

## § 110.72

for the Secretary to make the applicable determinations under this part, the Secretary will so notify the requester, or his or her representative. The requester will be given 60 calendar days from the date of the Secretary's notification to submit the required documentation. If the requester is unable to provide the additional documentation, he or she may provide a written explanation of the reason(s) that the requested documentation is unavailable and the efforts the requester has made to obtain the documents. The Secretary may accept such a statement in place of the required documentation or disapprove the Request for Benefits due to insufficient documentation. If insufficient documentation is submitted in response to the Secretary's letter, the Secretary may disapprove the Request for Benefits.

### **§ 110.72 Sufficient documentation for eligibility and benefits determinations.**

(a) *Eligibility determinations.* When the Secretary determines that there is sufficient documentation in the Request Package to evaluate a requester's eligibility, she will begin the review to determine whether the requester is eligible for Program benefits. If the Secretary determines that the requester is not eligible, the Secretary will inform the requester (or his or her representative) in writing of the disapproval, and the right to reconsideration of the determination, as described in subpart J.

(b) *Benefits determinations.* If the Secretary determines that the requester is eligible for benefits, she will, after receiving adequate documentation from the requester for a benefits determination, either calculate the amount and types of benefits, as described in subpart I of this part, or request additional documentation in order to calculate the benefits that can be paid (*e.g.*, an Explanation of Benefits from the requester's health insurance company, if none was submitted). As provided in subpart J, requesters have the right to reconsideration of the Secretary's determination of the category and amount of benefits payable under the Program.

(c) *Additional documentation required.* At any time after a Request Form has

## 42 CFR Ch. I (10–1–14 Edition)

been filed, the Secretary may ask a requester to supplement or amend the Request Package by providing additional information or documentation.

### **§ 110.73 Approval of benefits.**

When the Secretary has determined that benefits will be paid to a requester and has calculated the type and amount of such benefits, she will so notify the requester (or his or her representative) in writing. The Secretary will make payments in accordance with § 110.83. Once all benefits have been paid, the Request Package can no longer be amended (except for survivor benefits). The payment determination will constitute final agency action with regard to the particular countermeasure injury that is the subject of the Request for Benefits and payment (*i.e.*, the Request for Benefits is closed with regard to the injury that is the basis of the payment of benefits).

### **§ 110.74 Disapproval of benefits.**

(a) If the Secretary determines that a requester is not eligible for payments under the Program, the Secretary will disapprove the Request for Benefits and provide the requester, or his or her representative, with written notice of the basis for the disapproval, and the right to reconsideration of the determination, as provided in § 110.90.

(b) The Secretary may disapprove a Request for Benefits even before the requester has submitted all the required documentation (*e.g.*, the Secretary may determine that a requester did not meet the filing deadline, or that a covered countermeasure was not used or administered).

(c) The Secretary may re-open a disapproved Request for Benefits on her own accord should medical or scientific evidence later become available to justify a re-determination of the disapproval of eligibility or payments. In extraordinary circumstances, to be determined at the Secretary's discretion, she may re-open a disapproved Request for Benefits even after the requester has exercised the right to reconsideration and the disapproval determination has been upheld in accordance with the procedures set out in § 110.90.