



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; 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 Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. No comments were submitted during the first public review of this ICR.

OMB will accept further comments from the public during the review and approval period.

OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at paperwork@hrsa.gov or call (301) 443-3983.

SUPPLEMENTARY INFORMATION:

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 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. A 60-day notice published in the **Federal Register** on December 17, 2025, vol. 90, No. 240; pp. 58568. There were no public comments.

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 the 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
Request for Benefits Form and Supporting Medical Documentation	360	1	360	11.00	3,960

Document Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
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.

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