

(bb) *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.

(cc) *Survivor* means a person meeting the requirements of § 110.11 with respect to a deceased injured countermeasure recipient who died as a direct result of a covered injury.

(dd) *Table* or *Table of Injuries* means a Table of Covered Countermeasure Injuries to be included under Subpart K of this part, including the definitions and requirements set out therein.

(ee) *Third-party payer* means the United States (other than for payments of benefits under this Program) or any other third party, including but not limited to, any State or local governmental entity, private insurance carrier, or employer, any public or private entity with a legal or contractual obligation to pay for or provide benefits. The Program is the payer of last resort.

Subpart B—Persons Eligible To Receive Benefits

§ 110.10 Eligible requesters.

(a) The following requesters may, as determined by the Secretary, be eligible to receive benefits from this Program:

(1) Injured countermeasure recipients, as described in § 110.3(n);

(2) Survivors, as described in § 110.3(cc) and § 110.11; or

(3) Estates of deceased injured countermeasure recipients through individuals authorized to act on behalf of the deceased injured countermeasure recipient's estate under applicable State law (*i.e.*, executors or administrators).

(b) If a countermeasure recipient dies, his or her survivor(s) and/or the executor or administrator 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 injured countermeasure recipient, but must be filed within the filing deadlines described in

§ 110.42. Amendments to previously filed Request Packages and the filing deadlines for such amendments are described in § 110.46.

(c) The benefits available to different categories of requesters are described in § 110.30.

§ 110.11 Survivors.

(a) *Survivors of injured countermeasure recipients who died as the direct result of a covered injury.* If the Secretary determines that an injured countermeasure recipient died as the direct result of a covered injury (or injuries), his or her survivor(s) may be eligible for death benefits.

(b) *Survivors who may be eligible to receive benefits and the order of priority for benefits.* (1) The Act uses the same categories of survivors and order of priority for benefits as established and defined by the PSOB Program, except as provided in paragraphs (b)(3), (4), and (5) of this section.

(2) The PSOB Program's categories of survivors (known in the PSOB Program as beneficiaries) and order of priority for receipt of death benefits are detailed 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, as implemented in 28 CFR part 32.

(3) In the PSOB Program, the person who is survived must have satisfied the eligibility requirements for a deceased public safety officer, whereas the person who is survived under this Program must be a deceased injured countermeasure recipient who would otherwise have been eligible under this part.

(4) Unlike the PSOB Program, if there are no survivors eligible to receive death benefits under the PSOB Program (as set forth in paragraph (b)(2) of this section), the legal guardian of a deceased minor who was a countermeasure recipient may be eligible as a survivor under this Program. Such legal guardianship must be determined by a court of competent jurisdiction under applicable State law.

(5) A surviving dependent younger than the age of 18 whose legal guardian opts to receive a death benefit under 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