



## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Health Resources and Services Administration**

**[OMB No. 0915-0334 – Extension]**

#### **Agency Information Collection Activities: Proposed Collection: Comment Request**

#### **Information Collection Request Title: Countermeasures Injury Compensation Program**

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on this ICR should be received no later than **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, Maryland 20857.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443-1984.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the ICR title, below, for reference.

*Information Collection Request Title: Countermeasures Injury Compensation Program*

OMB No. 0915-0334 – Extension

*Abstract:* This is a request for continued OMB approval of the information collection requirements for the Countermeasures Injury Compensation Program (CICP or Program). The CICP, within the Division of Injury Compensation Programs, Healthcare Systems Bureau, HRSA, administers this compensation program as specified by the Public Readiness and Emergency Preparedness Act of 2005 (PREP Act).

The Secretary of the Department of HHS (Secretary) can issue a PREP Act declaration. When issued, the purpose of a declaration is to identify a disease, health condition, or a threat to health that is currently, or may in the future constitute, a public health emergency. The Secretary's declaration may recommend and encourage the development, manufacturing, distribution, dispensing, and administration or use of one or more covered countermeasures (e.g., anthrax vaccine) to treat, prevent, or diagnose the disease, condition, or threat specified in the declaration.

*Need and Proposed Use of the Information:* The CICP provides compensation to eligible individuals who suffer serious injuries directly caused by a covered countermeasure administered or used pursuant to a PREP Act Declaration or to their estates and/or to certain survivors.

To determine whether a requester is eligible for Program benefits (compensation) for a countermeasure injury, the CICP staff must review the Request for Benefits Package (RFB) that includes the following:

- 1) Request for Benefits Form and Supporting Documentation

The Request for Benefits Form and supporting documentation initiates the CICP claims review process. They also serve as the CICP's mechanism for gathering required information about the requester, documenting the use or administration of a countermeasure, and obtaining medical information about the countermeasure recipient.

2) Authorization for Use or Disclosure of Health Information Form (Authorization Form)

The requestor completes the Authorization Form and gives medical providers permission to disclose the countermeasure recipient's health information via medical records to the CICP for determining eligibility for CICP benefits.

3) Additional Documentation and Certification

During the eligibility review, the CICP provides requesters with the opportunity to supplement their RFB with additional medical records and supporting documentation before the Program makes a final decision. The CICP asks requesters to complete and sign a form indicating whether they intend to submit additional documentation prior to the final determination of their case. After the CICP makes a final decision on a case, there are no other opportunities for a requester to submit additional medical records or supporting documents.

4) Benefits Package and Supporting Documentation

A requester who is an injured countermeasure recipient may be eligible to receive benefits for unreimbursed medical expenses and/or lost employment income. The estate of a deceased countermeasure recipient may also be eligible to receive payment for unreimbursed medical expenses and/or lost employment income accrued prior to the injured countermeasure recipient's death. These documents ask the requester to submit

documentation of the countermeasure recipient's unreimbursed medical expenses and lost employment income. If death was the result of the administration or use of the countermeasure, certain survivor(s) of eligible deceased countermeasure recipients may be eligible to receive a death benefit, but not unreimbursed medical expenses or lost employment income benefits (42 CFR §110.33). These documents request additional information, such as a marriage license, from the requester to prove that they are a survivor of the deceased countermeasure recipient.

The RFB that the CICIP sends to requesters who may be eligible for compensation includes certification forms and instructions outlining the supporting documentation needed to determine the types and amounts of benefits. This documentation is required under 42 CFR §110.60-110.63 of the CICIP's implementing regulation to enable the Program to determine the types and amounts of benefits the requester may be eligible to receive.

*Likely Respondents:* Countermeasure recipients are the most likely respondents to this Federal Register notice regarding the CICIP information collection request because the CICIP reviews, and if eligible compensates, countermeasure recipient injury claims.

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the

collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

Total Estimated Annual Burden Hours

Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
Request for Benefits Form and Supporting Documentation	100	1	100	11.00	1,100.00
Authorization for Use or Disclosure of Health Information Form	100	1	100	2.00	200.00
Additional Documentation and Certification	30	1	30	.75	22.50
Benefits Package and Supporting Documentation	30	1	30	.13	3.75
Total	260	--	260	--	1,326.25

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**BILLING CODE 4165-15-P**

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