

of the Secretary, is the increased voluntary participation of persons in smallpox emergency response plans throughout the nation, which includes voluntary immunization with the smallpox vaccine. The sooner this regulation is in effect, the sooner the program is implemented and the sooner potential requesters will be able to assess their eligibility to receive benefits from the program. Once this implementing regulation is in effect, the Secretary expects individuals who believe that they may be entitled to benefits under the program will file requests for such benefits within a short time frame. In addition, publishing this regulation promptly is necessary given that the governing filing deadlines, as applied to particular requesters, will begin to occur within a short period of time.

For the same reasons, the Secretary has determined that there is good cause to waive a delay in the rule's effective date. Nonetheless, as noted above, comments on the procedures and requirements set forth in this interim final rule will be accepted at the above listed address for a period of 60 days following the publication of the rule in the **Federal Register**. Thus, although the rule is effective immediately upon publication, the Secretary will consider the comments received and, based on them, may amend the procedures and/or requirements pertaining to this program.

#### Economic and Regulatory Impact

*Regulatory Flexibility Act and Executive Order 12866.* Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when rulemaking is necessary, to select regulatory approaches that provide the greatest net benefits (including potential economic, environmental, public health, safety distributive and equity effects). In addition, under the Regulatory Flexibility Act of 1980 (RFA), if a rule has a significant economic effect on a substantial number of small entities, the Secretary must specifically consider the economic effect of a rule on small entities and analyze regulatory options that could lessen the impact of the rule.

Executive Order 12866 requires that all regulations reflect consideration of alternatives, of costs, of benefits, of incentives, of equity, and of available information. Regulations must meet certain standards, such as avoiding an unnecessary burden. Regulations that are "significant" because of cost, adverse effects on the economy, inconsistency with other agency actions,

effects on the budget, or novel legal or policy issues, require special analysis.

The Secretary has determined that minimal resources are required to implement the provisions included in this regulation. Therefore, in accordance with the RFA, and the Small Business Regulatory Enforcement Fairness Act of 1996, which amended the RFA, the Secretary certifies that this rule will not have a significant impact on a substantial number of small entities. Specifically, both the benefits and the burdens associated with this interim final rule will go almost entirely to individuals who are filing as requesters with the program. Any burdens on small entities associated with the implementation of this final rule (e.g., completing a certification form concerning a smallpox vaccine recipient who was vaccinated under the auspices of a small entity as part of a smallpox emergency response plan, providing records to requesters seeking to comply with the regulation's documentation requirements) will be minimal in nature. Moreover, the number of small entities affected in this way will be very small in number.

The Secretary has also determined that this proposed rule does not meet the criteria for a major rule as defined by Executive Order 12866 and would have no major effect on the economy or Federal expenditures. We have determined that the proposed rule is not a "major rule" within the meaning of the statute providing for Congressional Review of Agency Rulemaking, 5 U.S.C. 801.

Nonetheless, the Secretary believes that a discussion of the factors that led to the creation of the smallpox vaccination plan and of the Smallpox Vaccine Injury Compensation Program, as well as the likely impact of both programs, is warranted. As described earlier in this preamble, prior to its eradication, smallpox (variola) was a serious illness that manifested either as outbreaks of variola major with death rates of greater than 20% or variola minor with death rates approaching 1%. Those who survived were frequently left with significant disabilities, such as blindness. Smallpox vaccine was an essential tool for the successful global eradication of smallpox, announced by the World Health Organization in 1980. Despite such eradication, concern exists that terrorists may have access to the smallpox virus.

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, which the Secretary is actively working to implement, State and local governments have formed volunteer smallpox emergency response teams that will be prepared to provide critical services to the population of the United States in the event of a smallpox virus attack.

In furtherance of the President's plan, and as described earlier, the Secretary issued a Declaration Regarding Administration of Smallpox Countermeasures on January 24, 2003. In this Declaration, the Secretary stated that "a potential bioterrorist incident makes it advisable to administer, on a voluntary basis, covered countermeasures specified \* \* \* for prevention or treatment of smallpox [(virus infection)] or control or treatment of adverse events related to smallpox vaccination, to [specified] categories of individuals \* \* \*." The specific "covered countermeasures" described in the Declaration are smallpox vaccines, cidofovir and derivatives thereof, and Vaccinia Immune Globulin. 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 that essential personnel would be able to mobilize immediately and provide critical services to the population of the United States in the event of a smallpox virus attack.

As already stated, the SEPPA was enacted on April 30, 2003. This statute authorized the Secretary to establish the Smallpox Vaccine Injury Compensation Program (the program). This program has been appropriated \$42 million for the administration of the program and the payment of benefits under the program. The purpose of the program is to provide benefits to eligible members of smallpox emergency response plans who sustain a covered injury as the result of receiving the smallpox vaccine (or other smallpox covered countermeasures). In addition, certain persons who come in contact with a vaccinated member of a smallpox