

(4) Pneumococcal conjugate vaccines (Item XII of the Table) are included in the Table as of December 18, 1999.

(5) Other new vaccines (Item XIII 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.

[60 FR 7694, Feb. 8, 1995, as amended at 62 FR 7688, Feb. 20, 1997; 62 FR 10626, Mar. 7, 1997; 63 FR 25778, May 11, 1998; 64 FR 40518, July 27, 1999; 67 FR 48559, July 25, 2002; 73 FR 59530, Oct. 9, 2008]

## PART 102—SMALLPOX COMPENSATION PROGRAM

### Sec.

- 102.1 Purpose.
- 102.2 Summary of available benefits.
- 102.3 Definitions.

### Subpart B—Persons Eligible To Receive Benefits

- 102.10 Eligible requesters.
- 102.11 Survivors.

### Subpart C—Covered Injuries

- 102.20 How to establish a covered injury.
- 102.21 Smallpox (Vaccinia) Vaccine Injury Table.
- 102.22–102.29 [Reserved]

### Subpart D—Available Benefits

- 102.30 Benefits available to different categories of requesters under this program.
- 102.31 Medical benefits.
- 102.32 Benefits for lost employment income.
- 102.33 Death benefits.

### Subpart E—Procedures for Filing Request Packages

- 102.40 How to obtain forms and instructions.
- 102.41 How to file a Request Package.
- 102.42 Deadlines for filing request forms.
- 102.43 Deadlines for submitting documentation.
- 102.44 Representatives of requesters.
- 102.45 Multiple survivors.
- 102.46 Amending a request package.

### Subpart F—Required Documentation To Be Deemed Eligible

- 102.50 Medical records necessary to establish that a covered injury was sustained.

102.51 Documentation a smallpox vaccine recipient must submit to be deemed eligible by the Secretary.

102.52 Documentation a vaccinia contact must submit to be deemed eligible by the Secretary.

102.53 Documentation a survivor must submit to be deemed eligible by the Secretary.

102.54 Documentation the representative of the estate of a deceased smallpox vaccine recipient or vaccinia contact must submit to be deemed eligible by the Secretary.

### Subpart G—Required Documentation for Eligible Requesters To Receive Benefits

102.60 Documentation an eligible requester seeking medical benefits must submit.

102.61 Documentation an eligible requester seeking benefits for lost employment income must submit.

102.62 Documentation an eligible requester seeking a death benefit must submit.

102.63 Documentation a representative filing on behalf of an eligible requester who is a minor or a legally incompetent adult must submit.

### Subpart H—Secretarial Determinations

102.70 Determinations the Secretary must make before benefits can be paid.

102.71 Insufficient documentation for eligibility and benefits determinations.

102.72 Sufficient documentation for eligibility and benefits determinations.

102.73 Approval of benefits.

102.74 Disapproval of benefits.

### Subpart I—Calculation and Payment of Benefits

102.80 Calculation of medical benefits.

102.81 Calculation of benefits for lost employment income.

102.82 Calculation of death benefits.

102.83 Payment of all benefits.

102.84 The Secretary's right to recover benefits paid under this program from third-party payors.

### Subpart J—Reconsideration of the Secretary's Determinations.

102.90 Reconsideration of the Secretary's eligibility and benefits determinations.

102.91 Secretary's review authority.

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

AUTHORITY: 42 U.S.C. 216, 42 U.S.C. 239–239h.

SOURCE: 68 FR 51497, Aug. 27, 2003, unless otherwise noted.

**Subpart A—General Provisions**

SOURCE: 68 FR 70093, Dec. 16, 2003, unless otherwise noted.

**§ 102.1 Purpose.**

This part implements Section 2 of the Smallpox Emergency Personnel Protection Act of 2003 (the Act). The Act directs the Secretary of Health and Human Services to establish procedures for providing benefits to certain individuals who sustained a covered injury as the direct result of the administration of the smallpox vaccine or other covered countermeasure, and to certain individuals who sustained a covered injury as the direct result of accidental vaccinia inoculation through contact with certain persons vaccinated with the smallpox vaccine or with individuals accidentally inoculated by them. Also, if the Secretary determines that an individual died as a result of a covered injury, the Act provides for certain survivors of that individual to receive death benefits.

**§ 102.2 Summary of available benefits.**

(a) The Act authorizes three forms of benefits to requesters deemed eligible by the Secretary:

(1) Payment or reimbursement for reasonable and necessary medical services and items to diagnose or treat a covered injury or its health complications, as described in § 102.31.

(2) Lost employment income incurred as a result of a covered injury, as described in § 102.32.

(3) Death payments to survivors if the Secretary determines that the death of the smallpox vaccine recipient or vaccinia contact was the direct result of a covered injury, as described in § 102.33.

(b) The benefits paid under the Program, with the exception of death benefits paid under § 102.32(c), are secondary to any obligation of any third-party payor to pay for such benefits. Death benefits paid under § 102.32(c) are secondary to death and disability benefits under the PSOB Program. The benefits paid under the Program usually will only be paid after the requester has pursued all other available coverage from all third-party payors with an obligation to pay for or provide such

benefits (e.g., medical insurance for medical items, workers' compensation program(s) for lost employment income). However, as provided in § 102.84, the Secretary has the discretion to pay benefits under this Program before a potential third-party payor makes a determination on the availability of similar benefits and has the right to later pursue a claim against any third-party payor with a legal or contractual obligation to pay for, or provide, such benefits.

**§ 102.3 Definitions.**

This section defines certain words and phrases found throughout this part. Words and phrases that are used only in limited situations are defined in specific sections of this part.

(a) *Accidental vaccinia inoculation* means the transfer of vaccinia virus from an existing vaccination site (the skin surface where the vaccinia virus entered the body through vaccination) or inoculation site (the skin or mucous membrane surface where the vaccinia virus entered the body through means other than vaccination) on a person to a second person, resulting in a contact case.

(b) *Act* means the Smallpox Emergency Personnel Protection Act of 2003, Pub. L. 108-20, 117 Stat. 638.

(c) *Approval* means a decision by the Secretary that the requester will be paid benefits under the Program.

(d) *Benefits* means benefits and/or compensation.

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

(1) 18 years of age or under; or

(2) Over 18 years of age and a student as defined in section 8101 of title 5, United States Code; or

(3) Over 18 years of age and incapable of self-support because of physical or mental disability.

(f) *Contact case* means a case in which a person developed an initial vaccinia lesion or vaccinia infection through an exposure other than being vaccinated him/herself.

(g) *Covered countermeasure* means smallpox (vaccinia) vaccines, cidofovir

and its derivatives, or Vaccinia Immune Globulin, when used to prevent or treat the smallpox disease or control or treat the adverse effects of vaccinia vaccination or inoculation or of the administration of another countermeasure.

(h) *Covered injury* means an injury determined by the Secretary, in accordance with subpart C of this part, to be:

(1) An injury meeting the requirements of the Table, which is presumed to be the direct result of the administration of a smallpox vaccine or accidental vaccinia inoculation; or

(2) More likely than not, the direct result of:

(i) The administration of a covered countermeasure (including the smallpox vaccine) during the effective period of the Declaration, in the case of a smallpox vaccine recipient; or

(ii) Vaccinia contracted through accidental vaccinia inoculation (and not the result of receiving a smallpox vaccine) during the effective period of the Declaration (or within 30 days after the end of such period), in the case of a vaccinia contact.

(i) *Declaration* means the Declaration Regarding Administration of Smallpox Countermeasures issued by the Secretary on January 24, 2003, and published in the FEDERAL REGISTER on January 28, 2003 (68 FR 4212).

(j) *Dependent* means a person who would be considered a dependent by the Internal Revenue Service.

(k) *Disapproval* means a decision by the Secretary that the requester will not be paid benefits under the Program.

(l) *Effective period of the Declaration* means the time span specified in the Declaration, as amended by the Secretary.

(m) *FECA Program* means the workers' compensation benefits program for civilian officers and employees of the Federal Government established under the Federal Employees' Compensation Act (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.

(n) *Health care practitioner* means a health care provider licensed by a State and authorized to diagnose and prescribe medications and other treat-

ments or authorized to provide primary or specialty care.

(o) *Injury* means an injury (including death), disability, illness, or condition.

(p) *Legally incompetent* means a person who is considered to lack legal capacity under applicable State law.

(q) *Program* means the Smallpox Vaccine Injury Compensation Program.

(r) *Public Safety Officers' Benefits Program (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.

(s) *Requester* means a smallpox vaccine recipient, vaccinia contact, survivor, or representative of the estate of a deceased smallpox vaccine recipient or vaccinia contact (on behalf of the estate) who files a Request Package, or on whose behalf a Request Package is filed, under this part.

(t) *Request Form* means the form designated by the Secretary as the request form for purposes of this part.

(u) *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 eligibility and benefits under this part.

(v) *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 involved has been delegated.

(w) *Smallpox emergency response plan* means a State, local, or Department of Health and Human Services plan, approved by the Secretary, detailing actions to be taken in preparation for a possible smallpox-related emergency during the period prior to the identification of an active case of smallpox either within or outside the United States.

(x) *Smallpox (Vaccinia) Vaccine Injury Table or Table of Injuries* means the table of injuries included at § 102.21, including the definitions and requirements set forth at § 102.21(b).

(y) *Smallpox vaccine recipient* means a person:

(1) Who has been a health care worker, law enforcement officer, firefighter, security personnel, emergency medical personnel, other public safety personnel, or support personnel for such occupational specialties who has volunteered and been selected to be a member of a smallpox emergency response plan prior to the time at which the Secretary publicly announces that an active case of smallpox has been identified within or outside of the United States;

(2) Who is or will be functioning in a role identified in a smallpox emergency response plan;

(3) To whom a smallpox vaccine is administered pursuant to a smallpox emergency response plan during the effective period of the Declaration; and

(4) Who sustained a covered injury.

(z) *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.

(aa) *Survivor* means a survivor of a deceased smallpox vaccine recipient or vaccinia contact meeting the requirements of § 102.11.

(bb) *Third-party payor* means the United States (other than for payments of benefits under this Program) or any other third-party, including any State or local governmental entity, private insurance carrier, or employer, with a legal or contractual obligation to pay for or provide benefits.

(cc) *Vaccinia contact* means an individual who:

(1) Contracted vaccinia during the effective period of the Declaration (or within 30 days after the end of such period);

(2) Prior to contracting vaccinia, was accidentally inoculated by a person:

(i) Meeting the criteria set forth in § 102.3(x)(1)–(3) (a person meeting the definition of a smallpox vaccine recipient, except for the requirement that the person sustained a covered injury); or

(ii) Who was accidentally inoculated by a person meeting the criteria set forth in § 102.3(x)(1)–(3) (a person meeting the definition of a smallpox vaccine recipient, except for the requirement

that the person sustained a covered injury); and

(3) Sustained a covered injury.

[68 FR 70093, Dec. 16, 2003; 69 FR 7376, Feb. 17, 2004, as amended at 71 FR 29810, May 24, 2006]

### Subpart B—Persons Eligible To Receive Benefits

SOURCE: 68 FR 70093, Dec. 16, 2003, unless otherwise noted.

#### § 102.10 Eligible requesters.

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

(1) Smallpox vaccine recipients, as described in § 102.3(x);

(2) Vaccinia contacts, as described in § 102.3(bb); or

(3) Survivors, as described in § 102.3(z) and § 102.11.

(4) Representatives of the estates of deceased smallpox vaccine recipients or vaccinia contacts (*i.e.*, individuals authorized to act on behalf of the deceased person's estate under applicable state law, such as an executor).

(b) If a smallpox vaccine recipient or vaccinia contact dies, his or her survivor(s) or the representative 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 person, but must be filed within the filing deadlines described in § 102.42. Amendments to previously filed Request Packages and the filing deadlines for such amendments are described in § 102.46.

(c) The benefits available to different categories of requesters are described in § 102.30.

#### § 102.11 Survivors.

(a) *Survivors of individuals who died as the direct result of a covered injury.* If the Secretary determines that a smallpox vaccine recipient or vaccinia contact 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 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), (b)(4), and (b)(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, as amended.

(3) In the PSOB Program, the person who is survived must satisfy the eligibility requirements for a deceased public safety officer, whereas the person who is survived under this Program must be a deceased smallpox vaccine recipient or vaccinia contact 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 smallpox vaccine recipient or vaccinia contact 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 person 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 §102.82(d), and is not eligible to receive death benefits under the standard calculation described in §102.82(c). Because death benefits paid under the alternative calculation will be paid to the dependents' legal guardian(s) on behalf of all such

dependents, the Secretary will not divide or apportion such benefits among the 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

#### § 102.20 How to establish a covered injury.

(a) *General.* In order to receive benefits under the Program, a requester must submit documentation showing that a covered injury, as described in §102.3(g), was sustained. 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 or accidental vaccinia inoculation, as described in paragraph (d) of this section. The Secretary will consider all relevant medical and scientific evidence, such as medical records and documentation submitted by the requester, when determining whether a covered injury was established. In addition, the Secretary may obtain the views of qualified medical experts in making determinations concerning covered injuries. As set forth in the definition of covered countermeasures, if a covered injury is related to the administration of a covered countermeasure, the countermeasure must have been administered to prevent or treat the smallpox disease or to control or treat the adverse effects of vaccinia vaccination or inoculation or of the administration of another countermeasure. The time periods described in this part for receiving a covered countermeasure (during the effective period of the Declaration) or for vaccinia contracted from accidental

vaccinia inoculation (during the effective period of the Declaration or within 30 days after the end of such period) in relation to a covered injury must also be met.

(b) *Minor injuries.* Any injuries that the Secretary deems minor will not be considered covered injuries. Minor injuries include expected and routine responses to the smallpox vaccine, other covered countermeasures, or accidental vaccinia inoculation that are not severe (e.g., minor scarring or minor local reactions, for instance a mild systemic illness with a generalized maculopapular rash that resolves quickly).

(c) *Table injuries.* A requester may establish that a covered injury occurred by demonstrating that a smallpox vaccine recipient or vaccinia contact sustained an injury listed on the Smallpox (Vaccinia) Vaccine Injury Table, set forth in §120.21, within the time interval listed on the Table and as defined by the Table's Definitions and Requirements, set forth in §120.21(b). 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 of a smallpox vaccine or exposure to vaccinia. Even if the Table requirements are satisfied, however, an injury will not be considered a covered injury if the Secretary determines, based upon his review of the evidence, that a source other than the smallpox vaccine or exposure to vaccinia more likely than not caused the injury. In such circumstances, the Table presumption will be rebutted.

(d) *Injuries for which causation must be proven.* If an injury is not included on

the Table or if a requester is unable to meet all of the Table requirements with respect to an injury included on the Table (e.g., the first symptom or manifestation of onset of the injury within the time interval included on the Table), a requester may establish a covered injury by proving causation. To establish that a covered countermeasure or accidental vaccinia inoculation caused an injury, the requester must demonstrate, by a preponderance of the evidence (more likely than not), that:

(1) In the case of a smallpox vaccine recipient, he or she sustained an injury as the direct result of the administration of a covered countermeasure (including the smallpox vaccine) during the effective period of the Declaration; or

(2) In the case of a vaccinia contact, he or she sustained an injury as the direct result of vaccinia contracted through accidental vaccinia inoculation from a person described in §102.3(bb)(2) (a person meeting the definition of a smallpox vaccine recipient, except that the person need not sustain a covered injury, or the contact of such a person), and not as the result of receiving a smallpox vaccine. Such vaccinia must have been contracted during the effective period of the Declaration (or within 30 days after the end of such period). The Secretary will consider an injury that resulted from the administration of a covered countermeasure (other than the smallpox vaccine) to be the direct result of vaccinia contracted through accidental vaccinia inoculation if the covered countermeasure was administered as a result of such vaccinia.

[68 FR 70093, Dec. 16, 2003, as amended at 71 FR 29810, May 26, 2006]

**§ 102.21 Smallpox (Vaccinia) Vaccine Injury Table.**

(a) SMALLPOX (VACCINIA) VACCINE INJURY TABLE

Injury (illness, disability, injury, or condition)	Time interval for first symptom or manifestation of onset of injury after: (1) administration of smallpox (vaccinia) vaccine in recipients (R); or (2) exposure to vaccinia in contacts (C). Please note that these time intervals do not refer to time periods for the date of diagnosis of the injury.
1. Significant Local Skin Reaction .....	R or C: 1–21 days.
2. Stevens-Johnson Syndrome .....	R or C: 1–21 days.
3. Inadvertent Inoculation .....	R or C: 1–21 days.
4. Generalized Vaccinia .....	R or C: 1–21 days.

(a) SMALLPOX (VACCINIA) VACCINE INJURY TABLE—Continued

Injury (illness, disability, injury, or condition)	Time interval for first symptom or manifestation of onset of injury after: (1) administration of smallpox (vaccinia) vaccine in recipients (R); or (2) exposure to vaccinia in contacts (C). Please note that these time intervals do not refer to time periods for the date of diagnosis of the injury.
5. Eczema Vaccinatum .....	R or C: 1–21 days.
6. Progressive Vaccinia .....	R or C: 1–21 days.
7. Postvaccinial Encephalopathy, Encephalitis or Encephalomyelitis.	R or C: 1–21 days.
8. Fetal Vaccinia .....	Maternal R or C: any time in gestation until 7 days after birth.
9. Secondary Infection .....	R or C: 0–30 days.
10. Anaphylaxis or Anaphylactic Shock .....	R: 0–4 hours. C: Not Covered.
11. Vaccinial Myocarditis, Pericarditis, or Myopericarditis.	R or C: 1–21 days.
12. Death resulting from an injury referred to above in which the injury arose within the time interval referred to above (except as specifically provided in specified paragraph (b) of this section).	R or C: No time interval specified.

(b) *Table definitions and requirements.* The Table Definitions that follow shall apply to, define and describe the scope of, and be read in conjunction with paragraph (a) of this section.

(1) *Significant local skin reaction*—(i) *Definition.* Significant local skin reaction is, for purposes of the Table, 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 or inoculation site that generally occurs with smallpox vaccinations or inoculations. Minor scarring or minor local reactions do not constitute a Table injury. Even 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, in general is considered an expected response to the vaccination or inoculation. A robust take does not in itself constitute a Table 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).

(ii) *Table requirements.* A Table injury for a significant local skin reaction in a recipient or contact requires sufficient evidence in the medical records of the occurrence of a significant local skin reaction at the vaccination or inoculation site and a permanent, disfiguring scar that resulted from the significant local skin reaction. The

scar must be of sufficient severity to require surgical intervention to correct a significant cosmetic (e.g., keloid) or functional (e.g., contracture) deformity and such surgery must be included in the treatment plan documented in the medical records.

(2) *Stevens-Johnson Syndrome (SJS)*—(i) *Definition.* SJS (sometimes called erythema multiforme major) is an acute hypersensitivity reaction that affects skin, mucous membranes, and sometimes internal organs (systemic toxicity). For purposes of the Table, both skin and mucous membrane rash or lesions must be present and the rash or lesions may not cover less than ten percent of body surface area. In SJS, mucosal involvement generally predominates. Mucosal lesions generally occur at more than one location and manifest as painful lesions in sites such as the mouth or eyes. Skin rash or lesions in SJS usually consist of red raised areas (erythematous macules), blisters, and ulcerations.

(ii) *Table requirements.* A Table injury for SJS in a recipient or contact requires sufficient evidence in the medical records of the occurrence of SJS. The SJS, or related complications, must be of sufficient severity to require inpatient hospitalization.

(3) *Inadvertent Inoculation (II)*—(i) *Definition.* II is the spread of vaccinia virus from an existing vaccination or inoculation site to a second location usually by scratching the vaccination or inoculation site and subsequently spreading the virus, which produces a

new vaccinia lesion on the same person. Alternatively, II is the spread of vaccinia virus from an existing vaccination or inoculation site to another person usually by scratching an existing vaccination or inoculation site and subsequently spreading the virus, resulting in a contact case.

(ii) *Table requirements.* A Table injury for II in a recipient or contact requires sufficient evidence in the medical records of the occurrence of II and the occurrence of one of the following:

(A) Eye lesions, e.g., vaccinia keratitis or vaccinia blepharitis, that resulted from II and that led to a permanent sequela, e.g., decrease in visual acuity;

(B) Permanent and disfiguring scar(s) that resulted from II. The scar(s) must be of sufficient severity to require surgical intervention to correct a significant cosmetic (e.g., keloid) or functional (e.g., contracture) deformity and such surgery must be included in the treatment plan documented in the medical records; or

(C) Acute II or related complications of sufficient severity to require inpatient hospitalization.

(4) *Generalized Vaccinia (GV)*—(i) *Definition.* GV is a vaccinia infection that occurs from the spread of vaccinia from an existing vaccination or inoculation site to otherwise normal skin, resulting in multiple new areas of vaccinia rash or lesions. The vaccinia is believed to be spread through the blood. The rash or lesions are characterized by multiple blisters (vesicles or pustules) that generally evolve in a similar sequence or manner as the original vaccination or inoculation site.

(ii) *Table requirements.* A Table injury for GV in a recipient or contact requires sufficient evidence in the medical records of the occurrence of GV and the occurrence of one of the following:

(A) Permanent and disfiguring scar(s) that resulted from GV. The scar(s) must be of sufficient severity to require surgical intervention to correct a significant cosmetic (e.g., keloid) or functional (e.g., contracture) deformity and such surgery must be included in the treatment plan documented in the medical records; or

(B) Acute GV or related complications of sufficient severity to require inpatient hospitalization.

(5) *Eczema Vaccinatum (EV)*—(i) *Definition.* EV is the transmission or the spread of vaccinia virus from a vaccination or inoculation site 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 or inoculation 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. A person with EV may be quite ill with signs and symptoms that involve the whole body (systemic illness), such as fever, malaise, or enlarged glands (lymph nodes).

(ii) *Table requirements.* A Table injury for EV in a recipient or contact requires sufficient evidence in the medical records of the occurrence of EV and the occurrence of one of the following:

(A) Permanent and disfiguring scar(s) that resulted from EV. The scar(s) must be of sufficient severity to require surgical intervention to correct a significant cosmetic (e.g., keloid) or functional (e.g., contracture) deformity and such surgery must be included in the treatment plan documented in the medical records; or

(B) Acute EV or related complications of sufficient severity to require inpatient hospitalization.

(6) *Progressive Vaccinia (PV)*—(i) *Definition.* PV is the failure to initiate the healing process in an initial vaccination or inoculation site by 21 days after exposure to vaccinia with progressive ulceration or necrosis at the vaccination or inoculation site leading to a large destructive ulcer. PV is seen in people with an impaired immune system (immunocompromised) 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 or inoculation 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 or inoculation site. PV may spread through the blood to any location in the body. Any person who initiates a significant healing process of the vaccination or inoculation site by 21 days after receipt of the smallpox vaccine or exposure to vaccinia does not have PV.

(ii) *Table requirements.* A Table injury for PV in a recipient or contact requires sufficient evidence in the medical records of the occurrence of PV and the occurrence of one of the following:

(A) Permanent and disfiguring scar(s) that resulted from PV. The scar(s) must be of sufficient severity to require surgical intervention to correct a significant cosmetic (e.g., keloid) or functional (e.g., contracture) deformity and such surgery must be included in the treatment plan documented in the medical records; or

(B) Acute PV or related complications of sufficient severity to require inpatient hospitalization.

(7) *Postvaccinial Encephalopathy, Encephalitis or Encephalomyelitis (PVEM)*—

(i) *Definition.* PVEM is, for the purposes of the Table, an autoimmune central nervous system injury. 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. 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.

(ii) *Table requirements.* A Table injury for PVEM in a recipient or contact requires sufficient evidence in the medical records of the occurrence of acute PVEM. The acute PVEM or related complications must be of sufficient se-

verity to require inpatient hospitalization.

(8) *Fetal Vaccinia (FV)*—(i) *Definition.* FV is an intrauterine vaccinia infection subsequent to vaccinia vaccination or inoculation of the mother that results from the placental transmission of the vaccinia virus during any time in the pregnancy. FV manifests as multiple skin lesions or organ involvement and may result in significant scarring or death. FV skin lesions are similar to those seen in GV or PV and the lesions may come together to form larger lesions. Congenital malformations, other than those described above, are not Table injuries.

(ii) *Table requirements.* A Table injury for FV requires sufficient evidence in the medical records of the occurrence of the FV. The occurrence of the FV or related complications must be of sufficient severity to require inpatient hospitalization or result in permanent and disfiguring scar(s). In addition, a Table injury for FV requires one of the following:

(A) A maternal history of vaccinia vaccination or inoculation, with the occurrence of vaccinia skin or mucous membrane lesions within the incubation period for vaccinia during the pregnancy in a maternal recipient or contact; or

(B) Isolation of vaccinia from intrauterine or neonatal tissue.

(9) *Secondary Infection (SI)*—(i) *Definition.* SI is, for purposes of the Table, a non-vaccinia bacterial, fungal, or viral infection at the site of a vaccinia skin or mucous membrane lesion. SI occurs because the blister formation or ulceration that is part of the normal progression of a vaccinia skin or mucous membrane lesion disrupts the surface of the skin or mucous membrane, allowing potential germs to invade and infect the vaccinia skin or mucous membrane lesion leading to significant illness requiring hospitalization.

(ii) *Table requirements.* A Table injury for SI in a recipient or contact requires sufficient evidence in the medical records of the occurrence of SI. The acute SI or related complications must be of sufficient severity to require inpatient hospitalization.

(10) *Anaphylaxis or Anaphylactic shock*—(i) *Definition.* Anaphylaxis or

anaphylactic shock is, for purposes of the Table, as an acute, severe, and potentially lethal systemic allergic reaction to a component of the smallpox vaccine.

(ii) *Table requirements.* A Table injury for anaphylaxis or anaphylactic shock in a recipient requires sufficient evidence in the medical records of the occurrence of an acute anaphylaxis or anaphylactic shock. The anaphylaxis or anaphylactic shock must be of sufficient severity to require inpatient hospitalization. Anaphylaxis or anaphylactic shock is not a Table injury for contacts.

(11) *Vaccinial Myocarditis, Pericarditis, or Myopericarditis (MP)*—(i) *Definition.* MP is, for purposes of the Table, vaccinial myocarditis, pericarditis, or myopericarditis. Myocarditis is defined as an inflammation of the heart muscle (myocardium). Pericarditis is defined as an inflammation of the covering of the heart (pericardium). Myopericarditis is defined as an inflammation of both the heart muscle and its covering. 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.

(ii) *Table requirements.* A Table injury for MP in a recipient or contact requires sufficient evidence in the medical records of the occurrence of acute MP. The acute MP (or related complications) must be of sufficient severity to require inpatient hospitalization. A death resulting from MP requires sufficient microscopic (histopathologic) evidence of MP or its sequela in heart tissue.

(c) *Glossary for purposes of this section.*

(1) *Blister or vesicle* means a circumscribed, elevated skin or mucous

membrane lesion containing an accumulation of fluid.

(2) *Contact* means a person who developed a vaccinal lesion or infection through inoculation (and not vaccination).

(3) *Exposure period* means the span of time during which vaccinia virus can be transmitted from a vaccine recipient shedding vaccinia or through a contact case shedding vaccinia.

(4) *Inoculation* means transmission of and infection with the vaccinia virus through a means other than smallpox vaccination. Spread (inoculation) of vaccinia virus may occur in two ways: either self-inoculation in which the vaccinia virus is spread from the vaccinal lesion at the vaccination site to one or more areas on the same person or person-to-person inoculation when the vaccinia virus is spread to another person, a contact.

(5) *Inoculation site* means the skin or mucous membrane surface where the vaccinia virus entered the body through means other than vaccination.

(6) *Lesion* means a pathologic change.

(7) *Pustule* means a circumscribed, elevated skin or mucous membrane lesion containing an accumulation of white blood cells.

(8) *Recipient* means a person to whom the smallpox vaccine was administered.

(9) *Ulceration* means a specific skin or mucous membrane lesion characterized by erosion of the skin or mucous membrane surface.

(10) *Vaccination* means the administration and receipt of the smallpox (vaccinia) vaccine, and not through contact.

(11) *Vaccination site* means the skin surface where the vaccinia virus entered the body through vaccination.

[68 FR 70093, Dec. 16, 2003, as amended at 71 FR 29808, May 24, 2006]

§§ 102.22–102.29 [Reserved]

### Subpart D—Available Benefits

SOURCE: 68 FR 70096, Dec. 16, 2003, unless otherwise noted.

**§ 102.30 Benefits available to different categories of requesters under this program.**

(a) *Benefits available to smallpox vaccine recipients and vaccinia contacts.* A requester who is an eligible smallpox vaccine recipient or vaccinia contact may be entitled 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 smallpox vaccine recipient or vaccinia contact may be entitled to receive a death benefit.

(c) *Benefits available to estates of deceased smallpox vaccine recipients or vaccinia contacts.* The estate of an otherwise eligible deceased smallpox vaccine recipient or vaccinia contact may be eligible to receive medical benefits or benefits for lost employment income, or both, if such benefits were accrued during the deceased person's lifetime as a result of a covered injury or its health complications, but were not paid while the deceased person was living. Such medical benefits and benefits for lost employment income may be available regardless of whether the death was the direct result of a covered injury or an unrelated factor. The estate of a deceased smallpox vaccine recipient or vaccinia contact may not receive a death benefit.

**§ 102.31 Medical benefits.**

(a) Smallpox vaccine recipients and vaccinia contacts 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 a health complication of a covered injury (*i.e.*, sequela). 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 monthly 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 the medical services and items have already

been provided or if they are likely to be provided 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 health care practitioner.

(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, complications of a covered injury that occur as part of the natural course of the underlying disease, an adverse reaction to a prescribed medication or 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 § 102.80. Although there are no caps on medical benefits available under this Program, the Secretary may limit payments to the amount he deems reasonable for those services and items he considers reasonable and necessary. All payment or reimbursement for medical services and items is secondary to any obligation of any third-party payor to pay for or provide such services or items to the requester. As provided in § 102.84, the Secretary retains the right to recover medical benefits paid to requesters by third-party payors.

(d) The Secretary may make payments or reimbursements of medical benefits to the estate of a deceased smallpox vaccine recipient or vaccinia contact as long as such benefits were accrued during the deceased person's lifetime as the result of a covered injury or its health complications and were not paid during the deceased person's lifetime.

**§ 102.32 Benefits for lost employment income.**

(a) Requesters who are smallpox vaccine recipients or vaccinia contacts 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

§102.31(b)). These benefits are a percentage of the employment income lost due to the covered injury or its health complications.

(b) The method and amount of benefits for lost employment income are described in §102.81. Benefits for lost employment income will be adjusted if there are fewer than 10 days of lost employment income. 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 payor to pay for lost employment income or to provide disability or retirement benefits to the requester. As provided in §102.84, the Secretary retains the right to recover benefits for lost employment income paid to requesters from third-party payors.

(c) The Secretary is not requiring an individual to use paid leave (e.g., sick leave or vacation leave) to be paid for lost work days. However, if an individual uses such paid leave in order to be paid for lost work days, the Secretary will not consider the days in which such leave was used to be days of lost employment income, unless the individual's employer restores the leave that was used. By restoring paid leave, an employer puts the individual in the same position as if he or she had not used paid leave on the lost work day (*i.e.*, takes back the payments made when the leave was taken and gives back the leave to the employee for future use).

(d) The Secretary may pay benefits for lost employment income to the estate of a deceased smallpox vaccine recipient or vaccinia contact as long as such benefits were accrued during the deceased person's lifetime as the result of a covered injury or its health complications and were not paid to the deceased person during his or her lifetime.

#### § 102.33 Death benefits.

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

Annual and lifetime caps may apply to the death benefits provided. The method and amount of death benefits are described in §102.82. As provided in §102.84, the Secretary retains the right to recover death benefits paid to requesters from third-party payors. Death benefits may be paid under two different calculations.

(b) The standard calculation, described in §102.82(c), is based upon the death benefit available under the PSOB Program and is available to all eligible survivors (except for surviving dependents younger than the age of 18 who are not also surviving eligible children). In the event that death benefits were paid under the PSOB Program with respect to the deceased person, 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. Any death benefit paid under the standard calculation will be reduced by the total amount of benefits for lost employment income paid to the smallpox vaccine recipient or vaccinia contact during his or her lifetime and to his or her estate after death.

(c) The alternative calculation, described in §102.82(c), is calculated based on the person's employment income at the time of the covered injury. This calculation is only available to surviving dependents who are younger than the age of 18. The legal guardian(s) of such surviving dependents must select the death benefit as calculated under this alternative calculation before it will be paid. The payment of a death benefit as calculated under this alternative calculation is secondary to other benefits received (compensation for loss of employment income, death benefits (including PSOB Program death benefits), disability benefits, or retirement benefits on behalf of the dependent(s) or his or her legal guardian or life insurance benefits on behalf of the dependent(s)).

#### Subpart E—Procedures for Filing Request Packages

SOURCE: 68 FR 70096, Dec. 16, 2003, unless otherwise noted.

## § 102.40

### § 102.40 How to obtain forms and instructions.

Interested parties may obtain copies of all necessary forms and instructions by sending a letter through the U.S. Postal Service, commercial carrier, or private courier service, by telephone, or by downloading them from the Program's website.

(a) If using the U.S. Postal Service, interested parties should send letters asking for forms and instructions to the Smallpox Vaccine Injury Compensation Program Office, Healthcare Systems Bureau, Health Resources and Services Administration, Parklawn Building, Room 11C-06, 5600 Fishers Lane, Rockville, MD 20857.

(b) If using a commercial carrier or private courier service, interested parties should send letters asking for forms and instructions to the Smallpox Vaccine Injury Compensation Program Office, Healthcare Systems Bureau, Health Resources and Services Administration, Parklawn Building, Room 11C-06, 5600 Fishers Lane, Rockville, Maryland 20857.

(c) For forms and instructions, interested parties can call (888) 496-0338. This is a toll-free number.

(d) Interested parties can download forms and instructions from the Internet at <http://www.hrsa.gov/smallpoxinjury>. Click on the link to "Forms and Instructions."

[68 FR 70096, Dec. 16, 2003, as amended at 71 FR 29810, May 24, 2006]

### § 102.41 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 payments. Request Packages may be filed through the U.S. Postal Service, commercial carrier, or private courier service. The Smallpox Vaccine Injury Compensation Program Office will not accept Request Packages electronically or by hand-delivery.

(a) If using the U.S. Postal Service, requesters (or their representatives) should send all forms and documentation to the Smallpox Vaccine Injury Compensation Program Office, Healthcare Systems Bureau, Health Resources and Services Administra-

## 42 CFR Ch. I (10-1-09 Edition)

tion, Parklawn Building, Room 11C-06, 5600 Fishers Lane, Rockville, MD 20857.

(b) If using a commercial carrier or private courier service, requesters (or their representatives) should send all forms and documentation to the Smallpox Vaccine Injury Compensation Program Office, Healthcare Systems Bureau, Health Resources and Services Administration, Parklawn Building, Room 11C-06, 5600 Fishers Lane, Rockville, Maryland 20857.

[68 FR 70096, Dec. 16, 2003, as amended at 71 FR 29810, May 24, 2006]

### § 102.42 Deadlines for filing request forms.

(a) *General.* Filing deadlines vary depending on whether the injured individual is a smallpox vaccine recipient or a vaccinia contact. In all cases, the filing date is the date the Request Form is postmarked. A legibly dated receipt from a commercial carrier, a private courier service, or the U.S. Postal Service (e.g., the date that a commercial carrier places on the package at the time of drop-off) will be considered equivalent to a postmark. 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 representative. After filing a Request Form within the governing filing deadline, a requester can and should update the Request Form to reflect new information.

(b) *Request forms not filed within deadline.* If the Secretary determines that a Request Form was not filed within the governing filing deadline set out in this section, the Request Form will not be processed and the requester will not be entitled to any benefits under this Program.

(c) *Smallpox vaccine recipients.* All Request Forms filed by, or on behalf of, a smallpox vaccine recipient must be filed within one year of the date of the administration of a smallpox vaccine to the smallpox vaccine recipient. This deadline also applies to a deceased smallpox vaccine recipient's survivor(s) and the representative of his or

her estate. This deadline applies to Request Forms concerning injuries resulting from the administration of a smallpox vaccine or other covered countermeasures.

(d) *Vaccinia contacts.* All Request Forms filed by, or on behalf of, a vaccinia contact must be filed within two years after the date of the first symptom or manifestation of onset of the covered injury in the vaccinia contact. This deadline also applies to a deceased vaccinia contact's survivor(s) and the representative of his or her estate. This deadline applies to Request Forms concerning injuries resulting from vaccinia contracted through accidental vaccinia inoculation or from the administration of covered countermeasures (other than the smallpox vaccine) as a result of such accidental vaccinia inoculation.

(e) *Request forms (or amendments to request forms) based on modifications to the table of injuries.* The Secretary may amend the Table set forth in §102.21. The effect of such an amendment may enable a requester who previously could not establish a Table injury to establish a Table injury. In such circumstances, the requester must file a new Request Form or an amendment to a previously filed Request Form as follows:

(1) If the injured person is a smallpox vaccine recipient, within one year after the effective date of the amendment to the Table; or

(2) If the injured person is a vaccinia contact, within two years after the effective date of the amendment to the Table.

**§102.43 Deadlines for submitting documentation.**

(a) *Documentation for eligibility determinations.* All eligibility documentation required by the Program should be filed together with the Request Form. However, if this is not possible, 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 §102.42. The Secretary will not generally begin his review of a requester's eligibility until the documentation necessary for the Secretary to make

this determination has been submitted. All such documentation must be submitted before the Program terminates.

(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 his review of the benefits available to a requester until the documentation necessary for the Secretary to make a benefits determination has been submitted. All such documentation must be submitted before the Program terminates.

**§102.44 Representatives of requesters.**

(a) Persons other than a requester (*e.g.*, a lawyer, guardian, friend) may file a Request Package on a requester's behalf as his or her representative. A requester need not use the services of a lawyer to secure benefits under this Program. A representative (who does not need to be a lawyer) is only required, as described in this section, for requesters who are minors or legally incompetent adults. In the event that a 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 forth in this regulation. If a requester has a representative, all communications from the Secretary will be directed exclusively to the representative.

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

## § 102.45

(c) *Representatives of minors and legally incompetent adults.* A requester who is a minor or a legally incompetent adult *must* use a representative to pursue benefits under this Program on his or her behalf. In such circumstances, the representative must certify, in the place provided on the Request Form, that the requester is a minor or a legally incompetent adult 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 §102.63.

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

[68 FR 70096, Dec. 16, 2003, as amended at 71 FR 29811, May 24, 2006]

### § 102.45 Multiple survivors.

Multiple survivors of the same smallpox vaccine recipient or vaccinia contact 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.

### § 102.46 Amending a request package.

(a) *Generally.* All requesters may amend their documentation concerning eligibility until the Secretary has made an eligibility determination. Requesters also may amend their information or documentation concerning the calculation of benefits until the Secretary has made a benefits determination. The Secretary may, at his discretion, accept eligibility or benefits documents even after eligibility or benefits determinations have been made (e.g., the Secretary may accept new documents concerning eligibility after determining that a requester is ineligible and may use such documents to reevaluate the earlier eligibility determination). However, such new documentation will not be used in any reconsideration regarding the initial determination. The Secretary will not

## 42 CFR Ch. I (10–1–09 Edition)

consider any documentation submitted after the Program terminates.

(b) *Requesters who are survivors.* If a smallpox vaccine recipient or vaccinia contact submitted a Request Form within the filing deadline, but subsequently dies, his or her survivor(s) may amend his or her Request Package at any time before the Program terminates in order to be considered eligible 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 person's Request Package. However, a survivor filing an amendment to a previously filed Request Package may only be entitled to 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 person 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 §102.11. Such an amendment may be filed at any time before the Program terminates.

(c) *Requests in which benefits are sought by the estate of a deceased smallpox vaccine recipient or vaccinia contact.* If a smallpox vaccine recipient or vaccinia contact submitted a Request Form within the filing deadline, but subsequently dies, a representative of his or her estate may amend his or her Request Package at any time before the Program terminates in order to be considered eligible for benefits. Such an amendment can be filed regardless of whether the Secretary made an eligibility determination or paid benefits with respect to the deceased person's Request Package. However, a representative of an estate filing an amendment to a previously filed Request Package may only be entitled to benefits if the previously filed Request Package was filed within the governing filing deadline. All required documentation that has already been submitted with respect to the deceased person will be considered part of the amended Request Package, and the

representative of the estate is not required to resubmit such documentation.

### Subpart F—Required Documentation To Be Deemed Eligible

SOURCE: 68 FR 70096, Dec. 16, 2003, unless otherwise noted.

#### § 102.50 Medical records necessary to establish that a covered injury was sustained.

(a) In order to establish that a smallpox vaccine recipient or vaccinia contact sustained a covered injury, a requester must submit the following medical records:

(1) All physician, clinic, or hospital outpatient medical records documenting medical visits, consultations, and test results that occurred on or after the date of the smallpox vaccination or exposure to vaccinia; and

(2) All inpatient hospital medical records, including the admission history and physical examination, the discharge summary, all physician subspecialty consultation reports, all progress notes, and all test results that occurred on or after the date of the smallpox vaccination or exposure to vaccinia.

(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 need to introduce additional medical documentation or scientific evidence in order to establish that an injury was caused by a covered countermeasure (including the smallpox vaccine) or vaccinia contracted through accidental vaccinia inoculation.

(c) If certain medical records listed in paragraph (a) of this section are unavailable to the requester after he or she has made reasonable efforts to obtain the records, the requester must submit a statement describing the reasons for the records' unavailability and the efforts he or she has taken to obtain the records. The Secretary has the discretion to accept such a statement in place of the unavailable medical records. In this circumstance, the Secretary may require an authorization

from the requester (or his or her representative) to try to obtain the records on his or her behalf.

(d) In certain circumstances, the Secretary may require additional medical records to make a determination that a covered injury was sustained (e.g., medical records prior to the date of vaccination or accidental vaccinia exposure) or may determine that certain records described in paragraph (a) of this section are not necessary for an eligibility determination (e.g., records that are duplicative of other records submitted). If the Program requests additional medical records (or information) from a requester's health care practitioner, then the requester may use a release form in order to have the medical records sent directly to the Program.

#### § 102.51 Documentation a smallpox vaccine recipient must submit to be deemed eligible by the Secretary.

(a) A smallpox vaccine recipient must submit the following documentation in order to be deemed eligible by the Secretary:

(1) A completed (to the fullest extent possible) and signed Request Form.

(2) Documentation demonstrating that the requester:

(i) Is a health care worker, law enforcement officer, firefighter, security personnel, emergency medical personnel, other public safety personnel, or support personnel for such occupational specialties who has volunteered and been selected to be a member of a smallpox emergency response plan prior to the time at which the Secretary publicly announces that an active case of smallpox has been identified within or outside of the United States and that the requester is or will be functioning in a role identified in a smallpox emergency response plan; and

(ii) Was administered a smallpox vaccine pursuant to an approved smallpox emergency response plan during the effective period of the Declaration.

(3) If the requester's injury relates to the administration of cidofovir or its derivatives or Vaccinia Immune Globulin, and not the smallpox vaccine, documentation demonstrating that the

requester was administered such a covered countermeasure during the effective period of the Declaration.

(4) Medical records sufficient to demonstrate that the requester sustained a covered injury, as described in §102.3(g), in accordance with the requirements set forth in §102.50.

(b) As an alternative to the documentation described in paragraphs (a)(2)(i)–(ii) of this section (documentation concerning a vaccine recipient's participation in, and receipt of the smallpox vaccine under, an approved smallpox emergency response plan), a requester may submit a certification, by a Federal, State, or local government entity or private health care entity participating in the administration of covered countermeasures through a smallpox emergency response plan, that the requester is a person described in §102.3(x)(1)–(3) (a person meeting the definition of a smallpox vaccine recipient, except for the requirement that the person sustained a covered injury). A certification form that may be used for this purpose is available from the Program.

[68 FR 70093, Dec. 16, 2003; 69 FR 7376, Feb. 17, 2004]

**§ 102.52 Documentation a vaccinia contact must submit to be deemed eligible by the Secretary.**

A requester who is a vaccinia contact must submit the following documentation in order to be deemed eligible by the Secretary:

(a) A completed (to the fullest extent possible) and signed Request Form;

(b) Documentation identifying the individual who was the source of the accidental vaccinia inoculation. This documentation must demonstrate that the source of the vaccinia was an individual described in §102.3(x)(1)–(3) (a person meeting the definition of a smallpox vaccine recipient, except for the requirement that the person sustained a covered injury) or an individual who was accidentally inoculated by an individual described in §102.3(x)(1)–(3) (a person meeting the definition of a smallpox vaccine recipient, except for the requirement that the person sustained a covered injury). If the requester is unable to provide the identity of the person who was the

source of the accidental exposure, he or she must explain in writing both why this criterion cannot be met and the circumstances of the accidental vaccinia inoculation that support an individual described above as the source of the accidental vaccinia inoculation. The Secretary has the discretion to accept the requester's statement as evidence of the requester's source of exposure; and

(c) Medical records sufficient to demonstrate that the requester contracted vaccinia during the effective period of the Declaration (or within 30 days thereafter) and sustained a covered injury, as described in §102.3(g), in accordance with the requirements set forth in §102.50. These records must be consistent with the requester contracting vaccinia after the accidental vaccinia inoculation described in paragraph (b) of this section.

**§ 102.53 Documentation a survivor must submit to be deemed eligible by the Secretary.**

A requester who is a survivor must submit the following documentation in order to be deemed eligible by the Secretary:

(a) A completed (to the fullest extent possible) and signed Request Form;

(b) All of the documentation required in:

(1) Section 102.51(a)(2)–(4) (documentation requirements for smallpox vaccine recipients), in the case of a deceased smallpox vaccine recipient. The survivor requester may submit a certification, as described in §102.51(b) in the place of the documentation described in §102.51(a)(2) (documentation concerning a vaccine recipient's participation in, and receipt of the smallpox vaccine under, an approved smallpox emergency response plan); or

(2) Section 102.52(b)–(d) (documentation requirements for vaccinia contacts), in the case of a deceased vaccinia contact;

(c) A death certificate for the deceased smallpox vaccine recipient or vaccinia contact. 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 smallpox recipient or vaccinia contact is deceased;

(d) Medical records sufficient to demonstrate that the deceased smallpox vaccine recipient or vaccinia contact died as the result of the covered injury. Such medical records may be the same as those required under §102.50. If an autopsy was performed on the deceased smallpox vaccine recipient or vaccinia contact, the requester must submit a complete copy of the final autopsy report.

(e) Documentation showing that the requester is an eligible survivor, pursuant to §102.11 (e.g., birth certificate or marriage certificate); and

(f) A certification, on the place provided on the Request Form, either that there are no other eligible survivors (e.g., for surviving eligible children, a certification 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 102.11 lists eligible survivors and the priorities of survivorship.

**§102.54 Documentation the representative of the estate of a deceased smallpox vaccine recipient or vaccinia contact must submit to be deemed eligible by the Secretary.**

A requester who is the representative of the estate of a deceased smallpox vaccine recipient or vaccinia contact must submit the following documentation in order for the estate to be deemed eligible by the Secretary:

(a) A completed (to the fullest extent possible) and signed Request Form;

(b) All of the documentation required in:

(1) Section 102.51(a)(2)–(4) (documentation requirements for smallpox vaccine recipients), in the case of a deceased smallpox vaccine recipient. The requester may submit a certification, as described in §102.51(b) in the place of the documentation described in §102.51(a)(2) (documentation concerning a vaccine recipient's participation in, and receipt of the smallpox

vaccine under, an approved smallpox emergency response plan); or

(2) Section 102.52(b)–(d) (documentation requirements for vaccinia contacts), in the case of a deceased vaccinia contact;

(c) A death certificate for the deceased smallpox vaccine recipient or vaccinia contact. 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 smallpox recipient or vaccinia contact is deceased; and

(d) Documentation showing that the requester is the representative of the estate of the deceased smallpox vaccine recipient or vaccinia contact.

**Subpart G—Required Documentation for Eligible Requesters To Receive Benefits**

SOURCE: 68 FR 70096, Dec. 16, 2003, unless otherwise noted.

**§102.60 Documentation an eligible requester seeking medical benefits must submit.**

A requester deemed eligible by the Secretary who seeks payment or reimbursement for medical services or items must submit the following, in addition to the documentation submitted under subpart F:

(a) *List of third-party payors.* The requester must submit a list of all third-party payors that may have an obligation to pay for or provide any medical services or items for which payment or reimbursement is being sought under this Program. Such third-party payors may include, but are not limited to, health maintenance organizations, health insurance companies, Medicare, Medicaid, and other entities obligated to provide medical services or items or recompense individuals for medical expenses. Such a list must include the individual's account numbers and other applicable information. If the requester knows of no such third-party payor, he or she must certify to that fact. If the requester becomes aware that a third-party payor may have such an obligation, the requester must inform the

Secretary within 10 business days of becoming aware of this information.

(b) *Documents for medical services or items provided in the past.* A requester seeking payment or reimbursement for medical services or items provided in the past must submit an itemized statement from each health care entity (e.g., clinic, hospital, doctor, or pharmacy) and third-party payor 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 payor has an obligation to pay for or provide such services or items, the requester must certify to that fact 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 its health complications, the requester may submit, in addition to the required medical records, documentation showing that a health care practitioner prescribed or recommended such services or items. The medical records must support the requested services and items;

(c) *Documents for medical services and items expected to be provided in the future.* A requester seeking payments for medical services or items expected to be provided in the future must submit a statement from one or more health care practitioner(s) (e.g., a treating neurologist for neurologic issues and a treating cardiologist for cardiologic issues) describing those services and items that appear likely to be needed to diagnose or treat the covered injury or 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 paid by third-party payors for, such services or items.

**§ 102.61 Documentation an eligible requester seeking benefits for lost employment income must submit.**

A requester deemed eligible by the Secretary who seeks benefits for lost employment income from the Program must submit, in addition to the documentation submitted under subpart F, documentation describing:

(a) The number of days (including partial days) of work missed by the smallpox vaccine recipient or vaccinia contact as a result of the covered injury or its health complications for which employment income was lost (e.g., time sheet from pay period reflecting work days missed). As stated in § 102.32(c), days for which an individual used paid leave in order to be paid for lost work will be considered days of work for which employment income was received (unless the individual's employer restores the leave that was used by putting the individual in the same position as if he or she had not used paid leave);

(b) The smallpox vaccine recipient or vaccinia contact's gross employment income at the time the covered injury was sustained (e.g., the individual's most recent Federal tax return or a pay stub from the time of the covered injury);

(c) Whether the smallpox vaccine recipient or vaccinia contact had one or more dependents at the time the covered injury was sustained (e.g., the individual's most recent Federal tax return); and

(d) All third-party payors that have paid for or that may be required to pay the requester benefits for loss of employment income or provide disability and retirement benefits for which payment or reimbursement is being sought under this Program (e.g., State workers' compensation programs, disability insurance programs, etc.). A requester must submit documentation, if available, concerning the amount of such payments or benefits expected to be paid by third-party payors. If the requester knows of no such third-party payor, he or she must certify to that fact. If, at any time, the requester becomes aware that a third-party payor may have such an obligation, the requester must inform the Secretary

within 10 business days of becoming aware of this information.

**§102.62 Documentation an eligible requester seeking a death benefit must submit.**

(a) A requester deemed an eligible survivor by the Secretary who seeks a death benefit under §102.82(c) must submit, in addition to the documentation submitted under subpart F, a certification informing the Secretary whether a disability or death benefit was paid under the PSOB Program with respect to the deceased smallpox vaccine recipient or vaccinia contact. If such a benefit(s) was provided, the requester must submit documentation showing the amount of the benefit(s) provided by the PSOB Program. If no such benefits were provided, the certification must explain whether any survivors are eligible for a death benefit under the PSOB Program and, if so, whether death benefits have been sought under the PSOB Program.

(b) A representative seeking a death benefit under §102.82(d) on behalf of a dependent requester younger than the age of 18 deemed an eligible survivor by the Secretary must submit, in addition to the documentation submitted under subpart F, the following:

(1) Documentation showing that the deceased smallpox vaccine recipient or vaccinia contact 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) 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 §102.82(d), in place of proportional benefits available under the standard calculation as described in §102.82(c). Written selections are described in §102.82(d)(1).

(3) 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 §102.63(b). If multiple dependents have different legal guardians, the legal

guardian of each dependent(s) must submit such documentation;

(4) Documentation showing the deceased smallpox vaccine recipient or vaccinia contact's gross employment income at the time the covered injury was sustained (e.g., the decedent's most recent Federal tax return or a pay stub from the time of the covered injury); and

(5) A description of all third-party payors that have paid for or that may be required to pay for the benefits described in §102.82(d)(3)(A). This description must include the amount of such benefits that have been paid or that may be authorized to be paid in the future. If the representative knows of no such third-party payor, he or she must certify to that fact. If, at any time, the representative becomes aware that a third-party payor may have such an obligation, he or she must inform the Secretary within 10 business days of becoming aware of this information.

**§102.63 Documentation a representative filing on behalf of an eligible requester who is a minor or a legally incompetent adult must submit.**

Before benefits will be paid under by the Program to an eligible requester who is a minor or legally incompetent adult, his or her representative must submit, in addition to the documentation submitted under subpart F and under §§102.60-102.62, the following:

(a) Documentation showing that the requester is:

(1) A minor (e.g., birth certificate); or  
(2) A legally incompetent adult (e.g., court decree of incompetency); and

(b) Documentation showing that:

(1) In the case of a minor, the requester is the legal guardian of the minor (e.g., birth certificates for parents who are legal guardians or, for other legal guardians, a decree by a court of competent jurisdiction establishing the legal guardianship of a person other than the minor's parents under applicable State law). If a minor has more than one legal guardian, this information is required only of one legal guardian; or

(2) In the case of a legally incompetent adult, a decree by a court of competent jurisdiction establishing a guardianship or conservatorship of the

requester's estate under applicable State law.

### Subpart H—Secretarial Determinations

SOURCE: 68 FR 70096, Dec. 16, 2003, unless otherwise noted.

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

(a) Before reviewing a Request Package, the Secretary will assign a Program number to the Request Package 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 Package will be referenced by this Program number.

(b) Before the Secretary will pay benefits under this Program, he must determine that:

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

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

(3) 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.

(c) Once the Secretary has sufficient documentation to make an eligibility or benefits determination, he will make the decision in a timely manner.

#### § 102.71 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 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 write to the Secretary

and explain the reason that the requested documentation is unavailable and the efforts the requester has taken to obtain the documents. The Secretary may accept such a letter in place of the required documentation or disapprove the request due to insufficient documentation. If no documentation is submitted in response to the Secretary's letter, the Secretary may disapprove the request. The Secretary also may require an authorization from the requester (or his or her representative) to try to obtain required documentation on his or her behalf.

#### § 102.72 Sufficient documentation for eligibility and benefits determinations.

(a) *Eligibility determinations.* When the Secretary determines that there is sufficient documentation in the Request Package to conduct an evaluation of a requester's eligibility, he will begin the review to determine whether the requester is eligible. 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 options available to the requester, including reconsideration.

(b) *Benefits determinations.* If the Secretary determines that the requester is eligible for benefits, he will, after receiving 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 insurance company if none was provided).

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

#### § 102.73 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, he will notify the requester (or his or her representative) in writing. The Secretary will

make payments in accordance with § 102.83.

**§ 102.74 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 and provide the requester, or his or her representative, with a written notice of the basis for the disapproval and the options available to the requester, including reconsideration.

(b) The Secretary may disapprove a request at any time, even before the requester has submitted required documentation (e.g., the Secretary may determine that a requester did not meet the filing deadline, even before required documentation is submitted or reviewed).

**Subpart I—Calculation and Payment of Benefits**

SOURCE: 68 FR 70096, Dec. 16, 2003, unless otherwise noted.

**§ 102.80 Calculation of medical benefits.**

In calculating medical benefits, the Secretary will take into consideration all reasonable costs for those medical items and services that are reasonable and necessary to diagnose or treat a smallpox vaccine recipient or vaccinia contact's covered injury or its health complications, as described in § 102.31. 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 § 102.60. The Secretary will make such payments only to the extent that such costs were not, and will not be, paid by any third-party payor and only if no third-party payor had or has an obligation to provide such services or items to the requester, except as provided in § 103.83(c) and § 103.84. There are no caps on medical benefits that may be provided under the Program.

**§ 102.81 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 smallpox vaccine recipient or vaccinia contact lost employment income for the lost work days. As described in § 102.32(c), days in which an individual used paid leave (including vacation and sick leave) for lost work days will not be considered days for which the individual lost employment income (unless the individual's employer restores the leave taken by putting the employee in the same position as if he or she had not used paid leave).

(1) The Secretary will calculate the rate of benefits to be paid for the lost work days based on the smallpox vaccine recipient or vaccinia contact'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 a smallpox vaccine recipient or vaccinia contact with no dependents at the time the covered injury was sustained, the benefits are 66% of the individual's gross employment income at the time the covered injury was sustained.

(ii) For a smallpox vaccine recipient or vaccinia contact with one or more dependents at the time the covered injury was sustained, the benefits are 75% of the individual's gross employment income at the time the covered injury was sustained; and

(2) In the case of a smallpox vaccine recipient or vaccinia contact who is a minor, the Secretary may consider the provisions of 5 U.S.C. 8113 (part of the statute 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:

(1) *Annual limitation.* The maximum amount that a requester can receive in any one year in benefits for lost employment income under this Program is \$50,000;

(2) *Lifetime limitation.* The maximum amount that a requester 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 §102.82(c). However, this lifetime cap does not apply if the Secretary determines that the smallpox vaccine recipient or vaccinia contact 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); and

(3) *Number of lost work days.* A requester 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 5 days. If the smallpox vaccine recipient or vaccinia contact lost employment income for a period of 5 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 work days (or partial work days) lost as a result of a covered injury or its health complications in this calculation.

(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 requester for compensation of lost employment income or disability or retirement benefits, by any third-party payor in relation to the covered injury or its health complications, consistent with §102.32(b); and

(2) So that the total amount of benefits for lost employment income paid to a requester under this Program, together with the total amounts paid (or payable) by third-party payors, as described in paragraph (d)(1) of this section, does not exceed 66⅔% (or 75%, if the smallpox vaccine recipient or vaccinia contact 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. If a requester receives a lump-sum payment from any third-party payor, under any obligation described in paragraph (d)(1) of this section, the Secretary will deem 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; and

(e) *Termination of payments.* The Secretary will not pay benefits for lost employment income after the requester reaches the age of 65.

[68 FR 70093, Dec. 16, 2003; 69 FR 7376, Feb. 17, 2004]

#### § 102.82 Calculation of death benefits.

(a) *Definitions.* For purposes of this section:

(1) *Alternative calculation* means the calculation used under paragraph (d) of this section for the death benefit available to dependents.

(2) *Deceased person* means an otherwise eligible deceased smallpox vaccine recipient or vaccinia contact; and

(3) *Dependent* means a person whom the Internal Revenue Service would have considered the deceased person’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.

(4) *Standard calculation* means the calculation used under paragraph (c) of this section for the death benefit available to all eligible survivors (other

than dependents who do not meet another category of eligible survivors, such as surviving eligible children).

(b) *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 (d)(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 §102.11(b).

(2) If the Secretary approves a written selection to receive benefits under the alternative calculation, as described in paragraph (d)(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 smallpox vaccine recipient is survived by a dependent 10-year old child and a spouse who is not the child's legal guardian (e.g., the dependent child's parents were the deceased person and his or her former spouse), the 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 pro-

portionate share of the death benefit available under the alternative calculation (if the legal guardian filed a written selection for such a death benefit).

(c) *Standard calculation of death benefits.* (1) The maximum death benefit available under the standard calculation of death benefits is the amount of the comparable death benefit calculated under the PSOB Program in the same fiscal year as the year in which the death benefit under the standard calculation is paid under this Program (without regard to any reduction under the PSOB Program attributable to a limitation in appropriations), reduced by the total amount of benefits for lost employment income paid under this Program to the deceased person during his or her lifetime and to his or her estate after death.

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

(3) No death benefit will be paid under the standard calculation if a disability benefit has been paid under the PSOB Program with respect to the deceased person. However, 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 (c)(1) of this section.

(4) Death benefits will be paid under the standard calculation in a lump sum.

(d) *Alternative calculation of death benefits available to surviving dependents younger than the age of 18.* If a deceased smallpox vaccine recipient or vaccinia contact 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 (d)(1) of this section. 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 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% of the deceased person'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 (as appropriate), 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 will be reduced so that the total amount of payments made (or expected

to be made) under obligations described in paragraph (d)(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 (d)(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 payors have paid (or are expected to pay) for certain benefits so that such dependents will receive a total sum (combining the death benefit paid under the alternative calculation and the actual and expected benefits paid for by third-party payors) that is not greater than the death benefit that would be available under the alternative calculation if no third-party payor existed to pay such benefits.

(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 payor for:

(A) Compensation for the deceased person's loss of employment income on behalf of the dependents or their legal guardian(s);

(B) Disability, retirement, or death benefits in relation to the deceased person (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.

(ii) In calculating such reductions, the Secretary will deem any lump-sum payment made by a third-party payor under any obligation described in paragraph (d)(3)(A) of this section, as 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.

(4) *Timing of payments.* Payments made under this paragraph will be made on an annual basis, beginning at 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.

[68 FR 70093, Dec. 16, 2003; 69 FR 7376, Feb. 17, 2004]

**§ 102.83 Payment of all benefits.**

(a) The Secretary may 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 §102.82(d)) will be required for a period in excess of one year from the date the Secretary determines the requester is eligible for such benefits, the Secretary may make a lump-sum payment, purchase an annuity or medical insurance policy, or execute an appropriate structured settlement agreement, provided that such payment, annuity, policy, or agreement is 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 §§ 102.80, 102.81, and 102.82(d).

(b) Lump sum payments will be made through an electronic funds transfer to an account of the requester. However, if the requester is a minor, the payment will be made to the account of his or her legal guardian on behalf of the minor. In accepting such payments, the legal guardian of a minor requester is obliged 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 a legally incompetent adult, 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.

(c) The Secretary may, at his discretion, make interim payments of benefits under this Program, even before he makes a final determination as to the total type and total amount of benefits that will be paid. 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, in his discretion, 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 vaccine-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. Such a requester must agree that he or she will be obliged to repay the Secretary such benefits in the event that such payments are later determined to be inappropriate. 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 complete benefits determination.

[68 FR 70096, Dec. 16, 2003, as amended at 71 FR 29811, May 24, 2006]

**§ 102.84 The Secretary's right to recover benefits paid under this program from third-party payors.**

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 payor with a legal or contractual obligation to pay for (or provide) such benefits and may recover from such third-party payor(s) the amount of benefits paid up to the amount of benefits the third-party payor 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 payor in specific circumstances. In those circumstances, the Secretary has a right to be reimbursed by the third-party payor. 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 payor 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 payor after receiving the same type of benefits from the Secretary under this Program, the Secretary has a right to recover the amount of the benefits awarded from the requester.

### Subpart J—Reconsideration of the Secretary's Determinations

SOURCE: 68 FR 70096, Dec. 16, 2003, unless otherwise noted.

#### § 102.90 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 payment. In addition, a requester who asserts that the amount of the benefits paid by the Secretary (or the fact that certain benefits were not paid or payable) is incorrect may also seek reconsideration. Letters seeking 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. Because no new documentation will be considered in the reconsideration process, the letter seeking reconsideration may not include or refer to any documentation that was not before the Secretary at the time of his initial determination.

(b) *Letters seeking reconsideration.* A requester, or his or her representative, may send a letter seeking reconsideration through the U.S. Postal Service, commercial carrier, or a private courier

service. The Secretary will not accept letters seeking reconsideration electronically or by hand-delivery.

(1) Letters sent through the U.S. Postal 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.

(2) Letters sent through a commercial carrier or private courier service must be sent to the Associate Administrator, Healthcare Systems Bureau, Parklawn Building, Room 12-105, 5600 Fishers Lane, Rockville, Maryland 20857.

(c) *Reconsideration process.* When the Associate Administrator of the Healthcare Systems Bureau (the Associate Administrator), receives a letter seeking reconsideration, a qualified panel will be convened, independent of the Program, to review the Secretary's initial determination. The panel will base its recommendation on the documentation before the Secretary when the initial determination(s) 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 letter seeking reconsideration and will be considered the Secretary's final determination on the request. Requesters may not seek review of a decision made on reconsideration.

[68 FR 70096, Dec. 16, 2003, as amended at 71 FR 29811, May 24, 2006]

#### § 102.91 Secretary's review authority.

Under section 262(f)(1) of the Public Health Service Act (42 U.S.C. 239a(f)(1)), the Secretary may, at any time, review on his own motion or on application, any determination made under this part (including, but not limited to, determinations concerning eligibility, entitlement to benefits, and the calculation and payment of benefits under the Program). Upon review of such a determination, the Secretary

**Public Health Service, HHS**

**§ 102.92**

may affirm, vacate, or modify the determination in any manner the Secretary deems appropriate.

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

Under section 262(f)(2) of the Public Health Service Act (42 U.S.C. 239a(f)(2)), no further judicial review of the Secretary's actions under this part

(including, but not limited to, eligibility determinations, the calculation of benefits, and determinations about the method of payment of benefits) is permitted. In addition, no further administrative review of the Secretary's actions under this part is permitted unless the President specifically directs otherwise.

**PART 110 [RESERVED]**