith efforts to pursue medical benefits and services from their primary payers. The Secretary reserves the right to disapprove medical benefits if the requester fails to do so.

(d) The Secretary may make payments of medical benefits or reimbursements of medical expenses described in this section to the estate of a deceased injured countermeasure recipient as long as such payments or expenses were accrued during the deceased injured countermeasure recipient's lifetime, or at the time of death, as the result of the covered injury or its health complications, and were not paid in full by the Program before the deceased injured countermeasure recipient died.

§110.32 Benefits for lost employment income.

(a) Requesters who are determined to be eligible for Program benefits as injured countermeasure recipients may be able to receive benefits for loss of employment income incurred as a result of a covered injury (or its health complications, as described in §110.31(b)). Compensation for lost wages is paid as a percentage of the amount of employment income earned at the time of injury and lost as the result of the covered injury or its health complications. The period of time requested for lost employment income benefits must be supported by the severity of the covered injury as demonstrated by the medical and employment records.

(b) The method and amount of benefits for lost employment income are described in §110.81. Benefits for lost employment income will be adjusted if there are fewer than ten days of lost employment income. Pursuant to law, and as described in §110.81, benefits provided for lost employment income may also be adjusted for annual and lifetime caps. Payment of benefits for lost employment income is secondary to any obligation of any third-party payer to pay for lost employment income or to provide disability or retirement benefits to the requester. It is the obligation of requesters to follow all specified procedures to apply for and acquire third-party benefits. The Secretary has the discretion to disapprove lost employment income benefits if the requester fails to do so. As provided in §110.84, the Secretary reserves the right to recover lost employment income benefits paid by the Program to requesters if third-party payers are obligated to provide those benefits.

(c) The Secretary does not require an individual to use paid leave (*e.g.*, sick leave or vacation leave) for lost work days. However, if an individual uses paid leave for lost work days, the Secretary will not consider those days to be days of lost employment income unless the individual reimburses the employer for the paid leave taken and the employer restores the leave that was used. This puts the individual back in the same position as if he or she had not used paid leave for the lost work days.

(d) The Secretary may pay benefits for lost employment income to the estate of a deceased injured countermeasure recipient as long as such benefits were accrued during the deceased injured countermeasure recipient's lifetime as the result of a covered injury or its health complications, and were not paid in full by the Program before the deceased injured countermeasure recipient died. However, no such lost employment income may be paid after the receipt, by the survivor or survivors of a deceased injured countermeasure recipient, of death benefits under §110.82.

§110.33 Death benefits.

(a) Eligible survivors may be able to receive a death benefit under this Program if the Secretary determines that an otherwise eligible countermeasure recipient sustained a covered injury and died as a direct result of the injury

or its health complications. The method and amount of death benefits are described in §110.82. As provided in §110.84, the Secretary retains the right to recover death benefits paid by the Program if third-party payers are obligated to provide those benefits. There are two different calculations for death benefits: the standard calculation and the alternative calculation.

(b) The standard calculation, described in §110.82(b), is based upon the death benefit available under the PSOB Program and is available to all eligible survivors with one exception (surviving dependents younger than the age of 18 who do not fit the definition of ''child'' under §110.3(e)). In the event that death benefits were paid under the PSOB Program with respect to the deceased injured countermeasure recipient, no death benefits may be paid under the standard calculation. In addition, death benefits under this standard calculation are secondary to disability benefits under the PSOB Program. If a disability benefit was paid under the PSOB Program, the amount of that disability benefit would be deducted from benefits payable under the standard calculation.

(c) The alternative calculation, described in §110.82(c), is based on the injured countermeasure recipient's employment income at the time of the covered injury. Payment under this calculation is only available to surviving dependents who are younger than the age of 18 at the time of payment. The legal guardian(s) of such surviving dependents must select the death benefit as calculated under this alternative calculation before it will be paid. Annual and lifetime caps may apply. The payment of a death benefit as calculated under this alternative calculation is secondary to other benefits paid or payable with respect to the deceased injured countermeasure recipient, namely:

(1) Compensation for loss of employment income (except for lost employment income under this Program);

(2) Death or disability benefits (*i.e.*, payments including, but not limited to, those under the PSOB Program) on behalf of the dependent(s) or their legal guardian(s);

(3) Retirement benefits on behalf of the dependent(s) or their legal guardians; or

(4) Life insurance benefits on behalf of the dependent(s).

Subpart E—Procedures for Filing Request Packages

§110.40 How to obtain forms and instructions.

(a) Copies of all necessary forms and instructions will be available:

(1) By writing to the Countermeasures Injury Compensation Program, Healthcare Systems Bureau, Health Resources and Services Administration, Parklawn Building, Room 11C–26, 5600 Fishers Lane, Rockville, MD 20857.

(2) By calling 1–888–ASK–HRSA. This is a toll-free number.

(3) By downloading them from the Internet at *http://www.hrsa.gov/countermeasurescomp/*. Click on the link to ''Forms and Instructions.''

(b) Before reviewing a Request for Benefits, the Secretary will assign a case number to the Request for Benefits and so inform the requester (or his or her representative) in writing. All correspondence to the requester (or his or her representative) about a specific Request for Benefits will be referenced by this case number.

§110.41 How to file a Request Package.

A Request Package comprises all the forms and documentation that are submitted to enable the Secretary to determine eligibility and calculate benefits. Request Packages may be submitted through the U.S. Postal Service, commercial carrier, or private courier service. The Countermeasures Injury Compensation Program will not accept Request Packages that are hand-delivered. Electronic submissions are not currently accepted, but may be in the future. The Program will publish a notice if electronic filing becomes available. Requesters (or their representatives) should send all forms and documentation to the Countermeasures Injury Compensation Program, Healthcare Systems Bureau, Health Resources and Services Administration, Parklawn Building, Room 11C–26,

5600 Fishers Lane, Rockville, MD 20857. All documentation to the Program must include the case number once one has been assigned to the requester.

§ 110.42 Deadlines for filing Request Forms.

(a) *General.* All Request Forms (or Letters of Intent, described in paragraph (b) of this section) must be filed within one year of the date of the administration or use of a covered countermeasure that is alleged to have caused the injury. If no previous Request Form (or Letter of Intent) has been filed, this deadline also applies to survivor(s) of an injured countermeasure recipient who is deceased, and to the executor or administrator of his or her estate. If a Request Form (or Letter of Intent) was previously filed, § 110.46 describes amendments to Request Packages.

(b) *Letters of Intent.* Until Request Forms and Instructions are available, requesters must file a Letter of Intent to File, in order to establish that their Requests for Benefits are timely filed within the one-year deadline. Directions for submitting a Letter of Intent (to file) are available on the Program's Web site at *http://www.hrsa.gov/countermeasurescomp/* or by calling 1–888–ASK–HRSA. Even once Request Forms are available, the Secretary has the discretion to accept Letters of Intent (to file) for purposes of meeting the filing deadline. However, when Request Forms and Instructions are available, all requesters who have submitted Letters of Intent must still file Request Forms as soon as possible.

(c) *Determination of proper filing.* The filing date is the date the Request Form (or Letter of Intent) is postmarked. A legibly dated receipt from a commercial carrier, a private courier service, or the U.S. Postal Service will be considered equivalent to a postmark. If and when Request Forms are accepted electronically, the filing date is the date the Request Form is submitted electronically. A Request Form will not be considered filed unless it has been completed (to the fullest extent possible) and signed by the requester or his or her personal or legal representative. After filing a Request Form within the governing filing deadline, a requester must update the Request Package to reflect new information as it becomes available (*e.g.*, copies of medical records generated after the initial submission of the Request Package).

(d) *Request Forms not filed within the one-year deadline.* If the Secretary determines that a Request Form or Letter of Intent was not filed within the governing filing deadline set out in this section, the Request Form (or Letter of Intent) will not be processed and the requester will not be eligible for benefits under this Program.

(e) *Constructive receipt.* The Secretary reserves the right to consider a legal claim filed with the Federal Government (*e.g.*, a Federal Tort Claims Act claim or a petition with the National Vaccine Injury Compensation Program) concerning an alleged injury resulting from the administration or use of a covered countermeasure to be a filing of a Request Form or Letter of Intent for purposes of determining the filing date under this Program. The date of such constructive filing will be the official filing date of the action, *i.e.*, when all applicable requirements for proper filing in that forum have been met.

(f) *Request Forms (or amendments to Request Forms) based on initial publication of a Table of Injuries or modifications to an existing Table.* The Secretary may publish a new Table (or Tables) by amendment(s) to subpart K of this part. The effect of such a new Table or amendment may enable a requester who previously could not establish a Table injury to do so. In such circumstances, within one year after the effective date of the establishment of, or amendment to, the Table, the requester must file a new Request Form if one was previously submitted and eligibility was denied or if one was not previously submitted. If the Secretary has not made a determination, she will automatically review any pending Request Forms in light of the new or amended Table(s).

[75 FR 63675, Oct. 15, 2010, as amended at 76 FR 62309, Oct. 7, 2011]

§ 110.43 Deadlines for submitting documentation.

(a) *Documentation for eligibility determinations.* A requester will satisfy the filing deadline as long as the signed Request Form is completed (to the fullest extent possible) and submitted within the governing filing deadline described in § 110.42. The Secretary generally will not begin review of a requester's eligibility until all the documentation necessary to make this determination has been submitted.

(b) *Documentation for benefits determinations.* Although the Secretary will accept documentation required to make benefits determinations (*i.e.*, calculate benefits available, if any) at the time the Request Form is filed or any time thereafter, requesters need not submit such documentation until they have been notified that the Secretary has determined eligibility. The Secretary will not generally begin review of the benefits available to a requester until the documentation necessary to make a benefits determination has been submitted.

§ 110.44 Legal or personal representatives of requesters.

(a) *Generally.* Persons other than a requester (*e.g.*, a lawyer, guardian, family member, friend) may file a Request Package on a requester's behalf as his or her legal or personal representative. A requester need not use the services of a lawyer to apply for benefits under this Program. A legal representative, or a personal representative (who does not need to be a lawyer) is only required, as described in this section, for requesters who are minors or adults who lack legal capacity to receive payment of benefits. In the event that a legal or personal representative files on behalf of a requester, the representative will be bound by the obligations and documentation requirements that apply to the requester (*e.g.*, if a requester is required to submit employment records, the representative must file the requester's employment records). The representative must also satisfy the requirements specific to representatives set out in this part. If a requester has a representative, the Program will generally direct all communications to the representative. However, the Secretary reserves the right of the Program to contact the requester directly if necessary, and to conduct a follow-up survey to determine the ability of the Program to meet requesters' needs.

(b) *Legal or personal representatives of legally competent adults.* A requester who is a legally competent adult *may* use a legal or personal representative to submit a Request Package on his or her behalf. In such circumstances, the requester must indicate on the Request Form that he or she is authorizing the representative to seek benefits under this Program on his or her behalf.

(c) *Legal or personal representatives of minors and adults who lack legal capacity to receive payment of benefits.* A requester who is a minor or an adult who lacks legal capacity to receive payment of benefits *must* use a legal or personal representative to apply for benefits under this Program on his or her behalf. In such circumstances, the representative must indicate, in the place provided on the Request Form, that the requester is a minor or an adult who lacks legal capacity to receive payment of benefits and that the representative is filing on behalf of the requester. In addition, before the requester will be paid by the Program, the representative must submit the documentation described in § 110.63. A minor who is emancipated, as determined by a court of competent jurisdiction, does not need a legal or personal representative to file a Request Form or Request Package on his or her behalf.

(d) *No payment or reimbursement for legal or personal representatives' fees or costs.* The Act does not authorize the Secretary to pay for, or reimburse, any fees or costs associated with the requester's use of the services of a legal or personal representative under this Program, including those of an attorney.

§ 110.45 Multiple survivors.

Multiple survivors of the same deceased injured countermeasure recipient may file Request Forms separately or together. Multiple survivors may also submit one set of any required documentation on behalf of all of the requesting survivors as long as such

documentation is identical for each survivor.

§ 110.46 Amending a Request Package.

(a) *Generally*. All requesters may amend their documentation concerning eligibility up to the time the Secretary has made an eligibility determination. Requesters are expected to submit additional medical records as they become available. Requesters also may amend their information or documentation concerning the calculation of benefits until the Secretary has made a benefits determination. Once an *eligibility* determination has been made, the Secretary will not accept additional documentation concerning eligibility, except as described in paragraphs (b) and (c) of this section. Once a *benefits* determination has been made, the Secretary will not accept additional documentation regarding the type or amount of benefits for that covered injury, except as described in paragraphs (b) and (c) of this section.

(b) *Requesters who are survivors*. If an injured countermeasure recipient submitted a Request Form within the filing deadline, but subsequently dies, or the executor or administrator timely filed on behalf of the estate, the survivor(s) may amend the previously filed Request Package at any time by filing a new Request Form in order to be considered for death benefits. Such an amendment can be filed regardless of whether the Secretary made an eligibility determination or paid benefits with respect to the deceased injured countermeasure recipient's Request Package. However, a survivor filing an amendment to a previously filed Request Package may only be eligible for benefits if the previously filed Request Package was filed within the governing filing deadline. All documentation that has already been submitted with respect to the deceased injured countermeasure recipient will be considered part of the survivor requester's Request Package, and he or she is not required to resubmit such documentation. Survivor requesters must also file an amendment to a Request Package if there is a change in the order of priority of survivors, as described in § 110.11.

(c) *Requests in which the benefits are sought for the estate of a deceased injured countermeasure recipient*. If an injured countermeasure recipient submitted a Request Form within the filing deadline, but subsequently dies before all due benefits are paid by the Program, the executor or administrator of his or her estate may amend his or her Request Package at any time in order for the estate to be considered for benefits. This opportunity to amend applies also if the Request Form was timely filed by a survivor. Such an amendment can be filed regardless of whether the Secretary made an eligibility determination or paid benefits with respect to the deceased injured countermeasure recipient's Request Package. However, the executor or administrator of the deceased injured countermeasure recipient's estate filing an amendment to a previously filed Request Package may only be eligible to receive benefits on behalf of the estate if the previously filed Request Package was filed within the governing deadline. All documentation that has already been submitted with respect to the deceased injured countermeasure recipient will be considered part of that person's Request Package, and the executor or administrator of the estate is not required to resubmit such documentation.

Subpart F—Documentation Required for the Secretary To Determine Eligibility

§ 110.50 Medical records necessary for the Secretary to determine whether a covered injury was sustained.

(a) In order to determine whether an injured countermeasure recipient sustained a covered injury, a requester must arrange for his or her medical providers to submit to the Program the following medical records, as defined in § 110.3(p):

(1) All medical records documenting medical visits, procedures, consultations, and test results that occurred on or after the date of administration or use of the covered countermeasure; and

(2) All hospital records, including the admission history and physical examination, the discharge summary, all physician subspecialty consultation reports, all physician and nursing

progress notes, and all test results that occurred on or after the date of administration or use of the covered countermeasure; and

(3) All medical records for one year prior to administration or use of the covered countermeasure as necessary to indicate an injured countermeasure recipient's pre-existing medical history.

(b) A requester may submit additional medical documentation that he or she believes will support the Request Package. Although generally not required if a Table injury was sustained, a requester may introduce additional medical documentation or scientific evidence in order to establish that an injury was caused by a covered countermeasure. Letters from treating physicians may be submitted as additional evidence, but may not substitute for the medical documentation required in paragraph (a) of this section.

(c) If certain medical records listed in paragraph (a) of this section are unavailable to the Program after the requester has made reasonable efforts to facilitate the records being sent to the Program, the requester must submit a statement describing the reasons for the records' unavailability and the efforts he or she has made to arrange for the health care providers to submit them. The Secretary has the discretion to accept this statement in place of the unavailable medical records. In this circumstance, the Secretary may attempt to obtain the records on the requester's behalf.

(d) In certain circumstances, the Secretary may require additional records to make a determination that a covered injury was sustained (*e.g.*, medical records more than one year prior to the date of administration or use of the covered countermeasure) or may determine that certain records described in paragraph (a) of this section are not necessary for an eligibility determination.

(e) Although the Secretary prefers to receive medical records directly from healthcare providers, she has the discretion to accept them from the requester.

§ 110.51 Documentation an injured countermeasure recipient must submit for the Secretary to make a determination of eligibility for Program benefits.

(a) An injured countermeasure recipient (or his or her legal or personal representative) must submit all of the following documentation in order for the Secretary to make a determination of eligibility:

(1) A completed and signed Request Form submitted within the filing deadline described in § 110.42; and

(2) Records sufficient to demonstrate that the injured countermeasure recipient used or was administered a covered countermeasure; and

(3) Records sufficient to demonstrate that the injured countermeasure recipient sustained a covered injury, as defined in § 110.3(g), in accordance with the requirements set forth in § 110.50; and

(4) A copy of each signed Authorization for Health Information Form authorizing the release of records to the Program that was sent by the requester to each healthcare provider instructing that the records be submitted directly to the Program.

(b) In certain circumstances, some of the above documentation may not be required, or additional documentation may be required, in which case the Secretary will so notify the requester. For example, the Secretary may require records sufficient to demonstrate that the injured countermeasure recipient was administered or used a covered countermeasure in accordance with the provisions of a Secretarial declaration, or in the good faith belief that it was so administered or used, if she is unable to determine this from the records submitted. In order to meet the specifications of a declaration, some individuals will need to show that the activity giving rise to the injury (*i.e.*, administration or use of the covered countermeasure) was authorized in accordance with the public health and medical response of the Authority Having Jurisdiction, as defined in the pertinent declaration, to prescribe, administer, deliver, distribute or dispense the covered countermeasure following a declaration of an emergency, as defined

in the pertinent declaration. For purposes of this part, this requirement can be satisfied by showing that the covered countermeasure was administered or used following the declaration of an emergency, as defined in the pertinent declaration, by an Authority Having Jurisdiction, as defined in the pertinent declaration either:

(1) Pursuant to a written agreement or other formal arrangement with an Authority Having Jurisdiction; or

(2) In accordance with the written recommendations of an Authority Having Jurisdiction.

§ 110.52 Documentation a survivor must submit for the Secretary to make a determination of eligibility for death benefits.

(a) A requester who is a survivor under § 110.11 must submit the following documentation in order for a determination of eligibility for a death benefit to be made:

(1) All of the documentation required for individuals in § 110.51. There is no need to duplicate documentation already submitted to satisfy the requirements of other subparts in this part. For example, if the deceased injured countermeasure recipient had previously filed, the documentation submitted does not have to be re-submitted; and

(2) A death certificate for the deceased countermeasure recipient. If a death certificate is unavailable, the requester must submit a letter providing the reasons for its unavailability. The Secretary has the discretion to accept other documentation as evidence that the injured countermeasure recipient is deceased; and

(3) Medical records sufficient to establish that the deceased injured countermeasure recipient died as the result of the covered injury or its health complications. Such medical records may be the same as those required under § 110.50. If an autopsy was performed, the requester must submit a complete copy of the final autopsy report; and

(4) Documentation showing that the requester is an eligible survivor, pursuant to § 110.11 (*e.g.*, birth certificate or marriage certificate); and

(5) Verification, on the place provided on the Request Form, either that there are no other eligible survivors (*e.g.*, for surviving eligible children, that there is no surviving spouse, no other surviving eligible children, and no other surviving dependents younger than the age of 18 who may be eligible for the death benefit under the alternative calculation) or that other eligible survivors exist (along with the information known about such survivors). Section 110.11 describes eligible survivors and the priorities of survivorship; and

(6) Even if a Request Form had previously been filed by the injured countermeasure recipient, the survivor(s) must submit a new Request Form.

(b) [Reserved]

§ 110.53 Documentation the executor or administrator of the estate of a deceased injured countermeasure recipient must submit for the Secretary to make a determination of eligibility for benefits to the estate.

(a) The executor or administrator of the estate of a deceased injured countermeasure recipient must submit the following documentation in order for a determination of eligibility for benefits to the estate to be made:

(1) All of the documentation required for individuals in § 110.51;

(2) A death certificate for the deceased injured countermeasure recipient. If a death certificate is unavailable, the executor or administrator must submit a letter providing the reasons for its unavailability. The Secretary has the discretion to accept other documentation as evidence that the injured countermeasure recipient is deceased; and

(3) Documentation showing that the individual is the executor or administrator of the estate of the deceased injured countermeasure recipient, *e.g.*, Letter of Administration issued by a court of competent jurisdiction; and

(4) Even if a Request Form had previously been filed by the injured countermeasure recipient, the executor or administrator of the estate must submit a new Request Form.

(b) [Reserved]

Subpart G—Documentation Required for the Secretary To Determine Program Benefits

§ 110.60 Documentation a requester who is determined to be eligible must submit for the Secretary to make a determination of medical benefits.

(a) A requester determined by the Secretary to be eligible for Program benefits and who seeks payment or reimbursement for medical services or items must provide the following, in addition to the documentation submitted under subpart F of this part:

(1) *List of third-party payers.* The requester must submit a list of all third-party payers that may have an obligation to pay for or provide any medical services or items to the injured countermeasure recipient for which payment or reimbursement is being sought under this Program. Such third-party payers may include, but are not limited to, health maintenance organizations, health insurance companies, workers' compensation programs, Medicare, Medicaid, Department of Veterans Affairs, military treatment facilities (MTFs), and any other entities obligated to provide medical services or items or reimburse individuals for medical expenses. Such a list must include the injured countermeasure recipient's account numbers and other applicable information. If the requester knows of no such third-party payer, he or she must so certify in writing. If the requester becomes aware that a third-party payer may have such an obligation, the requester must inform the Secretary within ten business days of becoming aware of this information, even after benefits have been paid by the Program.

(2) *Documents for medical services or items provided since the onset of the covered injury.* A requester seeking payment or reimbursement for medical services or items already provided for a covered injury or its health complications must submit an itemized statement from each healthcare provider or entity (*e.g.*, clinic, hospital, doctor, or pharmacy) and third-party payer listing the services or items provided to diagnose or treat the covered injury or its health complications and the amounts paid or expected to be paid by third parties for such services or items (*e.g.*, an Explanation of Benefits from the individual's health insurance company). If no third-party payer has an obligation to pay for or provide such services or items, the requester must so certify in writing and submit an itemized list of the services or items provided (including the total cost of such services or items). To assist the Secretary in making a determination as to whether such services or items were reasonable and necessary to diagnose or treat a covered injury, or to diagnose, treat, or prevent its health complications, the requester may submit, in addition to the required medical records, documentation showing that a health-care provider prescribed or recommended such services or items. The medical records must support the requested services and items.

(3) *Documents for medical services and items expected to be provided in the future.* A requester seeking payments for medical services or items resulting from a covered injury or its health complications expected to be provided in the future must submit a statement from each healthcare provider (*e.g.*, a treating neurologist for neurological issues and a treating cardiologist for cardiac issues) describing those services and items that appear likely to be needed to diagnose or treat the covered injury, or to diagnose, treat, or prevent its health complications, in the future. The medical records must support the requested services and items. A requester must submit documentation, if available, concerning the likely cost of, and the amount expected to be covered by third-party payers for, such services or items. Consent for the Program to communicate directly with the healthcare providers may also be required.

(b) [Reserved]

§ 110.61 Documentation a requester who is determined to be eligible must submit for the Secretary to make a determination of lost employment income benefits.

(a) A requester determined by the Secretary to be eligible for Program benefits and who seeks benefits for lost employment income must provide, in

addition to the documentation submitted under subpart F of this part, documentation describing:

(1) The number of days (including partial days) of work missed by the injured countermeasure recipient as a result of the covered injury or its health complications for which employment income was lost (*e.g.*, time sheet from the relevant pay period(s) showing work days missed). As stated in §110.32(c), days for which an individual used paid leave will be considered days of work for which employment income was received and, therefore, would not qualify for lost employment income benefits. However, if the injured countermeasure recipient reimburses the employer for the paid leave taken and the employer restores the leave that was used, the individual may be eligible for lost employment income benefits for those days; and

(2) The injured countermeasure recipient's gross employment income at the time the covered injury was sustained (*e.g.*, the individual's Federal tax return or pay stub(s) from all employers at the time of the covered injury); and

(3) Whether the injured countermeasure recipient had one or more dependents at the time the covered injury was sustained (*e.g.*, the individual's Federal tax return at the time of the covered injury); and

(4) A list of all third-party payers that have paid, or that may be obligated to pay, benefits to the injured countermeasure recipient for loss of employment income or provide disability and/or retirement benefits for which payment or reimbursement is being sought under this Program (e.g., State workers' compensation programs, disability insurance programs, Uniform Services Retirement Board determinations, Department of Veterans Affairs determinations, etc.). A requester must submit documentation, if available, concerning the amount of such payments or benefits paid or payable to, or on behalf of, the injured countermeasure recipient by third-party payers. If the requester knows of no such third-party payer, he or she must so certify in writing. If, at any time, the requester becomes aware that a third-party payer may have such an obligation, the requester must inform the Secretary within ten business days of becoming aware of this information, even after benefits have been paid by the Program.

(b) [Reserved]

§ 110.62 Documentation a requester who is determined to be an eligible survivor must submit for the Secretary to make a determination of death benefits.

(a) A requester determined by the Secretary to be an eligible survivor and who seeks a death benefit under §110.82(b) (the standard calculation) must provide, in addition to the documentation submitted under subpart F of this part, a written certification informing the Secretary whether a disability or death benefit was paid or payable under the PSOB Program with respect to the deceased injured countermeasure recipient. If such benefit was provided, the requester must submit documentation showing the amount of the benefit paid by the PSOB Program. If the deceased injured countermeasure recipient was covered under the PSOB and no such benefit was, or will be provided, the certification must explain whether any survivors are eligible for a death benefit under the PSOB Program and, if so, whether a death benefit may be paid or payable under the PSOB Program.

(b) The legal guardian seeking a death benefit under §110.82(c) (the alternative calculation) on behalf of a dependent younger than the age of 18 determined by the Secretary to be an eligible survivor must provide, in addition to the documentation submitted under Subpart F of this part, the following:

(1) Documentation showing that the deceased injured countermeasure recipient is survived by one or more dependents younger than the age of 18. Such documentation must show the date of birth of all such dependents (*e.g.*, copies of birth certificates);

(2) Documentation showing that the requester is the legal guardian of all of the dependents described in paragraph (b)(1) of this section, as required under §110.63(a). If multiple dependents have different legal guardians, the legal guardian of each of the dependents must submit such documentation;

(3) A written selection by each legal guardian, on behalf of all of the dependents described in paragraph (b)(1) of this section for whom he or she is the legal guardian, to receive proportional death benefits under the alternative calculation as described in §110.82(c), in place of proportional benefits available under the standard calculation as described in §110.82(b). Written selections are described in §110.82(c)(1);

(4) Documentation showing the deceased injured countermeasure recipient's gross employment income at the time the covered injury was sustained (*e.g.*, the decedent's Federal tax return or pay stub(s) from all employers at the time of the covered injury); and

(5) A description of all third-party payers that have paid for, or that may be required to pay for, the benefits described in §110.82(c)(3)(i). This description must include the amount of such benefits that have been paid or that may be paid in the future. If the representative knows of no such third-party payer, he or she must so certify in writing. If, at any time, the representative becomes aware that a third-party payer may have such an obligation, he or she must inform the Secretary within ten business days of becoming aware of this information, even after benefits have been paid by the Program.

§110.63 Documentation a legal or personal representative must submit when filing on behalf of a minor or on behalf of an adult who lacks legal capacity to receive payment of benefits.

Before benefits will be paid by the Program to an eligible requester who is a minor or an adult who lacks legal capacity to receive payment of benefits, his or her legal or personal representative must submit the following, in addition to the documentation required under Subpart F of this part and, as applicable, §§110.60–110.62:

(a) For an eligible requester who is a minor:

(1) Documentation showing that the requester is a minor (*e.g.*, birth certificate); and

(2) Documentation showing that the representative is the legal guardian of the property or estate of the minor (*e.g.*, appointment of guardianship by a court of competent jurisdiction). If a minor has more than one legal guardian, this documentation is required only of one legal guardian. In the alternative, documentation showing that the minor is considered emancipated under applicable State law. In accordance with §110.83(b), the Program reserves the right to waive the requirement of documentation of guardianship for good cause.

(b) For an eligible requester who is an adult who lacks legal capacity to receive payment of benefits:

(1) Documentation showing that the requester is an adult who lacks this legal capacity (e.g., declaration of legal incapacity issued by a court of competent jurisdiction, or comparable documentation); and

(2) A decree by a court of competent jurisdiction establishing a guardianship or conservatorship of the requester's estate under applicable State law, or durable power of attorney, if applicable. In accordance with §110.83(b), the Program reserves the right to waive this requirement for good cause.

Subpart H—Secretarial Determinations

§110.70 Determinations the Secretary must make before benefits can be paid.

Before the Secretary will pay benefits under this Program, she must determine that:

(a) The requester or his or her representative submitted a completed and signed Request Form within the governing filing deadline; and

(b) The requester meets the eligibility requirements set out in this part (including a determination that a covered injury was sustained); and

(c) The requester is entitled to receive benefits from the Program. In making this determination, the Secretary will decide the type(s) and amounts of benefits that will be paid to the requester.

§110.71 Insufficient documentation for eligibility and benefits determinations.

In the event that there is insufficient documentation in the Request Package

for the Secretary to make the applicable determinations under this part, the Secretary will so notify the requester, or his or her representative. The requester will be given 60 calendar days from the date of the Secretary's notification to submit the required documentation. If the requester is unable to provide the additional documentation, he or she may provide a written explanation of the reason(s) that the requested documentation is unavailable and the efforts the requester has made to obtain the documents. The Secretary may accept such a statement in place of the required documentation or disapprove the Request for Benefits due to insufficient documentation. If insufficient documentation is submitted in response to the Secretary's letter, the Secretary may disapprove the Request for Benefits.

§ 110.72 Sufficient documentation for eligibility and benefits determinations.

(a) *Eligibility determinations.* When the Secretary determines that there is sufficient documentation in the Request Package to evaluate a requester's eligibility, she will begin the review to determine whether the requester is eligible for Program benefits. If the Secretary determines that the requester is not eligible, the Secretary will inform the requester (or his or her representative) in writing of the disapproval, and the right to reconsideration of the determination, as described in subpart J.

(b) *Benefits determinations.* If the Secretary determines that the requester is eligible for benefits, she will, after receiving adequate documentation from the requester for a benefits determination, either calculate the amount and types of benefits, as described in subpart I of this part, or request additional documentation in order to calculate the benefits that can be paid (*e.g.*, an Explanation of Benefits from the requester's health insurance company, if none was submitted). As provided in subpart J, requesters have the right to reconsideration of the Secretary's determination of the category and amount of benefits payable under the Program.

(c) *Additional documentation required.* At any time after a Request Form has been filed, the Secretary may ask a requester to supplement or amend the Request Package by providing additional information or documentation.

§ 110.73 Approval of benefits.

When the Secretary has determined that benefits will be paid to a requester and has calculated the type and amount of such benefits, she will so notify the requester (or his or her representative) in writing. The Secretary will make payments in accordance with § 110.83. Once all benefits have been paid, the Request Package can no longer be amended (except for survivor benefits). The payment determination will constitute final agency action with regard to the particular countermeasure injury that is the subject of the Request for Benefits and payment (*i.e.*, the Request for Benefits is closed with regard to the injury that is the basis of the payment of benefits).

§ 110.74 Disapproval of benefits.

(a) If the Secretary determines that a requester is not eligible for payments under the Program, the Secretary will disapprove the Request for Benefits and provide the requester, or his or her representative, with written notice of the basis for the disapproval, and the right to reconsideration of the determination, as provided in § 110.90.

(b) The Secretary may disapprove a Request for Benefits even before the requester has submitted all the required documentation (*e.g.*, the Secretary may determine that a requester did not meet the filing deadline, or that a covered countermeasure was not used or administered).

(c) The Secretary may re-open a disapproved Request for Benefits on her own accord should medical or scientific evidence later become available to justify a re-determination of the disapproval of eligibility or payments. In extraordinary circumstances, to be determined at the Secretary's discretion, she may re-open a disapproved Request for Benefits even after the requester has exercised the right to reconsideration and the disapproval determination has been upheld in accordance with the procedures set out in § 110.90.

Subpart I—Calculation and Payment of Benefits

§ 110.80 Calculation of medical benefits.

In calculating medical benefits, the Secretary will take into consideration all reasonable costs for reasonable and necessary medical items and services to diagnose or treat a countermeasure recipient's covered injury, or to diagnose, treat, or prevent its health complications, as described in § 110.31. The Secretary will consider and may rely upon benefits documentation submitted by the requester (*e.g.*, bills, Explanation of Benefits, and cost-related documentation to support the expenses relating to the covered injury or its health complications), as required by § 110.60. The Secretary will make such payments only to the extent that such costs were not, and will not be, paid by any third-party payer and only if no third-party payer had or has an obligation to pay for or provide such services or items to the requester, except as provided in §§ 110.83(c) and 110.84. There are no caps on the benefits for reasonable and necessary medical expenses that may be provided under the Program.

§ 110.81 Calculation of benefits for lost employment income.

(a) *Primary calculation.* Benefits under this section may be paid for days of work lost as a result of a covered injury or its health complications if the injured countermeasure recipient lost employment income for the lost work days as reasonable based on the degree of injury or disability. As stated in § 110.32(c), days for which an individual used paid leave will be considered days of work for which employment income was received and, therefore, would not qualify for lost employment income benefits. However, if the injured countermeasure recipient reimburses the employer for the paid leave taken and the employer restores the leave that was used, the individual may be eligible for lost employment income benefits for those days;

(1) The Secretary will calculate the rate of benefits to be paid for the lost work days based on the injured countermeasure recipient's gross employment income, which includes income from self-employment, at the time he or she sustained the covered injury. The Secretary may not, except with respect to injured individuals who are minors, consider projected future earnings in this calculation.

(i) For an injured countermeasure recipient with no dependents at the time the covered injury was sustained, the benefits are 66⅔ percent of the individual's gross employment income at the time of injury.

(ii) For an injured countermeasure recipient with one or more dependents at the time the covered injury was sustained, the benefits are 75 percent of the individual's gross employment income at the time of injury; and

(iii) In the case of an injured countermeasure recipient who is a minor, the Secretary may consider the provisions of 5 U.S.C. 8113 (authorizing the FECA Program), and any implementing regulations, in determining the amount of payments under this section and the circumstances under which such payments are reasonable and necessary.

(b) *Adjustment for inflation.* Benefits for lost employment income paid under the Program that represent future lost employment income will be adjusted annually to account for inflation.

(c) *Limitations on benefits paid.* The Secretary will reduce the benefits calculated under paragraphs (a) and (b) of this section according to the limitations described in this paragraph (c):

(1) *Number of lost work days.* An injured countermeasure recipient will be compensated for ten or more days of work lost if he or she lost employment income for those days as a result of the covered injury (or its health complications). If the number of days of lost employment income due to the covered injury (or its health complications) is fewer than ten, the Secretary will reduce the number of lost work days by five days. If the injured countermeasure recipient lost employment income for a period of five days or fewer, no benefits for lost employment income will be paid. Lost work days do not need to be consecutive. Partial days of lost employment income may be aggregated to calculate the total number of lost work days. The Secretary has the discretion to consider

the reasonableness of the number of work days (or partial work days) lost as a result of a covered injury or its health complications in this calculation, and to consider alternative work schedules in determining the number of work days lost.

(2) *Annual limitation.* The maximum amount that an injured countermeasure recipient may receive in any one year in benefits for lost employment income under this Program is $50,000.

(3) *Lifetime limitation.* The maximum amount that an injured countermeasure recipient can receive during his or her lifetime in benefits for lost employment income under this Program is the amount of the death benefit calculated under the PSOB Program in the same fiscal year as the year in which this lifetime cap is reached. This amount is the maximum death benefit payable to survivors under this Program using the standard calculation described in §110.82(b). However, this lifetime cap does not apply if the Secretary determines that the countermeasure recipient has a covered injury (or injuries) meeting the definition of ''disability'' in section 216(i) of the Social Security Act, 42 U.S.C. 416(i).

(4) *Termination of payments.* The Secretary will not pay benefits for lost employment income after the injured countermeasure recipient reaches the age of 65.

(d) *Reductions for other coverage.* From the amount of benefits calculated under paragraphs (a), (b), and (c) of this section, the Secretary will make reductions:

(1) For all payments made, or expected to be made in the future, to the injured countermeasure recipient for compensation of lost employment income or disability or retirement benefits, by any third-party payer in relation to the covered injury or its health complications, consistent with §110.32(b); and

(2) So that the total amount of benefits for lost employment income paid to an injured countermeasure recipient under this Program, together with the total amounts paid (or payable) by third-party payers, as described in paragraph (d)(1) of this section, does not exceed 66⅔ percent (or 75 percent, if the injured countermeasure recipient had at least one dependent at the time the covered injury was sustained) of his or her employment income at the time of the covered injury for the lost work days.

(3) If an injured countermeasure recipient receives a lump-sum payment from any third-party payer under any obligation described in paragraph (d)(1) of this section, the Secretary shall consider such a payment to be received over a period of years, rather than in a single year. The Secretary has discretion as to how to apportion such payments over multiple years.

§110.82 Calculation of death benefits.

(a) *General.* (1) If the legal guardian(s) of dependents younger than 18 years of age does not file a written selection to receive death benefits under the alternative calculation, as described in paragraph (c)(1) of this section, or if the Secretary does not approve such a selection, the Secretary will pay proportionate death benefits under the standard calculation to all of the eligible survivors with priority to receive death benefits under the standard calculation, as described in §110.33(b) and paragraph (b) of this section.

(2) If the Secretary approves a written selection to receive benefits under the alternative calculation, as described in paragraph (c)(1) of this section:

(i) If no other eligible survivors are of equal priority to receive death benefits, the Secretary will pay a death benefit in an amount calculated under the alternative calculation to the aggregate of the dependents on whose behalf the election was filed; and

(ii) If other eligible survivors are of equal priority to receive death benefits as the dependents receiving death benefits under the alternative calculation, the Secretary will pay the other eligible survivors a proportionate amount of the death benefit available and calculated under the standard calculation. In such circumstances, the Secretary will pay the aggregate of the dependents receiving a death benefit under the alternative calculation a proportionate share of the benefits available under that calculation (in place of the

proportionate share of the death benefit that would be available under the standard calculation). For example, if a deceased countermeasure recipient is survived by a dependent ten year-old child and a spouse who is not the child's legal guardian (*e.g.*, the dependent child's parents were the deceased injured countermeasure recipient and his or her former spouse), the current surviving spouse would be able to receive his or her share of the death benefit under the standard calculation, and the dependent child's legal guardian, on behalf of the minor, would receive either the child's proportionate share of the death benefit under the standard calculation or the child's proportionate share of the death benefit available under the alternative calculation (if the legal guardian filed a written selection for such a death benefit and the Secretary approved the selection).

(b) *Standard calculation of death benefits.* (1) The maximum death benefit available under the standard calculation of death benefits (described in this paragraph) is the amount of the comparable death benefit calculated under the PSOB Program in the same fiscal year in which the injured countermeasure recipient died (regardless of whether the PSOB Program reduces the amount of its death benefits because of a limit in appropriations).

(2) No death benefit will be paid under the standard calculation if a death benefit is paid, or if survivors are eligible to receive a death benefit, under the PSOB Program with respect to the deceased injured countermeasure recipient.

(3) The death benefit will not be reduced under the standard calculation if a total and permanent disability benefit has been, or will be paid under the PSOB Program with respect to the deceased injured countermeasure recipient. However, the death benefit will be reduced if a temporary and partial disability benefit has been, or will be paid under the PSOB Program with respect to that individual. If the PSOB Program disability benefit paid was reduced because of a limitation on appropriations, a death benefit will be available under the standard calculation to the extent necessary to ensure that the total amount of disability benefits paid under the PSOB Program, together with the amount of death benefits paid under the standard calculation, equals the amount of the death benefit described in paragraph (b)(1) of this section.

(4) Under the standard calculation, death benefits will be paid in a lump sum.

(c) *Alternative calculation of death benefits available to surviving dependents younger than the age of 18.* If a deceased countermeasure recipient had at least one dependent who is younger than the age of 18 (and will be younger than the age of 18 at the time of the payment), the legal guardian(s) of all such dependents may request benefits under the alternative calculation described in this paragraph. To receive such a benefit, the legal guardian, on behalf of all such dependents for whom he or she is the legal guardian, must file a selection to receive benefits under the alternative calculation, as described in paragraph (c)(1) of this section, and the Secretary must approve such selection. If multiple dependents have different legal guardians, each legal guardian is responsible for requesting benefits under the standard calculation or for filing a selection for a death benefit under the alternative calculation. If a single dependent has more than one legal guardian, one legal guardian may file the selection. Payments made under the alternative calculation will be made to the legal guardian(s) of all of the dependents on behalf of all of those dependents until they reach the age of 18.

(1) *Selection of benefits under the alternative calculation.* Before a payment of a death benefit will be approved under the alternative calculation, the legal guardian(s) of the dependents for whom he or she is the legal guardian must file a written selection, on behalf of all such dependents, to receive a death benefit under the alternative calculation. If such a selection is approved by the Secretary, these dependents will be paid a proportionate share of the death benefit under the alternative calculation in place of the proportionate share of benefits that would otherwise be available to them under the standard calculation.

(2) *Amount of payments.* The maximum death benefit available under this paragraph is 75 percent of the deceased injured countermeasure recipient's income (including income from self-employment) at the time he or she sustained the covered injury that resulted in death, adjusted to account for inflation, except as follows:

(i) The maximum payment of death benefits that may be made on behalf of the aggregate of the dependents in any one year is $50,000;

(ii) All payments made under this paragraph will stop once the youngest of the dependents reaches the age of 18.

(3) *Reductions for other coverage.* The total amount of death benefits provided under the alternative calculation (described in this paragraph) will be reduced so that the total amount of payments made (or expected to be made) under obligations described in paragraph (c)(3)(i) of this section, together with the death benefits paid under the alternative calculation, is not greater than the amount of payments described in paragraph (c)(2) of this section. In other words, the total amount of death benefits paid to dependents under the alternative calculation may be reduced if third-party payers have paid (or are expected to pay) for certain benefits so that such dependents will receive a total sum (combining the death benefit under the alternative calculation and the actual and expected benefits covered by third-party payers) that is not greater than the death benefit that would be available under the alternative calculation if there were no third-party payer(s) to pay such benefits. The total amount of death benefits will *not* be reduced by lost employment income paid by the Program.

(i) The amount of death benefits paid under the alternative calculation will be reduced for all payments made, or expected to be made in the future, by any third-party payer for:

(A) Compensation for the deceased countermeasure recipient's loss of employment income on behalf of the dependents or their legal guardians(s) (but not any lost employment income benefits paid by the Program);

(B) Disability, retirement, or death benefits in relation to the deceased countermeasure recipient (including, but not limited to, death and disability benefits under the PSOB Program) on behalf of the dependents or their legal guardian(s); and

(C) Life insurance benefits on behalf of the dependents;

(4) *Timing of payments.* Payments made under this paragraph will be made on an annual basis, beginning from the time of the initial payment, to the legal guardian(s) on behalf of the aggregate of the dependents receiving the payment. In the year in which the youngest dependent reaches the age of 18, payments under this section will be paid on a *pro rata* basis for the period of time before that dependent reaches the age of 18. Once a dependent reaches the age of 18, the payments under this alternative calculation will no longer be made on his or her behalf. Because payments under the alternative calculation are to be made on behalf of dependents who are younger than the age of 18, if a dependent meets this requirement at the time of filing of the Request Form, but reaches the age of 18 (or is older than 18 years of age) at the time of the initial payment, no payment will be made to the dependent's legal guardian on his or her behalf under the alternative calculation.

§ 110.83 Payment of all benefits.

(a) The Secretary determines the mechanism of payment of Program benefits. She may choose to pay any benefits under this Program through lump-sum payments. If the Secretary determines that there is a reasonable likelihood that the payments of medical benefits, benefits for lost employment income, or death benefits paid under the alternative calculation (described in § 110.82(c)) will be required for a period in excess of one year from the date the Secretary determines the requester is eligible for such benefits, payments may be made through a lump-sum payment, the purchase of an annuity or medical insurance policy, establishment of a trust (including a U.S. grantor reversionary trust) or execution of an appropriate structured settlement agreement, at the Secretary's discretion. Payments, annuities, policies, or agreements must be actuarially determined to have a value

equal to the present value of the projected total amount of benefits that the requester is eligible to receive under §§ 110.80, 110.81, and 110.82. Lump sum payments will be made through an electronic funds transfer to an account of the requester.

(b) If the requester is a minor, the payment will be made on the minor's behalf to the account of the legal guardian of the estate or property of the minor. In accepting such payments, the legal guardian of a minor requester is obligated to use the funds for the benefit of the minor and to take any actions necessary to comply with State law requirements pertaining to such payments. If the requester is an adult who lacks the legal capacity to receive payment(s), the legal guardian must establish a guardianship or conservatorship of the estate account with court oversight, in accordance with State law, and payment will be made to that account. Documentation of guardianship (or conservatorship) is required for requesters who are minors or adults who lack legal capacity unless the Secretary waives this requirement for good cause.

(c) The Secretary has the discretion to make interim payments of benefits under this Program, even before a final determination as to the type(s) and total amount of benefits that will be paid. Interim payments will be made only in exceptional cases. The Secretary may, for example, make an interim payment of medical benefits that have been calculated before a final determination on benefits for lost employment income is completed, or of past medical benefits that have been calculated before a final calculation of future medical benefits is completed. The Secretary may make an interim payment even before a final eligibility or benefits determination is made (*e.g.*, if a piece of documentation has not been obtained because a person with a severe countermeasure-related injury is hospitalized, but all other documentation is consistent with the requester meeting the eligibility requirements). If such a requester's documentation is incomplete, the requester must submit the required documentation within the time-frame determined by the Secretary. The requester must agree that he or she will be obligated to repay the Secretary such benefits in the event that a Program payment is later determined to be incorrect. Any payments made on an interim basis will not entitle a requester to seek reconsideration of the Secretary's decision on these benefits until the Secretary makes a final benefits determination.

§ 110.84 The Secretary's right to recover benefits paid under this Program from third-party payers.

Upon payment of benefits under this Program, the Secretary will be subrogated to the rights of the requester and may assert a claim against any third-party payer with a legal or contractual obligation to pay for (or provide) such benefits and may recover from such third-party payer(s) the amount of benefits paid up to the amount of benefits the third-party payer has or had an obligation to pay for (or provide). In other words, the Secretary may pay benefits before the requester receives a payment from a third-party payer in certain circumstances. In those circumstances, the Secretary has a right to be reimbursed by the third-party payer. The circumstances in which the Secretary may assert this right include those in which the Secretary pays benefits under this Program to a requester before a final decision is made that a third-party payer has an obligation to pay such benefits to the requester. Requesters receiving benefits under this Program (or their representatives) shall assist the Secretary in recovering such benefits. In the event that a requester receives a benefit from a third-party payer after receiving the same type of benefits from the Secretary under this Program, the Secretary has a right to recover from the requester the amount of the benefit(s) received. The requester must notify and reimburse the Program within ten business days of receiving the third-party payment(s).

Subpart J—Reconsideration of the Secretary's Determinations

§ 110.90 Reconsideration of the Secretary's eligibility and benefits determinations.

(a) *Right of reconsideration.* A requester has the right to seek reconsideration of the Secretary's determination that he or she is not eligible for Program benefits. In addition, a requester who asserts that the amount of the benefits paid (or the fact that certain benefits were not paid or payable) is incorrect may also seek reconsideration. A requester may not seek reconsideration of the Secretary's decision as to the mechanism of payment. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of the Secretary's decision on the Request for Benefits. Because no new documentation will be considered in the reconsideration process, the reconsideration request may not include or refer to any documentation that was not before the Secretary at the time of her determination.

(b) *Letters seeking reconsideration.* A requester, or his or her representative, may send the letter seeking reconsideration through the U.S. Postal Service, commercial carrier, or a private courier service. The Secretary will not accept reconsideration requests delivered by hand. Electronic submissions of letters seeking reconsideration are not currently accepted, but may be accepted in the future. The Program will publish a notice if an electronic method becomes available. Letters sent through the U.S. Postal Service, commercial carrier or private courier service must be sent to the Associate Administrator, Healthcare Systems Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 12–105, Rockville, Maryland 20857.

(c) *Reconsideration process.* When the Associate Administrator of the Healthcare Systems Bureau (the Associate Administrator), receives a request for reconsideration, a qualified panel, independent of the Program, will be convened to review the Secretary's determination. The panel will base its recommendation on the documentation before the Secretary when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to the requester (or his or her representative). This will be the Secretary's final action on the request for reconsideration and will be considered the Secretary's final determination on the request for Program benefits with regard to the injury that is the subject of that Request Package. Requesters may not seek review of a decision made on reconsideration.

(d) *Effect of reconsideration on amending a Request Package.* As stated in § 110.46, a Request Package cannot be amended after exhaustion of the reconsideration process, except for amendments by survivors seeking death benefits or executors or administrators on behalf of an estate.

§ 110.91 Secretary's review authority.

Under section 319F–4(b)(4) of the Public Health Service Act (42 U.S.C. 247d–6e(b)(4)) (referencing section 262 of the PHS Act (42 U.S.C. 239a)), the Secretary may, at any time, on her own motion or on application, review any determination made under this part (including, but not limited to, determinations concerning eligibility, entitlement to benefits, and the calculation of amount of benefits under the Program). Upon review, the Secretary may affirm, vacate, or modify the determination in any manner the Secretary deems appropriate.

§ 110.92 No additional judicial or administrative review of determinations made under this part.

(a) Under section 319F–4(b)(4) of the PHS Act (42 U.S.C. 247d–6e(b)(4)) (referencing section 262 of the PHS Act (42 U.S.C. 239a)), no judicial review of the Secretary's actions concerning eligibility and benefits determinations

under this part (including, but not limited to, determinations concerning eligibility, the type or amount of benefits, and the method of payment of benefits) is permitted. In addition, no further administrative review of such actions are permitted unless the President specifically directs otherwise.

(b) Under section 319F–4(b)(5)(c) of the PHS Act (42 U.S.C. 247d–6e(b)(5)(c)), no judicial review of the Secretary's actions in establishing or amending a Table (or Tables) for purposes of this part (which include, but are not limited to, identifying injuries on a Table (or choosing not to identify injuries on a Table), establishing time-frames or definitions for Table injuries, and amending a Table) is permitted.

Subpart K—Covered Countermeasures Injury Tables

§ 110.100 Injury Tables.

(a) *Pandemic influenza countermeasures injury table.*

Covered countermeasures under Secretarial declarations	Serious physical injury (illness, disability, injury, or condition) [1]	Time interval (for first symptom or manifestation of onset of injury after administration or use of covered countermeasure, unless otherwise specified)
I. Pandemic influenza vaccines administered by needle into or through the skin.	A. Anaphylaxis	A. 0–4 hours.
	B. Deltoid Bursitis	B. 0–48 hours.
	C. Vasovagal Syncope	C. 0–1 hour.
II. Pandemic influenza intranasal vaccines	A. Anaphylaxis	A. 0–4 hours.
III. Pandemic influenza 2009 H1N1 vaccine.	A. Guillain-Barré Syndrome	A. 3–42 days (not less than 72 hours and not more than 42 days).
IV. Oseltamivir Phosphate (Tamiflu) when administered or used for pandemic influenza.	A. Anaphylaxis	A. 0–4 hours.
V. Zanamivir (Relenza) when administered or used for pandemic influenza.	A. Anaphylaxis	A. 0–4 hours.
VI. Peramivir when administered or used for 2009 H1N1 influenza.	A. Anaphylaxis	A. 0–4 hours.
VII. Pandemic influenza personal respiratory protection devices.	A. No condition covered [2]	A. Not applicable.
VIII. Pandemic influenza respiratory support devices.	A. Postintubation Tracheal Stenosis	A. 2–42 days (not less than 48 hours and not more than 42 days) after extubation (removal of a tracheostomy or endotracheal tube).
	B. Ventilator-Associated Pneumonia and Ventilator-Associated Tracheobronchitis.	B. More than 48 hours after intubation (placement of an endotracheal or tracheostomy tube) and up to 48 hours after extubation (removal of the tube).
	C. Ventilator-Induced Lung Injury	C. Throughout the time of intubation (breathing through an endotracheal or tracheostomy tube) and up to 48 hours after extubation (removal of the tube).
IX. Pandemic influenza respiratory support device: Extra-corporeal membrane oxygenation (ECMO).	A. Bleeding Events	A. Throughout the time of anticoagulation treatment for ECMO therapy, including the time needed to clear the effect of the anti-coagulant treatment from the body.
X. Pandemic influenza diagnostic testing devices.	A. No condition covered	A. Not applicable.

[1] Serious physical injury as defined in 42 CFR 110.3(z). Only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability will be considered serious physical injuries.

[2] The use of ''No condition covered'' in the Table reflects that the Secretary at this time does not find compelling, reliable, valid, medical and scientific evidence to support that any serious injury is presumed to be caused by the associated covered countermeasure. For injuries alleged to be due to covered countermeasures for which there is no associated Table injury, requesters must demonstrate that the injury occurred as the direct result of the administration or use of the covered countermeasure. *See* 42 CFR 110.20(b), (c).

(b) *Qualifications and aids to interpretation (table definitions and requirements).* The following definitions and requirements shall apply to the Table

set forth in paragraph (a) of this section and only apply for purposes of this subpart.

(1) *Anaphylaxis.* Anaphylaxis is an acute, severe, and potentially lethal systemic reaction that occurs as a single discrete event with simultaneous involvement of two or more organ systems. 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. There are no specific pathological findings to confirm a diagnosis of anaphylaxis.

(2) *Deltoid bursitis.* Deltoid bursitis is an inflammation of the bursa that lies beneath the deltoid muscle and between the acromion process and the rotator cuff. Subdeltoid bursitis manifests with pain in the lateral aspect of the shoulder similar to rotator cuff tendonitis. The presence of tenderness on direct palpation beneath the acromion process distinguishes this bursitis from rotator cuff tendonitis. Similar to tendonitis, isolated bursitis will have full passive range of motion. Other causes of bursitis such as trauma (other than from vaccination), metabolic disorders, and systemic diseases such as rheumatoid arthritis, dialysis, and infection will not be considered Table injuries. This list is not exhaustive. The deltoid bursitis must occur in the same shoulder that received the pandemic influenza vaccine.

(3) *Vasovagal syncope.* Vasovagal syncope (also sometimes called neurocardiogenic syncope) means loss of consciousness (fainting) and loss of postural tone caused by a transient decrease in blood flow to the brain occurring after the administration of an injected countermeasure. Vasovagal syncope is usually a benign condition but may result in falling and injury with significant *sequelae*. Vasovagal syncope may be preceded by symptoms such as nausea, lightheadedness, diaphoresis, and/or pallor. Vasovagal syncope may be associated with transient seizure-like activity, but recovery of orientation and consciousness generally occurs simultaneously. Loss of consciousness resulting from the following conditions will not be considered vasovagal syncope: Organic heart disease; cardiac arrhythmias; transient ischemic attacks; hyperventilation; metabolic conditions; neurological conditions; psychiatric conditions; seizures; trauma; and situational as can occur with urination, defecation, or cough. This list is not complete. Episodes of recurrent syncope occurring after the applicable time period are not considered to be *sequelae* of an episode of syncope meeting the Table requirements.

(4) *Guillain-Barré Syndrome (GBS).* (i) GBS is an acute monophasic peripheral neuropathy that currently is known to encompass a spectrum of four clinicopathological subtypes described below. For each subtype of GBS, the interval between the first appearance of symptoms and the nadir of weakness is between 12 hours and 28 days. This is followed in all subtypes by a clinical plateau with stabilization at the nadir of symptoms, or subsequent improvement without significant relapse. Death may occur without a clinical plateau. Treatment related fluctuations in all subtypes of GBS can occur within 9 weeks of GBS symptom onset and recurrence of symptoms after this time frame would not be consistent with GBS.

(ii) The most common subtype in North America and Europe, comprising more than 90 percent of cases, is acute inflammatory demyelinating polyneuropathy (AIDP) which has the pathologic and electrodiagnostic features of focal demyelination of motor and sensory peripheral nerves and nerve roots. Another subtype called acute motor axonal neuropathy (AMAN) is generally seen in other parts of the world and is predominated by axonal damage that primarily affects motor nerves. AMAN lacks features of demyelination. Another less common subtype of GBS includes acute motor and sensory neuropathy (AMSAN), which is an axonal form of GBS that is similar to AMAN, but also affects the sensory nerves and roots.

AIDP, AMAN, and AMSAN are typically characterized by symmetric motor flaccid weakness, sensory abnormalities, and/or autonomic dysfunction caused by autoimmune damage to peripheral nerves and nerve roots. The diagnosis of AIDP, AMAN, and AMSAN requires bilateral flaccid limb weakness and decreased or absent deep tendon reflexes in weak limbs; a monophasic illness pattern; an interval between onset and nadir of weakness between 12 hours and 28 days; subsequent clinical plateau (the clinical plateau leads to either stabilization at the nadir of symptoms, or subsequent improvement without significant relapse); and, the absence of an identified more likely alternative diagnosis. Death may occur without a clinical plateau.

(iii) Fisher syndrome (FS), also known as Miller-Fisher Syndrome, is a subtype of GBS characterized by ataxia, areflexia, and ophthalmoplegia, and overlap between FS and AIDP may be seen with limb weakness. The diagnosis of FS requires bilateral ophthalmoparesis; bilateral reduced or absent tendon reflexes; ataxia; the absence of limb weakness (the presence of limb weakness suggests a diagnosis of AIDP); a monophasic illness pattern; an interval between onset and nadir of weakness between 12 hours and 28 days; subsequent clinical plateau (the clinical plateau leads to either stabilization at the nadir of symptoms, or subsequent improvement without significant relapse); no alteration in consciousness; no corticospinal track signs; and, the absence of an identified more likely alternative diagnosis. Death may occur without a clinical plateau.

(iv) Evidence that is supportive, but not required, of a diagnosis of all subtypes of GBS includes electrophysiologic findings consistent with GBS or an elevation of cerebral spinal fluid (CSF) protein with a total CSF white blood cell count below 50 cells per microliter. The results of both CSF and electrophysiologic studies are frequently normal in the first week of illness in otherwise typical cases of GBS.

(v) For GBS to qualify as a Table injury there must not be a more likely alternative diagnosis for the weakness. Exclusionary criteria for the diagnosis of all subtypes of GBS include the ultimate diagnosis of any of the following conditions: Chronic immune demyelinating polyradiculopathy (''CIDP''), carcinomatous meningitis, brain stem encephalitis (other than Bickerstaff brainstem encephalitis), myelitis, spinal cord infarct, spinal cord compression, anterior horn cell diseases such as polio or West Nile virus infection, subacute inflammatory demyelinating polyradiculoneuropathy, multiple sclerosis, cauda equina compression, metabolic conditions such as hypermagnesemia or hypophosphatemia, tick paralysis, heavy metal toxicity (such as arsenic, gold, or thallium), drug-induced neuropathy (such as vincristine, platinum compounds, or nitrofurantoin), porphyria, critical illness neuropathy, vasculitis, diphtheria, myasthenia gravis, organophosphate poisoning, botulism, critical illness myopathy, polymyositis, dermatomyositis, hypokalemia, or hyperkalemia. The above list is not exhaustive.

(5) *Tracheal stenosis.* (i) Postintubation tracheal stenosis means an iatrogenic (caused by medical treatment) and symptomatic stricture of the airway (narrowing of the windpipe) resulting from:

(A) Trauma or necrosis from an endotracheal tube; or

(B) Stomal injury from a tracheostomy; or

(C) A combination of the two.

(ii) Tracheal stenosis or narrowing due to tumors (malignant or benign), infections of the trachea (such as tuberculosis, fungal diseases), radiotherapy, tracheal surgery, trauma, congenital, and inflammatory or autoimmune diseases will not be considered post-intubation tracheal stenosis. Post-intubation tracheal stenosis requires either tracheostomy with placement of a tracheostomy tube or endotracheal intubation. Diagnosis requires symptoms of upper airway obstruction such as stridor (inspiratory wheeze) or exertional dyspnea (increased shortness of breath with exertion), and positive radiologic studies showing abnormal narrowing of the trachea or

bronchoscopic evaluation that demonstrates abnormal narrowing.

(6) *Ventilator-Associated Pneumonia (VAP) and Ventilator-Associated Tracheobronchitis (VAT).* (i) VAP is defined as an iatrogenic pneumonia caused by the medical treatment of mechanical ventilation. Similarly, VAT is an iatrogenic infection of the trachea and/or bronchi caused by mechanical ventilation. The initial manifestation of VAP and VAT must occur more than 48 hours after intubation (placement of the breathing tube) and up to 48 hours after extubation (removal of the breathing tube). VAP will be considered to be present when the patient demonstrates a new or progressive radiographic infiltrate that is in the lungs and consistent with pneumonia, fever, leukocytosis (increased white blood cell count) or leucopenia (decreased white blood cell count), purulent (containing pus) tracheal secretions from a tracheal aspirate, and a positive lower respiratory tract culture. The positive lower respiratory tract culture is a diagnostic requirement only if there has not been a change in antibiotics in the 72 hours prior to collection of the culture. In addition, a tracheal aspirate that does not demonstrate bacteria or inflammatory cells in a patient without a change in antibiotics in the previous 72 hours is unlikely to be VAP and shall not be considered a condition set forth in the Table.

(ii) VAT will be considered to be present when the patient demonstrates fever, leukocytosis or leukopenia, purulent tracheal secretions, and a positive tracheal aspirate culture in the absence of a change of antibiotics within the 72 hours prior to culture. Tracheal colonization with microorganisms is common in intubated patients, but in the absence of clinical findings is not a sign of VAT.

(7) *Ventilator-Induced Lung Injury (VILI).* VILI results from mechanical trauma such as volutrauma leading to rupture of alveoli (air sacs in the lungs where oxygen and carbon dioxide are exchanged with the blood) with subsequent abnormal leakage of air. VILI manifests as iatrogenic pneumothorax (abnormal air from alveolar rupture in the pleural space), pneumomediastinum (abnormal air from alveolar rupture in the mediastinum (middle part of the chest between the lungs)), pulmonary interstitial emphysema (abnormal air in the lung interstitial space between the alveoli), subpleural air cysts (an extreme form of pulmonary emphysema where the abnormal air in the interstitial space has pooled into larger pockets), subcutaneous emphysema (abnormal air from alveolar rupture that has dissected into the skin), pneumopericardium (abnormal air from alveolar rupture that has traveled to the pericardium (covering of the heart)), pneumoperitoneum (abnormal air from alveolar rupture that has moved into the abdominal space), or systemic air embolism (abnormal air from alveolar rupture that has moved into the blood). To qualify as Table injuries, these manifestations must occur in patients who are being mechanically ventilated at the time of initial manifestation of the VILI.

(8) *Bleeding events.* Bleeding events are defined as excessive or abnormal bleeding in patients who are under the pharmacologic effects of anticoagulant therapy provided for extracorporeal membrane oxygenation (ECMO) treatment.

(c) *Smallpox countermeasures injury table.*

TABLE 2 TO PARAGRAPH (c)

Covered countermeasures under declarations	Serious physical injury (illness, disability, injury, or condition) [1]	Time interval (for first symptom or manifestation of onset of injury after administration or use of covered countermeasure, unless otherwise specified)
I. Smallpox Vaccines Replication-Deficient.	A. Anaphylaxis	A. 0–4 hours.
	B. Vasovagal Syncope.	B. 0–1 hour.
II. Smallpox Vaccines Replication-Competent.	A. Anaphylaxis	A. 0–4 hours.
	B. Vasovagal Syncope.	B. 0–1 hour.
	C. Significant Local Skin Reaction.	C. 1–21 days.
	D. Stevens-Johnson Syndrome/Toxic Epidermal Necrolysis.	D. 4–28 days.
	E. Inadvertent Autoinoculation.	E. 1–21 days.
	F. Generalized *Vaccinia.*	F. 6–9 days.
	G. Eczema *Vaccinatum.*	G. 3–21 days.

TABLE 2 TO PARAGRAPH (c)—Continued

Covered countermeasures under declarations	Serious physical injury (illness, disability, injury, or condition) [1]	Time interval (for first symptom or manifestation of onset of injury after administration or use of covered countermeasure, unless otherwise specified)
	H. Progressive *Vaccinia*.	H. 3–21 days.
	I. Post-*vaccinial* Encephalopathy, Encephalitis or Encephalomyelitis (PVEM).	I. 5–14 days.
	J. *Vaccinial* Myocarditis, Pericarditis, or Myopericarditis (MP).	J. 0–21 days.
III. *Vaccinia* Immunoglobulin Intravenous (VIGIV).	A. Anaphylaxis	A. 0–4 hours.
	B. Transfusion-Related Acute Lung Injury (TRALI).	B. 0–72 hours.
	C. Acute Renal Failure (ARF).	C. 0–10 days.
	D. Drug-Induced Aseptic Meningitis (DIAM).	D. Within 48 hours after the first dose and up to 48 hours after the last dose of VIGIV.
	E. Hemolysis	E. 12 hours to 14 days.
IV. Cidofovir	A. No Condition Covered [2].	A. Not Applicable.
V. Tecovirimat	A. No Condition Covered [2].	A. Not Applicable.
VI. Brincidofovir	A. No Condition Covered [2].	A. Not Applicable.
VII. Smallpox Infection Diagnostic Testing Devices.	A. No Condition Covered [2].	A. Not Applicable.

[1] Serious physical injury as defined in § 110.3(z). Only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability will be considered serious physical injuries.

[2] The use of "No condition covered" in this Table 2 reflects that the Secretary evaluated the countermeasure, but at this time does not find compelling, reliable, valid, medical, and scientific evidence to support that any serious injury is presumed to be caused by the associated covered countermeasure. For injuries alleged to be due to covered countermeasures for which there is no associated Table 2 injury, requesters must demonstrate that the injury occurred as the direct result of the administration or use of the covered countermeasure. *See* § 110.20(b) and (c).

(d) *Qualifications and aids to interpretation (table definitions and requirements).* The following definitions and requirements shall apply to the Table set forth in paragraph (c) of this section and only apply for purposes of this subpart.

(1) *Anaphylaxis.* Anaphylaxis is an acute, severe, and potentially lethal systemic reaction that occurs as a single discrete event with simultaneous involvement of two or more organ systems. Most cases resolve without *sequelae*. Signs and symptoms begin within 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. There are no specific pathological findings to confirm a diagnosis of anaphylaxis.

(2) *Vasovagal syncope.* Vasovagal syncope (also sometimes called neurocardiogenic syncope) means loss of consciousness (fainting) and loss of postural tone caused by a transient decrease in blood flow to the brain occurring after the administration of an injected countermeasure. Vasovagal syncope is usually a benign condition, but may result in falling and injury with significant *sequelae*. Vasovagal syncope may be preceded by symptoms, such as nausea, lightheadedness, diaphoresis (sweating), and/or pallor. Vasovagal syncope may be associated with transient seizure-like activity, but recovery of orientation and consciousness generally occurs simultaneously. Loss of consciousness resulting from the following conditions will not be considered vasovagal syncope: Organic heart disease, cardiac arrhythmias, transient ischemic attacks, hyperventilation, metabolic conditions, neurological conditions, psychiatric conditions, seizures, trauma, and situational as can occur with urination, defecation, or cough. This list is not complete as other conditions that are not associated with the vaccine also may cause loss of consciousness. Episodes of recurrent syncope occurring after the applicable timeframe are not considered to be *sequelae* of an episode of syncope meeting the Table 2 requirements.

(3) *Significant local skin reaction.* Significant local skin reaction is an unexpected and extreme response at the vaccination or inoculation site that results in a significant scar that is serious enough to require surgical intervention. The onset of this injury is the

initial skin lesion at the vaccination site that generally occurs with replication-competent smallpox vaccinations. Minor scarring or minor local reactions do not constitute a Table 2 injury. A robust take, defined as an area of redness at the vaccination site that exceeds 7.5 cm in diameter with associated swelling, warmth and pain, is generally considered an expected response to the vaccination or inoculation. A robust take, in itself, does not constitute a Table 2 injury, even when the redness and swelling involves the entire upper arm with associated enlargement and tenderness of the glands (lymph nodes) in the underarm (axilla).

(4) *Stevens-Johnson syndrome/Toxic epidermal necrolysis (SJS/TEN).* SJS/TEN is a spectrum of acute hypersensitivity reactions that affects skin, mucous membranes, and sometimes, internal organs (systemic toxicity) associated with the use or administration of replication- competent smallpox vaccines. For purposes of Table 2, both skin and mucous membrane rash or lesions must be present. Rash or lesion distribution must be widespread. Rash must not have a symmetric acral distribution (affecting arms, hands, legs or feet). Two or more mucosal sites must be involved. Mucosal lesions generally manifest as painful lesions in sites, such as the mouth or eyes. Skin rash or lesions in SJS/TEN usually consist of red or purple raised areas (erythematous macules), blisters, and ulcerations.

(5) *Inadvertent autoinoculation (IA).* IA is the spread of *vaccinia* virus from an existing vaccination site to a second location usually by scratching the vaccination site and subsequently spreading the virus, which produces a new *vaccinial* lesion on the same person who received the vaccination. IA is the most common adverse event associated with the replication-competent smallpox vaccine.

(6) *Generalized vaccinia (GV).* GV is a *vaccinial* infection that occurs from the spread of *vaccinia* from an existing vaccination or inoculation site, with the use or administration of a replication-competent smallpox vaccine, to otherwise normal skin, resulting in multiple new areas of *vaccinial* rash or lesions. The *vaccinia* is believed to be spread through the blood. The rash or lesions, characterized by multiple blisters (vesicles or pustules), generally evolve in a similar sequence or manner as the original vaccination site.

(7) *Eczema vaccinatum (EV).* EV is the transmission or the spread of *vaccinia* virus from a vaccination site, after the use or administration of a replication-competent smallpox vaccine, to skin that has been affected by, or is currently affected with, eczema or atopic dermatitis. EV is characterized by lesions that include multiple blisters (vesicles or pustules), which generally evolve in a similar sequence or manner as the original vaccination site. The lesions may come together to form larger lesions. Lesions may also spread to patches of skin that have never been involved with eczema or atopic dermatitis. The new lesions, if cultured, will be positive for *vaccinia* virus. A person with EV may become severely ill with signs and symptoms that involve the whole body (systemic illness), such as fever, malaise, or enlarged glands (lymph nodes).

(8) *Progressive vaccinia (PV).* PV is the failure to initiate the healing process in an initial vaccination or inoculation site, after the use or administration of a replication-competent smallpox vaccine, by 21 days after exposure to *vaccinia*, with progressive ulceration or necrosis at the vaccination site leading to a large destructive ulcer. PV is seen in people who are immunocompromised (have an impaired immune system) and is characterized by a complete or near complete lack of inflammation or absence of inflammatory cells in the dermis of the skin at the vaccination site. The diagnosis of PV may be made before 21 days after exposure, especially in a known immunocompromised individual who develops a lesion at the vaccination site. PV may spread through the blood to any location in the body. No one who experiences a significant healing process of the vaccination site within 21 days after receipt of the replication-competent smallpox vaccine or exposure to *vaccinia* has PV.

(9) *Post-vaccinial encephalopathy, encephalitis, and encephalomyelitis (PVEM).* PVEM is a spectrum of overlapping conditions that includes post-*vaccinial* encephalopathy, encephalitis,

and encephalomyelitis, and, for the purposes of Table 2, is treated as one injury. For the purposes of Table 2, PVEM is an autoimmune central nervous system injury that occurs after the use or administration of a replication-competent smallpox vaccine. In rare cases, the *vaccinia* virus is isolated from the central nervous system. Manifestations usually occur abruptly and may include fever, vomiting, loss of appetite (anorexia), headache, general malaise, impaired consciousness, confusion, disorientation, delirium, drowsiness, seizures, language difficulties (aphasia), coma, muscular incoordination (ataxia), urinary incontinence, urinary retention, and clinical signs consistent with inflammation of the spinal cord (myelitis), such as paralysis or meningismus (meningeal irritation). Long-term central nervous system impairments, such as paralysis, seizure disorders, or developmental delays are known to occur as *sequelae* of the acute PVEM. No clinical criteria, radiographic findings, or laboratory tests are specific for the diagnosis of PVEM. Symptoms that occur before 5 days or more than 14 days after receiving the smallpox vaccine should not be attributed to it. In addition, encephalopathy caused by an infection, a toxin, a metabolic disturbance, a structural lesion, a genetic disorder, or trauma would not meet the Table 2 definition.

(10) *Vaccinial myocarditis, pericarditis, or myopericarditis (MP).* For purposes of Table 2, MP is *vaccinial* myocarditis, pericarditis, or myopericarditis. *Vaccinial* myocarditis is defined as an inflammation of the heart muscle (myocardium) because of receiving the replication-competent smallpox vaccine. *Vaccinial* pericarditis is defined as an inflammation of the covering of the heart (pericardium) because of receiving the smallpox vaccine. *Vaccinial* myopericarditis is defined as an inflammation of both the heart muscle and its covering because of receiving the smallpox vaccine. The inflammation associated with MP may range in severity from very mild (subclinical) to life threatening. In many mild cases, myocarditis is diagnosed solely by transient electrocardiographic (EKG) abnormalities (*e.g.,* ST segment and T wave changes), increased cardiac enzymes, or mild echocardiographic abnormalities. Arrhythmias, abnormal heart sounds, heart failure, and death may occur in more severe cases. Pericarditis generally manifests with chest pain, abnormal heart sounds (pericardial friction rub), EKG abnormalities (*e.g.,* ST segment and T wave changes), and/or increased fluid accumulation around the heart. A Table 2 injury of MP requires sufficient evidence in the medical records of the occurrence of acute MP.

(11) *Transfusion-related acute lung injury (TRALI).* TRALI is defined as the onset of respiratory distress within 6 hours in non-critically ill patients, and 72 hours in critically ill patients, after receipt of blood products containing plasma, in this case, VIGIV. The relative level of illness will be determined on a case-by-case basis after reviewing the medical records and the medical history. The respiratory distress is the result of receiving a plasma containing transfusion (VIGIV) and subsequently developing pulmonary edema, respiratory distress, and hypoxia. TRALI occurs as the result of an antibody response in the host to the donor antibodies within the plasma product. Pulmonary edema is non-cardiac in nature and does not occur more than 72 hours after receiving VIGIV. Pulmonary edema occurring more than 72 hours after receiving a blood product containing plasma (VIGIV) or associated with cardiac dysfunction is not TRALI and is excluded as a countermeasure-related injury. TRALI has been identified as a major cause of mortality in those individual receiving plasma-containing transfusions. A Table 2 injury for TRALI has occurred in a recipient if there is sufficient evidence in the medical record of an occurrence of TRALI and the pulmonary edema is not caused by cardiac dysfunction or other causes and occurs within 72 of receiving a blood product containing plasma, in this case VIGIV.

(12) *Acute renal failure (ARF).* ARF is the sudden loss of the kidneys' ability to perform their main function of eliminating excess fluids and electrolytes (salts), as well as waste material from the blood. ARF, which is also called acute kidney injury, develops

rapidly over a few hours or a few days. ARF can be fatal and requires intensive treatment; however, ARF may be reversible. ARF may cause permanent loss of kidney function, or end-stage renal disease necessitating dialysis or transplant. A Table 2 injury for ARF has occurred if there is sufficient evidence in the medical record of an occurrence of ARF within the identified timeframe and the individual received the associated countermeasure (VIGIV).

(13) *Drug-induced aseptic meningitis (DIAM).* (i) DIAM is an inflammation of the meninges (linings of the brain) that is not caused by a bacteria or virus, but is caused by a drug or medication. The symptoms of meningitis include severe headache, nuchal (neck) rigidity, drowsiness, fever, photophobia (light sensitivity), painful eye movements, nausea, and vomiting. Discontinuation of the medication leads to a resolution of the symptoms. DIAM is thought to occur because of an immunological hypersensitivity reaction to a specific medication. In the case of immunoglobulins, DIAM may be precipitated by the immunologically active components within the plasma or because of the stabilizers used within the product. The symptoms of DIAM may reoccur with another exposure to the offending agent.

(ii) A Table 2 injury for DIAM has occurred in a recipient if there is sufficient evidence in the medical record of an occurrence of DIAM within the identified timeframe and the individual received the associated countermeasure (VIGIV). DIAM occurring in the absence of the use of VIGIV, or DIAM occurring with the use of VIGIV outside the established timeframe of onset, which is any time after the first dose and up to 48 hours after the last dose of this medication, is not a Table 2 injury.

(14) *Hemolysis.* Hemolysis is the physical breakdown of red blood cells (RBCs) either through natural attrition or as caused by external factors. The RBC's function is to transport oxygen throughout the body in the hemoglobin contained within the RBC. Additionally, the RBCs contain the majority of the body's potassium stores. With hemolysis, the body is unable to transport oxygen effectively, and the person develops hypoxia. Additionally, the rapid breakdown of the cell releases large amounts of potassium into the blood stream, which can cause abnormal heart rhythms and cardiac arrest. In severe cases of hemolysis, a blood transfusion may be required to correct the resulting anemia. A Table 2 injury for hemolysis has occurred if there is sufficient evidence in the medical record of an occurrence of hemolysis, and the patient received the associated countermeasure (VIGIV). Hemolysis occurring in the absence of the use of VIGIV and outside of the timeframe of 12 hours to 14 days after receiving VIGIV is not a Table 2 injury. Hemolysis occurring from a more likely alternative diagnosis, such as infections, toxins, poisons, hemodialysis, or medications, is not a Table 2 injury. This list of conditions that can cause hemolysis, not associated with VIGIV, is not exhaustive, and all additional diagnoses within the medical documentation will be evaluated.

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