

(4) *Representatives of estates of deceased smallpox vaccine recipients or vaccinia contacts.*

Representatives of estates of deceased smallpox vaccine recipients or vaccinia contacts may file Request Packages with the program as long as they are seeking benefits on behalf of the deceased person's estate.

Benefits Available to Different Categories of Requesters (§ 102.30)

An eligible requester who is a smallpox vaccine recipient or a vaccinia contact may be entitled to receive either medical benefits or benefits for lost employment income or both as long as they provide the proper documentation. For example, such requesters must submit documentation showing that they have out-of-pocket reasonable and necessary medical expenses as a result of a covered injury or its health complications in order to receive medical benefits, and documentation showing that they lost employment income as a result of a covered injury or its health complications in order to receive benefits for lost employment income. Such documentation requirements are discussed later in this preamble.

An eligible requester who is the survivor of a deceased smallpox vaccine recipient or vaccinia contact may be entitled to receive a death benefit.

The estate of a 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 direct result of a covered injury or its health complications, but were not paid during the deceased person's lifetime. However, the estate would not be eligible to receive payments for benefits that were not accrued during the deceased person's lifetime. For example, the estate would not be entitled to benefits for projected lost employment income that the person might have accrued if he or she had not died.

Covered Injuries (§ 102.20—§ 102.21)

Covered injuries are defined in § 102.3(g) and set out in subpart C of this rule. Covered injuries are those injuries in smallpox vaccine recipients or vaccinia contacts that the Secretary determines are more likely than not (*i.e.*, by a preponderance of the evidence) the direct result of the administration of a covered countermeasure (including a smallpox vaccine) or of vaccinia acquired through accidental vaccinia inoculation. Because even survivors of, and representatives of estates of,

deceased smallpox vaccine recipients and vaccinia contacts must demonstrate that the deceased person sustained a covered injury, a requester will not be deemed eligible for benefits under the program unless the Secretary determines that an eligible smallpox vaccine recipient or vaccinia contact sustained a covered injury.

One way that requesters can demonstrate that they sustained a covered injury is by demonstrating that they sustained an injury listed on the Smallpox (Vaccinia) Vaccine Injury Table (the table) within the required time interval, as set out in § 102.21. In accordance with the SEPPA, a smallpox vaccine recipient or vaccinia contact shall be presumed to have sustained a covered injury as the direct result of the administration of, or exposure to, the smallpox vaccine if the requester submits sufficient documentation demonstrating that he or she sustained an injury included on the table, with the onset of the first symptom or manifestation within the time interval specified on the table. The injury must also meet the table's definitions and requirements, set forth in § 102.21(b). In such circumstances, the Secretary will presume, solely for purposes of the program, that the smallpox vaccine recipient or vaccinia contact's injury was caused by the smallpox vaccine or exposure to vaccinia. Such a requester need not actually demonstrate that the vaccine (or the vaccinia contracted from accidental vaccinia inoculation) caused the underlying injury, only that an injury listed on the table was sustained and that it first manifested itself within the time interval listed.

In directing the Secretary to establish a table with such a presumption, Congress did not direct the Secretary to make this presumption conclusive. In the Secretary's view, it would be inconsistent with the purposes of the SEPPA to make this presumption absolutely conclusive. For this reason, based on his review of the submitted documentation and other relevant evidence, the Secretary may determine that an injury meeting the table requirements was more likely than not (*i.e.*, by a preponderance of the evidence) caused by other factors and was not caused by the smallpox vaccine or exposure to vaccinia (*e.g.*, if the Secretary determined that the medical records demonstrated that an individual's injury of encephalopathy was caused by a car accident that occurred post-vaccination and not by the smallpox vaccine or exposure to vaccinia). In these circumstances, which we expect to occur rarely, the Secretary could rebut the table presumption and

decide that the requester may not be entitled to benefits under the program.

Requesters who believe they sustained an injury included on the table, but did not meet all the table requirements (*e.g.*, the first manifestation of the injury did not become apparent within the required time interval), or requesters who believe they sustained an injury not included on the table, may still be able to demonstrate that the injury is one that is covered under the program. In order to establish a covered injury, such requesters may need to submit sufficient relevant medical documentation (such as isolation of vaccinia from the injured part of the body) or scientific evidence (such as results of studies published in peer-reviewed medical literature). In order to establish a covered injury, the Secretary, upon review of this evidence, must conclude that, more likely than not, the injury was actually caused by the administration of a covered countermeasure or by vaccinia through accidental inoculation during the time periods set forth by law. In other words, in evaluating such claims, the Secretary will employ a preponderance of the evidence standard, taking into consideration all relevant medical and scientific evidence, including all relevant medical records. As provided under the SEPPA, this determination, as with all other actions by the Secretary under this Act, is not reviewable by any court.

Any injury that the Secretary considers minor is not a covered injury. For example, covered injuries do not include expected skin reactions or expected minor scarring at the vaccination or inoculation site. No benefits will be paid for these reactions, as stated in § 102.20(b).

Medical Benefits—Summary and Calculation (§ 102.31 and § 102.80)

Medical benefits that may be available under the program are described in § 102.31. They include payment(s) or reimbursement for medical services and medical items that the Secretary determines are reasonable and necessary for the diagnosis or treatment of a covered injury or its direct health complications (*sequelae*). Past, current, and expected future medical services and items may be included in medical benefits.

In making determinations about which medical services and items provided in the past were reasonable and necessary, the Secretary may consider whether those medical services and items were prescribed or recommended by a health care practitioner. In considering benefits for