

to indicate an injured countermeasure recipient's pre-existing medical history.

(b) A requester may submit additional medical documentation that he or she believes will support the Request Package. Although generally not required if a Table injury was sustained, a requester may introduce additional medical documentation or scientific evidence in order to establish that an injury was caused by a covered countermeasure. Letters from treating physicians may be submitted as additional evidence, but may not substitute for the medical documentation required in paragraph (a) of this section.

(c) If certain medical records listed in paragraph (a) of this section are unavailable to the Program after the requester has made reasonable efforts to facilitate the records being sent to the Program, the requester must submit a statement describing the reasons for the records' unavailability and the efforts he or she has made to arrange for the health care providers to submit them. The Secretary has the discretion to accept this statement in place of the unavailable medical records. In this circumstance, the Secretary may attempt to obtain the records on the requester's behalf.

(d) In certain circumstances, the Secretary may require additional records to make a determination that a covered injury was sustained (*e.g.*, medical records more than one year prior to the date of administration or use of the covered countermeasure) or may determine that certain records described in paragraph (a) of this section are not necessary for an eligibility determination.

(e) Although the Secretary prefers to receive medical records directly from healthcare providers, she has the discretion to accept them from the requester.

§ 110.51 Documentation an injured countermeasure recipient must submit for the Secretary to make a determination of eligibility for Program benefits.

(a) An injured countermeasure recipient (or his or her legal or personal representative) must submit all of the following documentation in order for the

Secretary to make a determination of eligibility:

(1) A completed and signed Request Form submitted within the filing deadline described in § 110.42; and

(2) Records sufficient to demonstrate that the injured countermeasure recipient used or was administered a covered countermeasure; and

(3) Records sufficient to demonstrate that the injured countermeasure recipient sustained a covered injury, as defined in § 110.3(g), in accordance with the requirements set forth in § 110.50; and

(4) A copy of each signed Authorization for Health Information Form authorizing the release of records to the Program that was sent by the requester to each healthcare provider instructing that the records be submitted directly to the Program.

(b) In certain circumstances, some of the above documentation may not be required, or additional documentation may be required, in which case the Secretary will so notify the requester. For example, the Secretary may require records sufficient to demonstrate that the injured countermeasure recipient was administered or used a covered countermeasure in accordance with the provisions of a Secretarial declaration, or in the good faith belief that it was so administered or used, if she is unable to determine this from the records submitted. In order to meet the specifications of a declaration, some individuals will need to show that the activity giving rise to the injury (*i.e.*, administration or use of the covered countermeasure) was authorized in accordance with the public health and medical response of the Authority Having Jurisdiction, as defined in the pertinent declaration, to prescribe, administer, deliver, distribute or dispense the covered countermeasure following a declaration of an emergency, as defined in the pertinent declaration. For purposes of this part, this requirement can be satisfied by showing that the covered countermeasure was administered or used following the declaration of an emergency, as defined in the pertinent declaration, by an Authority Having Jurisdiction, as defined in the pertinent declaration either:

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(1) Pursuant to a written agreement or other formal arrangement with an Authority Having Jurisdiction; or

(2) In accordance with the written recommendations of an Authority Having Jurisdiction.

§ 110.52 Documentation a survivor must submit for the Secretary to make a determination of eligibility for death benefits.

(a) A requester who is a survivor under §110.11 must submit the following documentation in order for a determination of eligibility for a death benefit to be made:

(1) All of the documentation required for individuals in §110.51. There is no need to duplicate documentation already submitted to satisfy the requirements of other subparts in this part. For example, if the deceased injured countermeasure recipient had previously filed, the documentation submitted does not have to be re-submitted; and

(2) A death certificate for the deceased countermeasure recipient. If a death certificate is unavailable, the requester must submit a letter providing the reasons for its unavailability. The Secretary has the discretion to accept other documentation as evidence that the injured countermeasure recipient is deceased; and

(3) Medical records sufficient to establish that the deceased injured countermeasure recipient died as the result of the covered injury or its health complications. Such medical records may be the same as those required under §110.50. If an autopsy was performed, the requester must submit a complete copy of the final autopsy report; and

(4) Documentation showing that the requester is an eligible survivor, pursuant to §110.11 (*e.g.*, birth certificate or marriage certificate); and

(5) Verification, on the place provided on the Request Form, either that there are no other eligible survivors (*e.g.*, for surviving eligible children, that there is no surviving spouse, no other surviving eligible children, and no other surviving dependents younger than the age of 18 who may be eligible for the death benefit under the alternative calculation) or that other eligible survivors exist (along with the in-

formation known about such survivors). Section 110.11 describes eligible survivors and the priorities of survivorship; and

(6) Even if a Request Form had previously been filed by the injured countermeasure recipient, the survivor(s) must submit a new Request Form.

(b) [Reserved]

§ 110.53 Documentation the executor or administrator of the estate of a deceased injured countermeasure recipient must submit for the Secretary to make a determination of eligibility for benefits to the estate.

(a) The executor or administrator of the estate of a deceased injured countermeasure recipient must submit the following documentation in order for a determination of eligibility for benefits to the estate to be made:

(1) All of the documentation required for individuals in §110.51;

(2) A death certificate for the deceased injured countermeasure recipient. If a death certificate is unavailable, the executor or administrator must submit a letter providing the reasons for its unavailability. The Secretary has the discretion to accept other documentation as evidence that the injured countermeasure recipient is deceased; and

(3) Documentation showing that the individual is the executor or administrator of the estate of the deceased injured countermeasure recipient, *e.g.*, Letter of Administration issued by a court of competent jurisdiction; and

(4) Even if a Request Form had previously been filed by the injured countermeasure recipient, the executor or administrator of the estate must submit a new Request Form.

(b) [Reserved]

Subpart G—Documentation Required for the Secretary To Determine Program Benefits**§ 110.60 Documentation a requester who is determined to be eligible must submit for the Secretary to make a determination of medical benefits.**

(a) A requester determined by the Secretary to be eligible for Program benefits and who seeks payment or reimbursement for medical services or