



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

**Agency Information Collection Activities: Proposed Collection: Public Comment Request;
Information Collection Request Title: Countermeasures Injury Compensation Program -
OMB No. 0915-0334 – Revision**

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

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Before 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 or mail the HRSA Information Collection Clearance Officer, Room 13N82, 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 or call Samantha Miller, the HRSA Information Collection Clearance Officer, at (301) 443-3983.

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

Information Collection Request Title: Countermeasures Injury Compensation Program - OMB No. 0915-0334 – Revision

Abstract: This is a request for continued OMB approval of the information collection requirements for the Countermeasures Injury Compensation Program (CICP or Program). This request includes revisions to improve the efficiency of the information collection process and the quality of the information collected. The revisions streamline questions on the information collection documents and update CICP contact information. HRSA administers CICP in accordance with the Public Readiness and Emergency Preparedness Act (PREP Act) and CICP regulations at 42 C.F.R. Part 110. CICP is requesting continued approval for this information collection, which includes documents specified in CICP's regulations (42 C.F.R. Part 110).

The PREP Act authorized the establishment of the CICP and provides liability immunity to covered persons for claims of loss caused by, arising out of, relating to, or resulting from the administration or use of covered countermeasures for diseases, threats, and conditions identified in PREP Act declarations. The immunity extended in the PREP Act encourages the development, manufacture, testing, distribution, and administration/use of countermeasures (e.g., vaccine, medication, device) when a disease, health condition, or other threat to health constitutes a public health emergency, or there is a credible risk that it may in the future constitute such an emergency.

Need and Proposed Use of the Information: CICP provides compensation to eligible individuals who suffer serious injuries or death directly caused by a covered countermeasure administered or used pursuant to a PREP Act Declaration or to their estates and/or to certain survivors. An individual who is an injured countermeasure recipient, the estate or survivor(s) of a deceased injured countermeasure recipient, or their representative is responsible for submitting

the Request for Benefits (RFB) package, as well as the injured countermeasure recipient's medical records and supporting documentation. Individuals can apply at any time, but eligibility for compensation is subject to meeting applicable filing deadlines and other requirements.

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

(1) RFB Form and Supporting Medical Documentation: Submission of this RFB form and supporting medical documentation initiate the CICP claims review process. CICP assesses the RFB form and supporting medical documentation to gather required information about the requester, document the use or administration of a countermeasure, and obtain medical information about the countermeasure recipient.

(2) Authorization for Use or Disclosure of Health Information Form (Authorization Form): The requester or representative, if applicable, completes the Authorization Form and gives medical providers permission to disclose the countermeasure recipient's health information via medical records to CICP for the purpose of determining eligibility for CICP benefits.

(3) Additional Medical Documentation and Certification: During the eligibility review, CICP provides requesters with the opportunity to supplement their RFB package with additional medical records and supporting documentation before the Program makes a final decision. CICP may ask requesters and/or representatives to complete and sign a form indicating whether they intend to submit additional required documentation before the final determination of their case. After CICP makes a final decision on a case, there are no other opportunities for a requester or representative to submit additional medical records or supporting documents.

4) Supporting Benefits 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 injured countermeasure recipient may also be eligible to receive payment for unreimbursed medical expenses and/or lost employment income accrued before the injured countermeasure recipient's death. Requesters seeking such benefits

must submit documentation of the injured countermeasure recipient's unreimbursed medical expenses and lost employment income. If the administration or use of a covered countermeasure directly caused an individual's death, certain of the individual's survivors may be eligible to receive a death benefit, but not unreimbursed medical expenses or lost employment income benefits (42 C.F.R. § 110.33). Survivors or their representatives must submit additional information, such as a marriage license, to prove that they are a survivor of the deceased countermeasure recipient.

The RFB package instructions outline the supporting documentation needed to determine the type and amount of benefits. This documentation is required under 42 C.F.R. §§ 110.60-110.63 to enable the Program to determine the type and amount of benefits the requester may be eligible to receive.

Likely Respondents: Countermeasure recipients, their estates, survivors, and/or their representatives, are the most likely respondents to this Federal Register notice regarding the CICP information collection request because CICP 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 Annualized Burden Hours:

Document Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
RFB Form and Supporting Medical Documentation	360	1	360	11.00	3,960
Authorization for Use or Disclosure of Health Information Form (Authorization Form)	360	1	360	2.00	720
Additional Medical Documentation and Certification	324	1	324	0.75	243
Supporting Benefits Documentation	30	1	30	10.00	300
Total	1,074	--	1,074	--	5,223

HRSA specifically requests comments on: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.