

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., 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.

§§ 102.22–102.29 [Reserved]

3. In part 102, reserve §§ 102.22–102.29.

§§ 102.30–102.91 [Added]

4. In part 102, add sections 102.30–102.91 to read as follows:

Subpart D—Available Benefits

§ 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 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