

example, if a requester has made a good faith effort to obtain medical records, but is unable to access such records (e.g., if a physician's practice is no longer in business), the Secretary may choose to accept a statement by the requester describing the reasons for the records' unavailability and the reasonable efforts the requester has made to obtain them in place of the unavailable medical records. Likewise, if a vaccinia contact is unable to identify the source of his or her exposure to vaccinia, this interim final rule enables the requester to submit an affidavit explaining the circumstances under which he or she contracted the vaccinia. If this information is consistent with the vaccinia contact contracting vaccinia from an eligible vaccinee or the contact of such a person (e.g., the vaccinia contact works in a hospital and was in close contact with several individuals who received the smallpox vaccine under an approved smallpox emergency response plan and, to the best of his or her knowledge, was not in close contact with any person who received the smallpox vaccine outside such a plan), the Secretary may accept such an affidavit in place of the required documentation.

Unfunded Mandates Reform Act of 1995. The Secretary has determined that this interim final rule will not have effects on State, local, and tribal governments and on the private sector such as to require consultation under the Unfunded Mandates Reform Act of 1995.

Federalism Impact Statement. The Secretary has also reviewed this rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have "federalism implications." The rule does not "have substantial direct effects on the States, or on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

Impact on Family Well-Being. This interim final rule will not adversely affect the following elements of family well-being: Family safety, family stability, marital commitment; parental

rights in the education, nurture and supervision of their children; family functioning, disposable income or poverty; or the behavior and personal responsibility of youth, as determined under section 654(c) of the Treasury and General Government Appropriations Act of 1999. In fact, this interim final rule may have a positive impact on the disposable income and poverty elements of family well-being to the extent that families of injured persons (and of other persons deemed eligible to receive benefits under this part) receive, or are helped by, benefits paid under this part without imposing a corresponding burden on them.

Impact of the New Rule. In this interim final rule, the Secretary establishes the procedures and requirements applicable to requesters filing for benefits available under the program. This interim final rule is based on the SEPPA. It will have the effect of enabling certain eligible individuals who sustained covered injuries as the direct result of receiving a covered countermeasure under the Secretary's Declaration, or as a direct result of vaccinia contracted through accidental vaccinia inoculation in the case of certain vaccinia contacts, to receive benefits under the program. In the event that an otherwise eligible smallpox vaccine recipient or vaccinia contact has died, his or her estate and/or survivors may be entitled to certain benefits. This interim final rule sets out the eligibility requirements that apply to the program, and the documentation that must be submitted.

Paperwork Reduction Act of 1995. In accordance with section 3506(c)(2)(A) of the Paperwork Reduction Act (PRA) of 1995, the Department is required to solicit public comments, and receive final Office of Management and Budget (OMB) approval, on any information collection requirements set forth in rulemaking. As indicated, in order to implement the SEPPA, certain information is required as set forth in §§ 102.50–102.63 of this rule.

In accordance with the PRA, we have submitted and obtained OMB approval on this data collection and reporting of this information. An emergency review

was needed before the expiration of the normal time limits under OMB's regulations at 5 CFR part 1320, to ensure the timely availability of data as necessary to ensure the provision of benefits to eligible petitioners. Delaying the data collection would delay implementation of the statutory purpose of providing benefits to eligible individuals who sustained covered injuries, particularly because the statutory filing deadlines for certain eligible requesters may occur as early as January 2004. Implementing this regulation and providing benefits as soon as possible will ensure that the intent of SEPPA in making these benefits to eligible individuals will be implemented, to the extent possible. OMB has approved this collection, with a 180-day approval period. During this period, we will publish a separate **Federal Register** notice announcing the initiation of an extensive 60-day agency review and public comment period on the requirements set forth.

Collection of Information: The Smallpox Vaccine Injury Compensation Program.

Description of Respondents: Individuals who are members of smallpox emergency response plans who received a smallpox vaccine and sustained a covered injury from it or from other covered countermeasures. Individuals who were injured by vaccinia from contact with a vaccinated member of a smallpox emergency response plan or other vaccinia contacts also qualify. In addition, some survivors of smallpox vaccine recipients or of vaccinia contacts may be eligible for death benefits and the estates of such deceased persons may receive certain benefits.

Estimated Annual Reporting: The estimated annual reporting for this data collection is a total of six hours for reviewing and completing the Smallpox Vaccine Injury Compensation Request Form as well as the time to obtain and provide medical and financial documentation for eligibility and the computation of benefits. The estimated annual response burden is as follows:

Form	Number of respondents	Responses per respondent	Hourly response	Total burden hours	Wage rate	Total hour cost
Request Form and Supporting Documentation	1,250	1	5	6,250	\$37.50	\$234,375
Certification	1,250	1	1	1,250	37.50	46,875
Total	2,500	7,500	281,250