

Subpart J—Reconsideration of the Secretary's Determinations

110.90 Reconsideration of the Secretary's eligibility and benefits determinations.

110.91 Secretary's review authority.

110.92 No additional judicial or administrative review of determinations made under this part.

Subpart K—Covered Countermeasures Injury Tables

110.100 Injury Tables.

AUTHORITY: 42 U.S.C. 247d-6e.

SOURCE: 75 FR 63675, Oct. 15, 2010, unless otherwise noted.

Subpart A—General Provisions

§ 110.1 Purpose.

This part implements the Public Readiness and Emergency Preparedness Act (PREP Act), which amended the Public Health Service Act (herein after "PHS Act" or "the Act") by including section 319F-3, and section 319F-4 entitled "Covered Countermeasure Process." Section 319F-4 of the PHS Act directs the Secretary of Health and Human Services, following issuance of a declaration under section 319F-3(b), to establish procedures for the Countermeasures Injury Compensation Program (herein after "CICP" or "the Program") to provide medical and lost employment income benefits to certain individuals who sustained a covered injury as the direct result of the administration or use of a covered countermeasure consistent with a declaration issued pursuant to section 319F-3(b), or in the good faith belief that administration or use of the covered countermeasure was consistent with a declaration. Also, if the Secretary determines that an individual died as a direct result of a covered injury, the Act provides for certain survivors of that individual to receive death benefits.

§ 110.2 Summary of available benefits.

(a) The Act authorizes three forms of benefits to, or on behalf of, requesters determined to be eligible by the Secretary:

(1) Payment or reimbursement for reasonable and necessary medical services and items to diagnose or treat a

covered injury, or to diagnose, treat, or prevent its health complications, as described in § 110.31.

(2) Lost employment income incurred as a result of a covered injury, as described in § 110.32.

(3) Death benefits to certain survivors if the Secretary determines that the death of the injured countermeasure recipient was the direct result of a covered injury, as described in § 110.33.

(b) In general, the benefits paid under the Program, are secondary to any obligation of any third-party payer to provide or pay for such benefits. The benefits available under the CICP usually will be paid only after the requester has in good faith attempted to obtain all other available coverage from all third-party payers with an obligation to pay for or provide such benefits (*e.g.*, medical insurance for medical services or items, workers' compensation program(s) for lost employment income). However, as provided in § 110.84, the Secretary has the discretion to pay benefits under this Program before a potential third-party payer makes a determination on the availability of similar benefits and has the right to later pursue a claim against any third-party payer with a legal or contractual obligation to pay for, or provide, such benefits.

§ 110.3 Definitions.

This section defines certain words and phrases found throughout this part.

(a) *Act* or *PHS Act* means the Public Health Service Act, as amended.

(b) *Alternative calculation* means the calculation used in § 110.82(c) of this part for the death benefit available to dependents younger than 18 years old at the time of payment.

(c) *Approval* means a decision by the Secretary or her designee that the requester is eligible for benefits under the Program.

(d) *Benefits* means payments and/or compensation for reasonable and necessary medical expenses or provision of services described in § 110.31, lost employment income described in § 110.32, and/or payment to certain survivors of death benefits described in § 110.33.

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(e)(1) *Child* means any natural, illegitimate, adopted, posthumous child, or stepchild of a deceased injured countermeasure recipient who, at the time of the countermeasure recipient's death is:

- (i) 18 years of age or younger; or
- (ii) Between 19 and 22 years of age and a full-time student; or
- (iii) Incapable of self-support due to a physical or mental disability.

(2) *Posthumous child* means a child born after the death of the parent.

(3) *Stepchild* means a child of an injured countermeasure recipient's spouse but who is not the child of the injured countermeasure recipient. For a stepchild to be eligible for survivor death benefits under the Program, the stepchild's parent must have been married to the injured countermeasure recipient at the time of that injured countermeasure recipient's death, and the stepchild must have been supported by the injured countermeasure recipient.

(f) *Covered Countermeasure* means the term that is defined in section 319F-3(i)(1) of the PHS Act and described in a declaration issued under section 319F-3(b) of the PHS Act (42 U.S.C. 247d-6d(i)(I), (b)). To be a covered countermeasure for purposes of this part, the countermeasure must have been administered or used pursuant to the terms of a declaration, or in a good faith belief of such; and

(1) Administered or used within a State (as defined in §110.3(bb)), or otherwise in the territory of the United States; or

(2) Administered to, or used by, otherwise eligible individuals—

(i) At American embassies or military installations abroad (such as military bases, ships, and camps); or

(ii) At North Atlantic Treaty Organization (NATO) installations (subject to the NATO Status Agreement) where American servicemen and servicewomen are stationed.

(g) *Covered Injury* means death, or a serious injury as described in §110.3(z), and determined by the Secretary in accordance with §110.20 of this part to be:

(1) An injury meeting the requirements of a Covered Countermeasures Injury Table, which is presumed to be the direct result of the administration

or use of a covered countermeasure unless the Secretary determines there is another more likely cause; or

(2) An injury (or its health complications) that is the direct result of the administration or use of a covered countermeasure. This includes serious aggravation caused by a covered countermeasure of a pre-existing condition.

(h) *Declaration* means a recommendation issued by the Secretary under section 319F-3(b) of the PHS Act (42 U.S.C. 247d-6d(b)), for the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures, following her determination that a specific disease, condition, or threat represents a public health emergency or a credible risk of a future public health emergency.

(i) *Dependent* means, for purposes of lost employment income benefits, a person whom the Internal Revenue Service would consider to be the injured countermeasure recipient's dependent at the time the covered injury was sustained. For purposes of survivor death benefits, *dependent* means a person whom the Internal Revenue Service would consider to be the deceased injured countermeasure recipient's dependent at the time the covered injury was sustained, and who is younger than the age of 18 at the time of filing the Request Form.

(j) *Disapproval* means a decision by the Secretary that the individual requesting benefits is not eligible to receive benefits under the Program for the specified injury that is the basis of the Request for Benefits.

(k) *Effective period of the declaration* means the time span specified in a declaration, or as amended by the Secretary.

(l) *Federal Employees' Compensation Act (FECA) Program* means the workers' compensation benefits program for civilian officers and employees of the Federal Government established under 5 U.S.C. 8101 *et seq.* as amended, and implemented by the United States Department of Labor in regulations codified at 20 CFR part 10, as amended.

(m) *Healthcare provider* means an individual licensed, certified, or registered by an appropriate authority and who is qualified and authorized to

provide health care services, such as diagnosing and treating physical or mental health conditions, prescribing medications, and providing primary and/or specialty care.

(n) *Injured countermeasure recipient* means an individual:

(1) Who, with respect to administration or use of a covered countermeasure pursuant to a Secretarial declaration:

(i) Meets the specifications of the pertinent declaration; or

(ii) Is administered or uses a covered countermeasure in a good faith belief that he or she is in a category described by paragraph (1)(i) of this definition; and

(2) Sustained a covered injury as defined in §110.3(g).

(3) If a covered countermeasure is administered to, or used by, a pregnant woman in accordance with paragraphs (1)(i) or (1)(ii) of this definition, any child from that pregnancy who survives birth is an injured countermeasure recipient if the child is born with, or later sustains, a covered injury (as defined in section 110.3(g)) as the direct result of the covered countermeasure's administration to, or use by, the mother during her pregnancy.

(o) *Lacks legal capacity* means legally incompetent to receive payment(s) of benefits, as determined under applicable law.

(p) *Medical records* means documentation associated with primary care, hospital in-patient and out-patient care, specialty consultations, and diagnostic testing and results.

(q) *Payer of last resort* means that the Program pays benefits secondary to all other public and private third-party payers who have an obligation to pay for such benefits.

(r) *Program* means the Countermeasures Injury Compensation Program (CICP).

(s) *PREP Act* means the *Public Readiness and Emergency Preparedness Act*, codified as sections 319F-3 and 319F-4 of the PHS Act (42 U.S.C. 247d-6d, 42 U.S.C. 247d-6e).

(t) *Public Safety Officers' Benefits (PSOB) Program* means the Program established 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, and implemented by the United States Department of Justice in regulations codified at 28 CFR part 32, as amended.

(u) *Representative* (legal or personal) means someone other than the person for whom Program benefits are sought, and who is authorized to file the Request Package on the requester's behalf pursuant to §110.44.

(v) *Requester* means an injured countermeasure recipient, or survivor, or the estate of a deceased injured countermeasure recipient (through the executor or administrator of the estate) who files a Request Package for Program benefits, or on whose behalf a Request Package is filed, under this part.

(w) *Request Form or Request for Benefits Form* means the document designated by the Secretary for applying for Program benefits under this part.

(x) *Request Package* means the Request Form, all documentation submitted by, or on behalf of, the requester, and all documentation obtained by the Secretary as authorized by, or on behalf of, the requester for determinations of Program eligibility and benefits under this part.

(y) *Secretary* means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority conferred on the Secretary under the PREP Act has been delegated.

(z) *Serious injury* means serious physical injury. Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

(aa) *Standard calculation* means the calculation used in §110.82(b) of this part for the death benefit available to all eligible survivors (other than surviving dependents younger than the age of 18 who do not fit the definition of "child" under §110.3(e)).

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(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.

[75 FR 63675, Oct. 15, 2010, as amended at 76 FR 62308, Oct. 7, 2011]

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

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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