Countermeasures Injury Compensation Program

REGULATIONS - 42 CFR PART 110

Supporting Statement for the Request for Benefits Package

A. Justification

1. Circumstances of Information Collection

This is a request for OMB approval of the new information collection requirements for the Countermeasures Injury Compensation Program ("CICP" or "the Program") Interim Final Rule, which sets out the administrative policies, procedures, and requirements governing the Program (**Attachment A**) as authorized by the Public Readiness and Emergency Preparedness Act (PREP Act). The Rule establishes procedures for the administrative implementation and data collection under the Program. The PREP Act (**Attachment B**), stipulates that the CICP is to follow the Smallpox Emergency Personnel Protection Act (SEPPA), the Smallpox Vaccine Injury Compensation Program (SVICP) regulations implementing SEPPA (**Attachment C**), and such additional or alternate regulations as the Secretary may promulgate. The required documentation from requesters of the CICP closely follows the SVICP requirements. The approved information collection requirements for the SVICP are approved under OMB No. 0915-0282.

On December 30, 2005, the President 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 to issue regulations implementing the PREP Act as the Secretary deems reasonable and necessary.

The PREP Act amends the PHS Act by adding sections 319F-3 and 319F-4 (42 U.S.C. 247d-6d, 42 U.S.C. 247d-6e). Section 319F-4 of the PHS Act directs the Secretary to establish and administer the CICP. Further, section 319F-4 directs the Secretary to issue a Table of Injuries associated with certain covered countermeasures by Interim Final Rule.

The PREP Act provides liability protections after a Secretarial declaration of covered countermeasures for any disease or health condition that the Secretary views as constituting a public health emergency, either presently or in the future. Liability protections cover the manufacture, testing, development, distribution, or use of the designated covered countermeasure absent willful misconduct as defined in section 319F-3(c)(1) of the PHS Act. A Secretarial declaration specifies the categories of health threats or conditions for which countermeasures are recommended, the period liability protections are in effect, the population

of individuals protected, and the geographic areas for which the protections are in effect.

In addition to liability protections, the PREP Act provides the Secretary 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 Countermeasures Injury Compensation Program 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 ' 110.30-33. To be considered for Program benefits, requesters (i.e., countermeasure recipients, survivors, or the representatives of the estates of deceased countermeasure recipients), or persons filing on their behalf as their representatives, must file a Request for Benefits Form (**Attachment C**) and submit the documentation required under this regulation to show that they are eligible.

Approval is requested for the following requirements and continued information collection activities as required by the Rule:

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 110.40-41 and 110.44-45 Filing a Request Package

The Request Package comprises the Request Form, Authorization for Use or Disclosure of Health Information Form and accompanying documentation to determine eligibility for benefits.

42 CFR 110.42-43 Filing Deadlines

All requesters (or their representatives on their behalf) must file a complete Request for Benefits Package with the Secretary. In order to meet the one-year filing deadline, prior to publication of the Interim Final Rule, individuals who believe they may have been injured by the administration or use of a covered countermeasure (or their representatives) must send Letters of Intent to File a Request for Benefits to the Countermeasures Injury Compensation Program Office, Health Resources and Services Administration, Room 11C-06, 5600 Fishers Lane, Rockville, Maryland 20857. Once the Request Form and instructions are published, all individuals requesting CICP benefits must file a Request Package with the Secretary. Individuals who have filed a Letter of Intent will be mailed a hardcopy Request Package and asked to mail it back to the Countermeasures Injury Compensation Program Office. New requesters can obtain the Request Package and Instructions by calling 1-888-ASK-HRSA (275-4772), sending an e-mail to CICP@hrsa.gov, or downloading them from the internet at

http://www.hrsa.gov/countermeasurescomp/. In order to be considered for benefits, the Form must be filed in accordance with ' 110.42(c).

42 CFR 110.46 Amendments to Request Packages.

This section 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 documentation to allow the Secretary to determine if requesters are eligible for Program benefits. This documentation will vary somewhat depending on whether the requester is filing as an injured countermeasure recipient, a survivor, or a representative of an estate.

All requesters (or their representatives) must submit, or authorize their 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.

Since the Program is the secondary payer, requesters who are deemed eligible for benefits by the Secretary must submit documentation as specified in this section, 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. Special requirements apply with respect to requesters who are minors or are legally incompetent adults.

42 CFR 110.90-92 Reconsideration of the Secretary=s Eligibility and Benefits Determination.

This section 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

This Rule establishes the administrative implementation of the procedures by which individuals may submit Requests for Benefits under the CICP. This collection of information provides data and documentation **(Attachments D and E)** 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 in order for the Secretary to make a determination as to the requester's eligibility to receive benefits.

For each complete Request Package that is submitted, the Secretary shall determine whether the requester meets the requirements of eligibility. In order to make this determination, data must be collected consisting of the filing of a Request Form and submission of medical documentation. The following requesters may be eligible to receive benefits:

(1) Injured countermeasure recipients, as described in Section 110.3(n).

(2) Survivors, as described in Section 110.11.

(3) Legal or personal representatives of the estates of deceased injured countermeasure recipients, as described in Section 110.10(a)(3).

3. Use of Improved Information Technology

Section 110.50-110.53 of the Interim Final Rule requires that each Request Package must include written documentation to determine eligibility as described in Subparts F and G. Section 110.40-110.43 of this Rule establishes the Request Package filing requirements for a postmark or dated receipt from the U.S. Postal Service or a commercial carrier. Due to the limitations of the Program's current electronic database, the CICP is currently only accepting Request Packages and supporting documentation as hardcopies. Once a new system is established, 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

These data are unique to the Countermeasures Injury Compensation Program and are 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.

5. Involvement of Small Entities

This information is the minimum required by law to make a determination, and 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. Without these data the Secretary will be unable to make a determination of benefits to eligible individuals.

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

Once the interim final rule for the administrative requirements for the CICP is approved and published in the *Federal Register*, HRSA will obtain input from public comments received. Once comments are received, if any, the Secretary will review and consider them for publication in the Final Rule. The HHS Office of the General Counsel reviewed the forms for appropriate regulatory requirements.

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. A new system of records, ##-##-####, "Countermeasures Injury Compensation Program, HSB/HRSA/HHS," is being established and will be published in the *Federal Register.*

11. Questions of a Sensitive Nature

The nature of the issues being considered in the Request requires the collection of potentially sensitive information on respondents. However, these data are required in order to make a determination of medical, legal, and financial eligibility, and respondents will be informed of the precautions being taken to ensure confidentiality.

12. Estimates of Annualized Hour Burden

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

Form	Number of Respondents	Responses per Respondent	Hourly Response	Total Burden Hours	Wage Rate	Total Hour Cost
Request for Benefits Form and Supporting Documentation	2,520	1	5	12,600	$18.72	$235,872
Authorization for Use or Disclosure of Health Information Form	2,520	1	1	2,520	$18.72	$47,174

Total	2,520			15,120		$283,046

Number of Respondents

As a result of the 2009 H1N1 influenza outbreak, this was the first time that covered countermeasures identified in the PREP Act declarations were being distributed, administered to, and used in the general population of the United States. It is currently estimated that 90 million Americans have been administered the 2009 H1N1 influenza vaccine. As of May 29, 2010, CDC's Vaccine Adverse Event Reporting System (VAERS) had received 11,180 reports related to the 2009 H1N1 vaccination. The Program recognizes the difficulty inherent in predicting the number of individuals who will file for benefits under the Program and the number of individuals who will receive the 2009 H1N1 influenza vaccine and other covered countermeasures under approved emergency response plans. Nonetheless, with the anticipation of additional individuals receiving the 2009 H1N1 pandemic influenza vaccine, the Program predicts that there may be up to 1,167 requesters.

Individuals who use or are administered other covered countermeasures may be eligible for compensation from the CICP. In response to the 2009 H1N1 pandemic influenza outbreak, about 11 million courses of antiviral drugs were distributed to project areas and an additional 23 million to individual state stockpiles. Based on estimates of the antivirals that have been administered and the potential adverse incidents from these drugs, the CICP estimates that 672 Requests for Benefits will be filed for antivirals.

Certain ventilators used for life support of critically ill patients with 2009 H1N1 infections are covered countermeasures. Approximately 257,000 individuals were hospitalized with the 2009 H1N1 virus, and the CICP estimates that 31 requesters will file for injuries or deaths as a result of Ventilator Associated Pneumonia (VAP).

Since April 2009, 85 million N-95 filter face masks have been distributed to project areas, however; it is impossible to estimate how many were actually distributed by the individual project areas. Therefore the CICP cannot anticipate how many Requests for Benefits for filter face masks may be submitted.

In 2009, the Department of Defense (DoD) provided smallpox vaccines to 176,068 individuals, which is approximately four times the number of civilians who were administered the vaccine in 2003 and 2004. Of the 39,566 who were administered the vaccine between January 2003 and June 2004, approximately 65 civilians filed Requests for Benefits with the SVICP. Based on the number of requests filed with the SVICP and the current number of military personnel who have been administered the smallpox vaccine, the CICP estimates that 260 individuals will submit Requests for Benefits in 2010.

In 2009, DoD immunized 224,057 individuals with anthrax vaccinations. Since the anthrax vaccine is as reactogenic as the smallpox vaccine, the SVICP experience is used to derive the

estimate that the number of individuals who will submit a Request for Benefits with the CICP is approximately 390.

It is important to note that a large number of such requesters filing Request Forms with the Program may not be eligible for payments under the Program for a variety of reasons (e.g., they sustained minor injuries that do not qualify as covered injuries, the Secretary determines that their injuries do not qualify as Table injuries and that there is insufficient evidence to establish causation, they received the countermeasure outside of the eligible time frame of use or approved emergency response plan, or they did not file their Request Forms within the governing filing deadlines). The CICP estimates receiving an **annual total of 2,520 Requests for Benefits**, with the majority of requesters filing for adverse events from the 2009 H1N1 pandemic influenza vaccine due to its mass distribution to the public.

Burden Estimate

It is estimated that it will take approximately five hours to review the instructions and complete the Request Package. This estimate is based on approximations of the time needed to review the instructions, completing the Request Form, Authorization for the Use or Disclosure of Health Information Form, and obtain and assemble the supporting materials.

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-7 level ($42,209) for a total of $6,331 and 30% FTE at a GS-15 level ($123,758) for a total of $37,127 for processing and reviewing each individual Request for Benefits.

15. Change in Burden

This is a new program. There are no changes.

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, Interim-Final Rule

Attachment B – Public Readiness and Emergency Preparedness Act

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

Attachment D - Request for Benefits Forms and Instructions

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