

Countermeasures Injury Compensation Program

REGULATIONS - 42 CFR PART 110

Supporting Statement A- Extension Request

A. Justification

1. Circumstances of Information Collection

This is a request for continued OMB approval of the information collection requirements for the Countermeasures Injury Compensation Program (“CICP” or “the Program”) Final Rule Administrative Implementation, which sets out the administrative policies, procedures, and requirements governing the Program (**Attachment A**) as authorized by the Public Readiness and Emergency Preparedness Act of 2005 (PREP Act) (**Attachment B**). The Rule establishes procedures for the administrative implementation and data collection under the Program. The PREP Act (**Attachment B**), stipulates that (with limited exceptions) the CICP is to follow the Smallpox Emergency Personnel Protection Act of 2003 (SEPPA), the Smallpox Vaccine Injury Compensation Program (SVICP) Administrative Implementation Final Rule (**Attachment C**) and other regulations implementing SEPPA, and such additional or alternate regulations as the Secretary may promulgate. The required documentation from requesters filing for CICP benefits closely follows the SVICP requirements. The approved information collection requirements for the SVICP are approved under OMB No. 0915-0282. However, the SVICP no longer exists since the smallpox vaccine has been subsumed as a covered countermeasure under CICP.

On December 30, 2005, Congress enacted the PREP Act, which is part of the “Department of Defense, Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico, and Pandemic Influenza Act of 2006” (PL 109-148). The PREP Act confers broad liability protections on covered persons, as defined in section 319F-3(i)(2) of the Public Health Service (PHS) Act, and compensation to individuals injured by the administration or use of covered countermeasures, as defined in section 319F-3(i)(1) of the PHS Act, in the event of designated public health emergencies. Congress authorized the Secretary of the Department of Health and Human Services (Secretary) to issue regulations implementing the PREP Act.

The PREP Act provides the Secretary with the authority, which was delegated by the Secretary on November 8, 2006 to the Administrator of the Health Resources and Services Administration, to compensate eligible individuals for covered injuries from a covered countermeasure. The CICP is designed to provide compensation to individuals for serious physical injuries or deaths from pandemic, epidemic, or security countermeasures identified in declarations issued by the Secretary pursuant to section 319F-3(b) of the PHS Act.

The benefits available under the Program include compensation for reasonable and necessary medical care, lost employment income, and survivor death benefits, as explained in 42 CFR § 110.30-110.33. To be considered for Program benefits, requesters (i.e., injured countermeasure

recipients, survivors, the executors/administrators of the estates of deceased or injured countermeasure recipients), or persons filing on their behalf as their representatives, must file a Request for Benefits Form (Request Form) and follow its instructions (**Attachment D**) to submit the documentation required under the CICIP regulations to show eligibility.

Approval is requested for the following requirements and continued information collection activities as required by the CICIP Administrative Implementation regulations (42 CFR Part 110):

42 CFR 110.10-110.11 Persons Eligible to Receive Benefits.

This section lists the individuals who may be eligible to receive benefits from this Program.

42 CFR 110.40-110.41 and 110.44-110.45 Filing a Request Package

The Request for Benefits Package (Request Package) comprises the: Request Form, Authorization for Use or Disclosure of Health Information Form (**Attachment E**), medical records, additional Documentation Certification Form (i.e., Lost Employment Income Certification, Unreimbursed Medical Expenses Certification) (**Attachment F**) and accompanying documentation to determine eligibility for benefits.

42 CFR 110.42-110.43 Filing Deadlines

All requesters (or their representatives) must file a complete Request for Benefits Package with the Secretary. All individuals requesting CICIP benefits, generally, must file a Request Package with the Secretary within one year of the date of the administration or use of a covered countermeasure that is alleged to have caused the injury or death. New requesters can obtain the Request Package and Instructions by calling 1-855-266-2427, sending an e-mail to CICP@hrsa.gov, or downloading the materials from the internet at <https://www.hrsa.gov/cicp>. To be considered for benefits, the Form must be filed in accordance with § 110.42(c).

42 CFR 110.46 Amendments to Request Packages.

Section 42 CFR 110.46 provides the requirements for the filing of amendments to previously filed Request Packages.

42 CFR 110.50-110.53 Documentation Needed for the Secretary to Determine Eligibility.

Requesters (or their representatives) must submit appropriate Compensation Documentation Forms and follow instructions (**Attachment G**) to allow the Secretary to determine if requesters are eligible for Program benefits. This documentation will vary somewhat depending on whether the requester is an injured countermeasure recipient, a survivor, or an executor/administrator of the estate of a deceased or injured countermeasure recipient.

All requesters (or their representatives) must submit, or authorize their health care providers to submit, medical records sufficient to demonstrate that a covered injury was sustained by a covered countermeasure.

42 CFR 110.60-110.63 Documentation Needed for the Secretary to Calculate Benefits.

Requesters who are deemed eligible for benefits by the Secretary must submit documentation as specified in section 42 CFR 110.60-110.63 to allow the Secretary to determine the type(s) and amounts of benefits, if any, that will be paid to the requester. This documentation is in addition to the documentation submitted under §§ 110.50-110.53. This includes documentation needed to calculate benefits for reasonable and necessary medical services or items, benefits for lost employment income, and death benefits. This documentation will vary somewhat depending on whether the requester is an injured countermeasure recipient, a survivor, or an executor/administrator of the estate of a deceased or injured countermeasure recipient. Since the Program's payment of benefits is secondary to all other third-party payers, the documentation requirements include information about any third-party payers that may have an obligation to pay for such benefits.

42 CFR 110.90-110.92 Reconsideration of the Secretary's Eligibility and Benefits Determinations.

Section 42 CFR 110.90-110.92 provides the requirements for requesters who seek reconsideration of the Secretary's eligibility or benefits determinations. No new documentation is considered in the reconsideration process.

2. Purpose and Use of Information

The CICP Administrative Implementation regulations (42 CFR Part 110) establish the procedures by which individuals may submit Requests for Benefits under the CICP. This collection of information provides data and documentation that will be used by the Secretary to determine that the Request for Benefits meets the requirements of the CICP. Each Request Package must include the required written documentation for the relevant individual described in §§ 110.10-110.11 for the Secretary to make an eligibility determination.

For each complete Request Package submitted, the Secretary shall determine whether the requester meets the requirements of eligibility. To make this determination, data must be collected consisting of the filing of a Request Form and submission of medical records and other documentation required by §§ 110.50-110.53. The following requesters may be eligible to receive benefits:

- (1) Injured countermeasure recipients, as described in § 110.3(n).
- (2) Survivors, as described in §§ 110.3(cc) and 110.11.

- (3) Estates of deceased, injured countermeasure recipients, as described in § 110.10(a)
- (3).

3. Use of Improved Information Technology

Sections 110.40-110.46 describe how to obtain forms and instructions to apply for benefits, how to file a Request Package, and the deadline for submitting the Request Form and other documentation. Sections 110.50-110.53 identify the documentation required to determine eligibility. Due to the limitations of the Program's current information system, the CICIP is currently only accepting Request Packages and supporting documentation as hard copies. Once the information system has been enhanced, the Program will be accepting the Request Form, medical records and supporting documentation electronically. Guidelines for collecting electronic records will be established once the Program has that capability.

4. Efforts to Identify Duplication

The Request for Benefits package is unique to the CICIP and is not available elsewhere. Without this information, the Secretary would be unable to make a determination as to whether the Request for Benefits meets the requirements as specified.

The CICIP requests that medical records be submitted to the Program directly from the medical service providers to reduce and identify duplication and ensure authenticity.

5. Involvement of Small Entities

This collection will not significantly impact small businesses or small entities.

6. Consequences If Information Collected Less Frequently

Requesters are required to file only once for benefits; however, requesters also must provide updated information and records during the process, for purposes of determining eligibility and benefits. Without these data, the Secretary will not be able to determine whether individuals are eligible for benefits.

7. Consistency with the Guidelines in 5 CFR 1320.5(d)(2)

This collection is consistent with the guidelines under 5 CFR 1320.5(d)(2).

8. Consultation Outside the Agency

The HHS Office of the General Counsel has reviewed all of the forms included in this package. (Attachments D – G) The 60-day Notice was published in the Federal Register on July 16, 2019, Vol. 84, No. 136, pp. 33954-55.

9. Remuneration of Respondents

Respondents will not be remunerated.

10. Assurance of Confidentiality

Access to these records is strictly limited to authorized users who are aware of their responsibilities under the Privacy Act and who are required to maintain Privacy Act safeguards with respect to such records. The CICP System of Records Notice (09-15-0071) identifies authorized users.

11. Questions of a Sensitive Nature

The nature of the issues being considered in this request requires the collection of potentially sensitive information from respondents. However, these data are required to make a determination of eligibility for CICP benefits and the amount of those benefits, and respondents will be informed of the precautions being taken to ensure confidentiality.

12. Estimates of Annualized Hour Burden

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	1100
Authorization for Use or Disclosure of Health Information Form	100	1	100	2	200
Additional Documentation and Certification	30	1	30	.75	22.5
Benefits Package and Supporting Documentation	30	1	30	.125	3.75
Total	260		260		1326.25

The following is a summary of the annual reporting and recordkeeping burden associated with information collections for the Rule cited in this supporting statement.

Number of Respondents

As of December 2019, the CICP has received 489 claims.

13. Estimate of Annualized Cost Burden to Respondents

There is no capital or start-up cost associated with this data collection.

14. Estimate of Annualized Costs to the Government

The estimated annualized cost to the Federal Government for this Program is approximately 15% FTE at a GS-9 level (\$57,510) for a total of \$8,627 and 30% FTE at a GS-15 level (\$137,849) for a total of \$41,355 for processing and reviewing each individual Request for Benefits.

15. Change in Burden

The change in burden hours for this request is minimal at .75 hour. This is due to rounding.

16. Time Schedule, Publication and Analysis Plans

HRSA is requesting a three-year OMB clearance for this information collection. Statistical analyses of medical information or fact patterns of interest may be published in the medical literature without any personal identifiers.

17. Exemption for Display of Expiration Date

The expiration date will be displayed.

18. Certifications

This fully complies with the guidelines set forth in 5 CFR 1320.9.

LIST OF ATTACHMENTS

Attachment A – Countermeasures Injury Compensation Program: Administrative Implementation Final Rule

Attachment B – Public Readiness and Emergency Preparedness Act of 2005

Attachment C – Smallpox Vaccine Injury Compensation Program: Administrative Implementation Final Rule

Attachment D - Request for Benefits Form and Instructions

Attachment E - Authorization for Use or Disclosure of Health Information Form

Attachment F – Additional Documentation Certification Form

Attachment G – Compensation Documentation Forms and Instructions