

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Health Resources and Services Administration****42 CFR Part 102**

RIN 0906-AA61

Smallpox Vaccine Injury Compensation Program: Administrative Implementation**AGENCY:** Health Resources and Services Administration, HHS.**ACTION:** Interim final rule.

SUMMARY: The Smallpox Emergency Personnel Protection Act of 2003 (SEPPA), authorizes the Secretary of Health and Human Services (the Secretary), to establish the Smallpox Vaccine Injury Compensation Program ("the Program"). This program 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. In addition, the Secretary may provide death benefits to certain survivors of individuals who died as the direct result of these injuries.

On August 27, 2003, the Secretary published an interim final rule that set out a Smallpox (Vaccinia) Vaccine Injury Table ("the Table"). The table includes adverse effects (including injuries, disabilities, conditions, and deaths) within specific time periods that shall be presumed to result from the receipt of, or exposure to, the smallpox vaccine. The Secretary will use this table, as well as the procedures set out in this regulation, in deciding whether persons are eligible to receive benefits under the program.

In this interim final rule, the Secretary is setting out the administrative policies, procedures, and requirements governing the program, as authorized by the SEPPA. The Secretary is seeking public comment on this interim final rule.

DATES: This regulation is effective on December 16, 2003. Written comments must be submitted on or before February 17, 2004. The Secretary will consider the comments received and will decide whether to amend the current procedures and requirements based on such comments.

ADDRESSES: All written comments concerning this interim final rule should be submitted to the Director, Smallpox Vaccine Injury Compensation

Program, Special Programs Bureau, Health Resources and Services Administration, Parklawn Building, Room 16C-17, 5600 Fishers Lane, Rockville, MD 20857. Express and courier mail should be sent to the Director, Smallpox Vaccine Injury Compensation Program, Special Programs Bureau, Health Resources and Services Administration, 4350 East-West Highway, 10th Floor, Bethesda, Maryland 20814. Electronic comments should be sent to smallpox@hrsa.gov. Comments received will be available for public inspection at the Smallpox Vaccine Injury Compensation Program Office, Special Programs Bureau, Health Resources and Services Administration, 4350 East-West Highway, 10th Floor, Bethesda, Maryland 20814, between the hours of 8:30 a.m. and 5 p.m. on Federal government workdays.

FOR FURTHER INFORMATION CONTACT: Paul T. Clark, Director, Smallpox Vaccine Injury Compensation Program, telephone 1-888-496-0338. This is a toll-free number. Electronic inquiries should be sent to smallpox@hrsa.gov. Interested parties may also wish to consult the program's Web site at <http://www.hrsa.gov/smallpoxinjury>.

SUPPLEMENTARY INFORMATION:**Background**

Before it was eradicated, smallpox (variola) was a serious illness that manifested as outbreaks of either variola major with death rates of greater than 20% or variola minor with death rates of almost 1%. The smallpox (vaccinia) vaccine (referred to in this rule as the "smallpox vaccine") contains a live vaccinia virus that induces immunity to smallpox infection, but does not lead to variola infection or disease. Vaccinia virus is an orthopox type virus that is different from, but related to, the smallpox virus. The smallpox vaccine was an essential tool for the successful global eradication of the smallpox virus, 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 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 24, 2003 (68 FR 4212). This Declaration was issued pursuant to statutory authority, 42 U.S.C. 233(p)(2)(A), which was enacted by the Homeland Security Act of 2002, Pub. L. 107-296, 116 Stat. 2135. 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 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 its derivatives, 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, certain public safety personnel, other members of smallpox emergency response plans identified by State or local government entities or the Department of Health and Human Services, 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 will remain effective until January 23, 2004, unless the Secretary extends or shortens that time period by amendment.

Under the Smallpox Vaccine Injury Compensation Program authorized by the SEPPA, certain persons may be entitled to benefits (defined as benefits and/or compensation) for covered injuries, described below, suffered as a direct result of the administration of smallpox covered countermeasures (including the smallpox vaccine) or accidental vaccinia inoculation. Specifically, the SEPPA authorizes the Secretary to make the benefits available to two categories of eligible persons who sustained covered injuries, provided