

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 § 102.82(c), are secondary to any obligation of any third-party payor to pay for such benefits. Death benefits paid under § 102.82(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:

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(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

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that the person sustained a covered injury); and

(3) Sustained a covered injury.

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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.