

Secretary will amend the Table to add new injuries, to modify the governing time intervals, or to modify Table definitions, when the evidence supports doing so. Such amendments will apply to pending requests and to requests filed after the amendments take effect. Requesters who become eligible with respect to an injury on the Table as the result of such an amendment may file a request based on the amendment within the time period prescribed by law.

Justification for Omitting Notice of Proposed Rulemaking and for Waiver of Delayed Effective Date

Through the enactment by the SEPPA of Section 263(a)(1) of the PHS Act, the Secretary was directed to establish by interim final rule a table identifying injuries that shall be presumed to result from the administration of or exposure to the smallpox vaccine, and the time interval in which the first symptom or manifestation of each such injury must manifest in order for such presumption to apply. In accordance with that statutory directive, the Secretary is herein establishing such a Table, including Definitions and Requirements. As noted earlier, the establishment of this Table by interim final rule was authorized by statute.

The Secretary has further determined, under 5 U.S.C. 553(b), that it is contrary to the public interest to follow the notice of proposed rulemaking procedures 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 (variola) attack. A significant element of this plan, which is also an important priority 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 companion regulation, which will serve to implement the Program, will be issued after this regulation is in effect. The sooner that this regulation becomes effective, the sooner potential requesters will be able to assess their eligibility to recover benefits and/or compensation from the Program and to recover such benefits and/or compensation, if eligible. For the same reasons, the Secretary has determined that there is good cause to waive a delay in the rule's effective date.

As noted above, comments will be accepted at the above listed address for a period of 60 days following the publication of this rule.

Economic and Regulatory Impact

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 (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.

Congress has found it necessary to appropriate \$42,000,000 for the administration of, and payment of the Program. Because any resources required to implement the regulatory requirements imposed by the SEPPA are not required by virtue of the establishment of a Table, and because the Secretary will conduct an independent analysis concerning any burdens associated with the implementation of the Program when the Secretary publishes the companion regulations setting forth the Program's administrative implementation, the Secretary has determined that no resources are required to implement the provisions included in this regulation. Therefore, in accordance with the RFA of 1980, 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.

The Secretary has also determined that this proposed interim final 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. The Secretary has determined that the proposed interim final rule is not a "major rule" within the meaning of the statute providing for Congressional Review of Agency Rulemaking, 5 U.S.C. 801. Similarly, it 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.

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."

On the basis of family well-being, the provisions of this interim final rule will not affect the following family elements: 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.

Impact of the New Rule

In this interim final rule, the Secretary establishes a Smallpox (Vaccinia) Vaccine Injury Table identifying injuries that shall be presumed to result from the administration of or exposure to the smallpox vaccine, and the time interval in which the onset of the first symptom or manifestation of each such injury must manifest in order for such presumption to apply. The Secretary also is providing Table Definitions and Requirements. This interim final rule is based upon legal authority. This interim final rule will have the effect of affording certain persons a presumption that particular injuries were sustained as the result of the administration of or exposure to the smallpox vaccine. Because the Table establishes a presumption of causation, it relieves requesters of the burden of demonstrating causation for covered events.

Paperwork Reduction Act of 1995, as Amended

This interim final rule has no information collection requirements.

List of Subjects in 42 CFR Part 102

Benefits, Biologics, Compensation, Immunization, Public health, Smallpox, Vaccinia.