

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 countermeasure recipient 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 § 110.82(c), and is not eligible to receive death benefits under the standard calculation described in § 110.82(b). Death benefits paid under the alternative calculation will be paid to the dependents' legal guardian(s) on behalf of all such 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

§ 110.20 How to establish a covered injury.

(a) *General.* Only serious injuries, as described in § 110.3(z), or deaths are covered under the Program. In order to be eligible for benefits under the Program, a requester must submit documentation showing that a covered injury, as described in § 110.3(g), was sustained as the direct result of the administration or use of a covered countermeasure pursuant to the terms of a declaration under section 319F-3(b) of the PHS Act (including administration or use during the effective period of the declaration) or as the direct result of the administration or use of a covered countermeasure in a good faith belief that it was administered or used pursuant to the terms of a declaration (including administration or use during the effective period of the declaration). 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, as described in paragraph (d) of this section. The Secretary may obtain the opinions of qualified medical experts in making determinations concerning covered injuries.

(b) *Table injuries.* A Table lists and explains injuries that, based on compelling, reliable, valid, medical and scientific evidence, are presumed to be caused by a covered countermeasure, and the time periods in which the onset (*i.e.*, first sign or symptom) of these injuries must occur after administration or use of the covered countermeasures. If an injury occurred within the listed time periods, and at the level of severity required, there is a rebuttable presumption that the covered countermeasure was the cause of the injury. A Table is accompanied by Qualifications and Aids to Interpretation which provide an explanation of the injuries listed on a Table. A requester may establish that a covered injury occurred by demonstrating that the countermeasure recipient sustained an injury listed on a Table, within the time interval defined by the Table's Definitions and Requirements. 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 or use of a covered countermeasure. Even if the Table requirements are satisfied, however, an injury will not be considered a covered injury if the Secretary determines, based on her review of the evidence, that a source other than the countermeasure more likely caused the injury. In such circumstances, the Table presumption of causation will be rebutted.

(c) *Injuries for which causation must be shown (non-Table injuries).* If an injury is not included on a Table or if the injury does not meet the requirements set out for an injury that is listed on a Table (*e.g.*, the first sign or symptom of the injury did not occur within the time interval specified on the Table), the requester must demonstrate that

the injury occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. Temporal association between receipt of the countermeasure and onset of the injury is not sufficient by itself to prove that the countermeasure caused the injury.

(d) *Injuries resulting from the underlying condition for which the countermeasure was administered or used.* An injury sustained as the direct result of the covered condition or disease for which the countermeasure was administered or used, and not as the direct result of the administration or use of the covered countermeasure, is not a covered injury (e.g., if the covered countermeasure is ineffective in treating or preventing the underlying condition or disease).

Subpart D—Available Benefits

§ 110.30 Benefits available to different categories of requesters under this Program.

(a) *Benefits available to injured countermeasure recipients.* A requester who is an injured countermeasure recipient may be eligible 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 deceased injured countermeasure recipient may be eligible to receive a death benefit if the death was caused by the covered injury or its health complications.

(c) *Benefits available to estates of deceased injured countermeasure recipients.* The estate of an otherwise eligible deceased injured countermeasure recipient may be eligible to receive medical benefits or benefits for lost employment income, or both, if such benefits were accrued during the deceased countermeasure recipient's lifetime, or at the time of death, as a result of a covered injury or its health complications, but have not yet been paid in full by the Program. Such medical benefits and benefits for lost employment income may be available regardless of the cause of death. The estate of the deceased injured countermeasure re-

ipient may not receive a death benefit. Death benefits are only available to certain survivors.

§ 110.31 Medical benefits.

(a) Injured countermeasure recipients 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 to diagnose, treat, or prevent the health complications of a covered injury. 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 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 reasonable and necessary medical services and items have already been provided or if they are likely to be needed 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 healthcare provider, and may consider whether the applicable service or item is within the standard of care for that condition.

(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, ill-effects that stem from the covered injury, an adverse reaction to a prescribed medication or as a result of a 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 §110.80. Although there are no caps on medical benefits, the Secretary may limit payments to the