

§ 102.50

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

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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