Smallpox Vaccine Injury Compensation Program

REGULATIONS - 42 CFR PART 102

Supporting Statement

A. Justification

1. Circumstances of Information Collection

This is a request for an extension of OMB approval of the information collection requirements for the Smallpox Vaccine Injury Compensation Program Interim-Final (I-F) rule which set out the administrative policies, procedures, and requirements governing the Program as authorized by the Smallpox Emergency Personnel Protection Act of 2003 (Pub. L.108-20).The rule established procedures and data collection for the administrative implementation of the program. The currently approved information collection requirements are approved under OMB No. 0915-0282 which expires August 31, 2007. **There are no changes to the forms.**

The Smallpox Emergency Personnel Protection Act (SEPPA) authorized the Secretary of Health and Human Services to establish the Smallpox Vaccine Injury Compensation Program which is designed to provide benefits and/or compensation to certain persons harmed as a direct result of receiving smallpox covered countermeasures, including the smallpox vaccine, or as a direct result of contracting vaccinia through certain accidental exposures.

On December 13, 2002, the President announced a plan to protect the population of the United States against the threat of a possible smallpox attack. This plan was based on heightened concerns, in the wake of the attacks of September and October 2001, that terrorists may have access to the smallpox virus and may attempt to use it against the population of the United States and Government facilities abroad. Under this plan, State and local governments have formed smallpox emergency response plans to facilitate the provision of critical services to the population of the United States in the event of a smallpox virus attack.

To further the President=s plan, the Secretary issued a Declaration Regarding Administration of Smallpox Countermeasures on January 28, 2003 (68 FR 4212), which recommended the administration of covered countermeasures to certain categories of individuals. The categories of persons to whom the Secretary recommended the administration of such covered countermeasures, on a voluntary basis, included certain health care workers, members of smallpox emergency response plans identified by State or local government entities or the Department of Health and Human Services, certain public safety personnel, and certain personnel associated with specific Federal facilities abroad. The Secretary recommended that such persons receive the smallpox vaccine to ensure the immediate mobilization of smallpox emergency response personnel who would provide critical services to the population of the United States in the event of a smallpox virus attack. The Secretary=s Declaration became effective on January 24, 2003, and remained effective until January 23, 2004.

The SEPPA was enacted on April 30, 2003 and authorized the Secretary to establish the Smallpox Vaccine Injury Compensation Program. The Program was appropriated $42 million for the administration of the Program and the payment of benefits under the Program. The SEPPA authorizes the Secretary to make the benefits available to two categories of eligible persons who sustained covered injuries, provided they meet the legal requirements (e.g., filing deadlines).

The first category, Asmallpox vaccine recipients,@ includes certain persons who volunteer for, and are selected to be members of, a smallpox emergency response plan, are vaccinated with a smallpox vaccine under such a plan, and sustain covered injuries. Smallpox vaccine recipients, as defined in ' 102.3(w), are as follows: a person who has received a smallpox vaccine is only considered a Asmallpox vaccine recipient,@ for purposes of this Program, if he or she meets the criteria described in the regulation. Specifically, he or she must have had a covered occupation (including health care workers, law enforcement officers, public safety personnel, and supporting personnel), received a smallpox vaccine as a participant in an approved smallpox emergency response plan, and sustained a covered injury (as described in the preamble). The exact requirements for smallpox vaccine recipients are set forth in ' 102.3(w). For example, the regulation provides that, in order to be eligible, a smallpox vaccine recipient must have received the smallpox vaccine between January 24, 2003 and January 23, 2004. In order to be covered by the Program, a smallpox vaccine recipient must also have volunteered for and been selected to be a member of a smallpox emergency response plan before the time that the Secretary publicly announces that an active case of smallpox has been identified anywhere in the world.

The second category, vaccinia contacts, includes certain persons who have covered injuries as the direct result of exposure to vaccinia through contact with certain persons who received the smallpox vaccine or with the contacts of such recipients. In addition, if a person in either category dies, his or her survivors or his or her estate may be eligible for selected benefits under this Program in certain circumstances.

The benefits available under the Program include compensation for medical care, lost employment income, and survivor death benefits, as explained in ' 102.2(b). To be considered for Program benefits, requesters (i.e., smallpox vaccine recipients, vaccinia contacts, survivors, or the representatives of the estates of deceased smallpox vaccine recipients or vaccinia contacts), or persons filing on their behalf as their representatives, must file a Request Form and the documentation required under this regulation to show that they are eligible.
Through the enactment by the SEPPA of Part C, Title II of the Public Health Service Act (PHS Act), the Secretary was authorized to establish and administer the Smallpox Vaccine Injury Compensation Program. Congress authorized the Secretary to issue regulations implementing the SEPPA as the Secretary deems reasonable and necessary. Congress directed the Secretary to issue a Table of Injuries associated with the smallpox vaccine by Interim Final Rule (which was published in the Federal Register on August 27, 2003) and authorized the Secretary to issue initial administrative regulations by Interim Final Rule. In accordance with that statutory authority, the rule established the procedures and requirements to govern the Program.

In addition, the Secretary determined, under 5 U.S.C. 553(b), that it was contrary to the public interest to follow proposed rulemaking procedures (i.e., issuing a proposed rule, with an accompanying solicitation of public comments) before issuance of these regulations, because such a process might delay the continuing implementation of the President=s plan to protect the population of the United States against the threat of a smallpox attack. As a result, the forms were first approved under an emergency processing request to OMB; since then, all approval requests have been under routine processing.

Extension of approval is requested for the following requirements and continued information collection activities as required by the rule:

42 CFR 102.10-102.11 Persons Eligible to Receive Benefits.

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

42 CFR 102.41 Filing a Request Package

The request package comprises the request form and accompanying documentation to determine eligibility for benefits.

42 CFR 102.42 Filing Deadlines

All eligible individuals must file a complete Request Package with the Secretary. If using the U.S. Postal Service, interested parties may download forms and instructions on the HRSA website at http://www.hrsa.gov/smallpoxinjury/ or make requests by mail to the Smallpox Vaccine Injury Compensation Program Office, Office of Special Programs, Health Resources and Services Administration, Room 16C-17, 5600 Fishers Lane, Rockville, Maryland 20857. In order to be eligible for review, requests may be postmarked on or after the date stated in ' 102.42.

42 CFR 102.46 Amendments to Request Packages.

This section provides the requirements for the filing of amendments to previously filed Request Packages.

42 CFR 102.50-102.54 Documentation Needed for the Secretary to Determine Eligibility.

Requesters must submit appropriate documentation to allow the Secretary to determine if the requesters are eligible for Program benefits. This documentation will vary somewhat depending on whether the requester is filing as a smallpox vaccine recipient, a vaccinia contact, a survivor, or a representative of an estate.

All requesters must submit medical records sufficient to demonstrate that a covered injury was sustained by a smallpox vaccine recipient or a vaccinia contact.

42 CFR 102.60-102.63 Documentation Needed for the Secretary to Calculate Benefits.

Requesters who are deemed eligible by the Secretary for payment or reimbursement for medical services or items must submit documentation as specified in this section, in addition to the documentation submitted under Subpart F. This includes documentation needed to calculate benefits for 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 102.90 Reconsideration of the Secretary=s Eligibility and Benefits Determination.

This section provides the requirements for requesters who seek reconsideration of the Secretary=s eligibility and benefits determination. 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 Act. This collection of information provides data and documentation that will be used by the Secretary to determine that the request meets the requirements of the Smallpox Vaccine Injury Compensation Program. Each Request Package must include the required written documentation that the relevant individual described in section 102.10-102.11 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) Smallpox vaccine recipients, as described in Section 102.3(w)

(2) Vaccinia contacts, as described in Section 102.3(aa)

(3) Survivors, as described in Section 102.3(y) and Section 102.11

(4) Representatives of the estates of deceased smallpox vaccine recipients or vaccinia contacts.

3. Use of Improved Information Technology

Section 102.50-102.54 of the Interim Final Rule requires that each Request Package must include written documentation to determine eligibility as described in Subpart B and C. Section 102.41-102.43 of this rule establishes procedures filing request packages requirements for a postmark or dated receipt from the U.S. Postal Service or a commercial carrier. Due to the postmark requirement and because medical records and supporting documentation obtained by requesters will be paper, the Request Package must therefore be collected on paper rather than via electronic medium.

4. Efforts to Identify Duplication

These data are unique to the Smallpox Vaccine 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 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

Public comment was solicited in the publication of a 60-day notice in the *Federal Register* (April 18, 2007, 72 FR 19540). No comments were received. The Office of General Counsel reviewed the forms for appropriate regulatory requirements.

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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, 09-15-0065, "Smallpox Vaccine Injury Compensation Program, HHS/HRSA/OSP,"was established and published in the *Federal Register* on November 3, 2003 (68 FR 62301-62304).

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 for payment, 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 Form	25	1	5	125	$37.50	$4,687.50
Certification	25	1	1	25	$37.50	$ 937.50
Total	25			150		$5,625

Number of Respondents

The program estimates that approximately 25 requests will be made annually, as most of the individuals who meet the eligibility requirements made requests when the program was established in 2003.

Burden Estimate

It takes approximately 5 hours to complete the Request Form and provide the supporting documentation, and one hour to complete the certification form. This estimate is based on approximations of the time needed to review the instructions, completing the request form, and obtaining/assembling the supporting materials.

13. Estimate of Annualized Cost Burden to Respondents

There are no capital or start up costs associated with this data collection.

14. Estimate of Annualized Costs to the Government

The estimated annualized cost to the government for this program is approximately 5% FTE at a GS-14 level ($90,000) for a total of $4,500 for reviewing individual requests.

15. Change in Burden

The OMB inventory of currently approved agency information collection activities has a total of 7,500 burden hours and 2,500 responses. This request is for a significant decrease in burden hours (150 hours) and respondents (25 respondents) as a result of a substantial decrease in the number of requests since the initial publication of the rule. This decrease in respondents and burden hours was expected, as most eligible individuals applied in the first year of the program. This is a program adjustment for a decrease of 7,350 total burden hours.

16. Time Schedule, Publication and Analysis Plans

There will be no statistical analysis of data or publication of information resulting from this effort.

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. The certifications are included in the package.