

According to CDC's Vaccine Adverse Event Reporting System (VAERS), there are reports of three fatalities and 92 serious injuries (out of approximately 800 total reported injuries) based on the administration of approximately 38,400 smallpox vaccinations to volunteers within the civilian sector (as of September 2003). The program recognizes the difficulty inherent in predicting the number of individuals who will file for benefits under approved smallpox emergency response plans. Nonetheless, with the anticipation of additional individuals receiving the smallpox vaccine, plus a number of potential contact cases, the program predicts that there may be up to 1,250 requesters. It is important to note that a large number of such requesters filing Request Forms with the program may not be eligible for payments under the program for a variety of reasons (e.g., they sustained minor injuries that do not qualify as covered injuries, the Secretary determines that their injuries do not qualify as table injuries and that there is insufficient evidence to establish causation, they received the smallpox vaccine outside of an approved smallpox emergency response plan, or they did not file their Request Form within the governing filing deadlines).

The annual burden estimate includes the time required to review and complete the Request Form as well as the time to obtain and provide further documentation necessary for eligibility and benefits determinations. Comments on this information collection activity should be sent to Lauren Wittenberg, OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, 725 17th Street, NW., Washington, DC 20053; FAX: (202) 395-6974.

List of Subjects in 42 CFR Part 102

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

Dated: October 27, 2003.

Elizabeth M. Duke,

Administrator, Health Resources and Services Administration.

Approved: December 8, 2003.

Tommy G. Thompson,

Secretary.

■ For the reasons stated above, the Department of Health and Human Services amends part 102 of 42 CFR as follows:

■ 1. The authority section for part 102 is revised to read as follows:

Authority: 42 U.S.C. 216, 42 U.S.C. 239-239h.

■ 2. In part 102, add sections 102.1—102.20 to read as follows:

PART 102—SMALLPOX VACCINE INJURY COMPENSATION PROGRAM

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Subpart A—General Provisions

§ 102.1 Purpose.

This part implements Section 2 of the Smallpox Emergency Personnel Protection Act of 2003 (the Act). The Act directs the Secretary of Health and Human Services to establish procedures for providing benefits to certain individuals who sustained a covered injury as the direct result of the administration of the smallpox vaccine or other covered countermeasure, and to certain individuals who sustained a covered injury as the direct result of accidental vaccinia inoculation through contact with certain persons vaccinated with the smallpox vaccine or with individuals accidentally inoculated by them. Also, if the Secretary determines that an individual died as a result of a covered injury, the Act provides for certain survivors of that individual to receive death benefits.

§ 102.2 Summary of available benefits.

(a) The Act authorizes three forms of benefits to requesters deemed eligible by the Secretary:

(1) Payment or reimbursement for reasonable and necessary medical services and items to diagnose or treat a covered injury or its health complications, as described in § 102.31.

(2) Lost employment income incurred as a result of a covered injury, as described in § 102.32.

(3) Death payments to survivors if the Secretary determines that the death of the smallpox vaccine recipient or vaccinia contact was the direct result of