Unfunded Mandates Reform Act of 1995

The Secretary has determined that this Final Rule will not have effects on State, local, or tribal governments or 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 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 Final Rule may have a positive impact on the disposable income and poverty elements of family well-being to the extent that injured persons (or their survivors who are eligible to receive compensation) receive benefits without a corresponding burden being imposed on them.

Paperwork Reduction Act

The information collection requirements remain unchanged.

List of Subjects in 42 CFR Part 102


Dated: November 14, 2005.

Elizabeth M. Duke,
Administrator.

Approved: December 22, 2005.

Michael O. Leavitt,
Secretary.

Editorial Note: This document was received at the Office of the Federal Register on May 18, 2006.

For the reasons stated above, the Secretary is adopting the Interim Final Rule adding 42 CFR part 102, published at 68 FR 51402 on Wednesday, August 27, 2003, as a Final Rule with the following amendment:

PART 102—SMALLPOX COMPENSATION PROGRAM

§ 102.83(c) to make clear that the
Secretary determines the timeframe for submission of required documentation.

DATES: The interim final rule, published on December 16, 2003, was effective on that date, and is adopted as the final rule with an amendment effective May 24, 2006.

FOR FURTHER INFORMATION CONTACT: Paul T. Clark, Director, Smallpox Vaccine Injury Compensation Program, Healthcare Systems Bureau, Health Resources and Services Administration, (301) 443–2330.

SUPPLEMENTS INFORMATION:

Background

The Smallpox Emergency Personnel Protection Act of 2003 (SEPPA), Pub. L. 108–20, 117 Stat. 638, directed the Secretary of Health and Human Services (the Secretary) to establish the Program. Secondary to other payers, the Program provides medical, lost employment income, and death benefits for eligible individuals who sustained covered injuries as a result of receiving smallpox vaccine or other covered countermeasures, or as a result of accidental exposure to vaccinia. Congress appropriated $42 million in fiscal year (FY) 2003 for the administration of, and payment of benefits under, the Program. The Consolidated Appropriations Act of 2005 reduced this amount by $20 million. The Departments of Labor, Health and Human Services and Education and Related Agencies Appropriations Act, 2006 (Pub. L. 109–149) further reduced the Program’s appropriation by $10 million to a total of $12 million. Section 220 of the Appropriations Act of 2006 (Pub. L. 109–149) further reduced the Program’s appropriation by $10 million to a total of $12 million.

Individuals who receive a smallpox vaccination under a Department of Health and Human Services (HHS), State, or local emergency response plan approved by HHS within the time period described in the Secretary’s Declaration, and who sustain a covered injury, may be eligible for benefits under SEPPA. Individuals who contracted vaccinia through contact with such individuals or other eligible vaccinia contacts and who sustain a covered injury may also be eligible for benefits. In the case of death resulting directly from receipt of the smallpox vaccine or exposure to vaccinia by eligible individuals, certain of their survivors may be considered for death benefits. If an eligible individual who sustained a covered injury dies from another cause before payment of benefits has been made under the
Program, the estate may qualify for payment of unreimbursed medical expenses incurred and employment income lost as a result of the covered injury, secondary to other payers.

SEPPA directed the Secretary to establish a table identifying adverse effects (including injuries, disabilities, conditions, and deaths) 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 listed injury must appear in order for such presumption to apply. An Interim Final Rule for the Smallpox (Vaccinia) Vaccine Injury Table was published in the Federal Register on August 27, 2003 (68 FR 51492). Following a public comment period, the Final Rule was published on May 24, 2006.

An Interim Final Rule for the Administrative Implementation of the Program was published in the Federal Register on December 16, 2003 (62 CFR Part 102), with a 60-day public comment period. The public comment period ended on February 17, 2004. HHS received no comments.

Technical corrections to the Interim Final Rule were published in the Federal Register on February 17, 2004 (69 FR 7376).

Explanation of Provisions

In accordance with section 266(a)(2)(A) of the Public Health Service Act, added by SEPPA, death benefit amounts payable under the Program are equal to those available under the Public Safety Officers’ Benefits (PSOB) Program. The PSOB Program death benefit amount is subject to change on October 1 each year. For example, in fiscal year (FY) 2003, the amount was $262,100; by FY 2006 the amount had increased to $283,385. To keep the public informed of the current amount, the Secretary will publish a Notice in the Federal Register announcing the new amount for each fiscal year consistent with the rate established under the PSOB Program. In accordance with PSOB Program provisions, the amount payable is determined by the date of death of the smallpox vaccine recipient or vaccinia contact, not the date of payment.

Also, this Final Rule is adding to the definition section, §102.3, a new paragraph (e) to clarify that, for purposes of survivorship benefits under the Program, the term “child” is defined in accordance with the PSOB Program’s statute, 42 U.S.C. at §3796b(3), as implemented in 28 CFR Part 32, as amended.

An adult child survivor of a deceased smallpox vaccine recipient or vaccinia contact may claim eligibility for death benefits if, at the time of the recipient or contact’s death, he or she is over 18 years of age and incapable of self-support because of physical or mental disability. Examples of the types of supporting documentation requesters should submit to support eligibility as a disabled adult child survivor include, but are not limited to: Determination of disability letter, or award letter, issued by the Social Security Administration; determination of disability by a court of competent jurisdiction (e.g., requiring the need for a guardianship or conservatorship); and medical documentation of the physical or mental condition that precludes the capacity for self-support.

The Secretary has amended the Declaration by extending the dates of its effective period each year. The Secretary will continue to publish a notice in the Federal Register as needed to update further the effective period of the Declaration. These amendments to the Declaration are made pursuant to the Secretary’s authority under section 261(a)(5) of the Public Health Service Act, added by SEPPA and section 224(p)(2)(A) of the Public Health Service Act. Therefore, this Final Rule updates the definition of the effective period of the Declaration in §102.3(k) of the Interim Final Rule (redesignated now as paragraph (l) to accommodate insertion of the new paragraph (e)).

Technical corrections to the Interim Final Rule were published in the Federal Register on February 17, 2004 (69 FR 7376).

For the presumption to apply that an injury resulted from the administration of, or exposure to, the smallpox vaccine, the injury must be listed on the Smallpox (Vaccinia) Vaccine Injury Table, and the first symptom or manifestation of the onset of the injury must occur within the time interval listed on the Table. Otherwise, the presumption of causation does not apply, and the requester must prove causation. The parenthetical example given in §102.20(d) of the Interim Final Rule erroneously states that one of the Table requirements to establish a covered injury is “onset of the injury within the time interval included on the Table.” However, it is not the onset of the injury that must manifest within that time interval. Rather, the requirement is that the onset of the first symptom or manifestation of the injury must manifest within the specified time period. Therefore, this Final Rule herein amends the parenthetical example in §102.20(d) to reflect the inadvertent omission of this language. This Final Rule also reflects the change in name of the HRSA Bureau that operates the Program. The Special

The Secretary has found that a delay in the effective date of this Final Rule is unnecessary and contrary to the public interest. The adoption of the Interim Final Rule as a Final Rule
reflects amendments, updates, and clarifications that will be helpful to requesters without imposing additional burdens. It has no effect on any individual’s rights or responsibilities.

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 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 Final Rule will not have a significant impact on a substantial number of small entities.

The Secretary has also determined that this 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. This rule is not a “major rule” within the meaning of the statute providing for Congressional Review of Agency Rulemaking, 5 U.S.C. 801.

Unfunded Mandates Reform Act of 1995

The Secretary has determined that this Final Rule will not have effects on State, local, or tribal governments or 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 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 Final Rule may have a positive impact on the disposable income and poverty elements of family well-being to the extent that injured persons (or their survivors who are eligible to receive compensation) receive benefits without a corresponding burden being imposed on them.

Paperwork Reduction Act

The information collection requirements remain unchanged.

List of Subjects in 42 CFR Part 102


Dated: November 14, 2005.

Elizabeth M. Duke,
Administrator.

Approved: December 22, 2005.

Michael O. Leavitt,
Secretary.

Editorial Note: This document was received at the Office of the Federal Register on May 18, 2006.

For the reasons stated above, the Secretary is adopting the Interim Final Rule adding 42 CFR part 102, published at 68 FR 70080 on Tuesday, December 16, 2003, as amended on February 17, 2004, at 69 FR 7376; as a Final Rule with the following amendments:

PART 102—SMALLPOX VACCINE INJURY COMPENSATION PROGRAM

1. The authority citation for part 102 continues to read as follows:


2. Amend §102.3 to read as follows:

A. Redesignate paragraphs (e) through (bb) as paragraphs (f) through (cc) and add new paragraph (e) to read as set forth below; and

B. Amend newly designated paragraph (l) (formerly designated paragraph (kk)) to read as set forth below:

§102.3 Definitions

(e) Child means any natural, illegitimate, adopted, or posthumous child or stepchild of a deceased smallpox vaccine recipient or vaccinia contact who, at the time of the recipient or contact’s death is:

(1) 18 years of age or under; or

(2) Over 18 years of age and a student as defined in section 8101 of title 5, United States Code; or

(3) Over 18 years of age and incapable of self-support because of physical or mental disability.

(l) Effective period of the Declaration means the time span specified in the Declaration, as amended by the Secretary.

3. Amend §102.20, paragraph (d) introductory text by adding the words “the first symptom or manifestation of” before the word “onset” in the parenthetical example.

4. Amend §102.40 as follows:

A. In paragraph (a), remove the words “Special Programs Bureau”, and add in their place “Healthcare Systems Bureau”, and remove the words Room “16C–17”, and add in their place “Room 11C–06”;

B. In paragraph (b), remove the words “Special Programs Bureau, Health Resources and Services Administration, 4350 East-West Highway, 10th Floor, Bethesda, Maryland 20814” and add in their place “Healthcare Systems Bureau, Health Resources and Services Administration, Parklawn Building, Room 11C–06, 5600 Fishers Lane, Rockville, Maryland 20857”.

5. Amend §102.41 as follows:

A. In paragraph (a), remove the words “Special Programs Bureau”, and add in their place “Healthcare Systems Bureau”, and remove the words Room “16C–17”, and add in their place “Room 11C–06”;

B. In paragraph (b), remove the words “Special Programs Bureau, Health Resources and Services Administration, Parklawn Building, 4350 East-West Highway, 10th Floor, Bethesda, Maryland 20814” and add in their place “Healthcare Systems Bureau, Health Resources and Services Administration,”
Petitions for Reconsideration and

SUPPLEMENTARY INFORMATION: This is a summary of the Commission’s Fourth Memorandum Opinion and Order, ET Docket No. 00–258, and WT Docket No. 02–8, FCC 06–43, adopted April 5, 2006, and released April 11, 2006. The full text of this document is available on the Commission’s Internet site at http://www.fcc.gov. It is also available for inspection and copying during regular business hours in the FCC Reference Center (Room CY–A257), 445 12th Street, SW., Washington, DC 20554. The full text of this document also may be purchased from the Commission’s duplicator contractor, Best Copy and Printing Inc., Portals II, 445 12th St., SW., Room CY–B402, Washington, DC 20554; telephone (202) 488–5300; fax (202) 488–5563; e-mail FCC@BCPIWEB.COM.

Summary of the Report and Order
1. The Commission considered two petitions for reconsideration (“Petitions”) of the Seventh Report and Order, 69 FR 77938, December 29, 2004, in this proceeding, one filed by the Association for Maximum Service Television and National Association of Broadcasters (together, “MSTV/NAB”) and the other by the Society of Broadcast Engineers, Inc. (“SBE”). In the Seventh Report and Order (“AWS Seventh Report and Order”) in this proceeding, the Commission, among other things, allowed primary access to the band 2025–2110 MHz for Department of Defense (“DOD”) uplink earth stations at 11 sites to support military space operations (also known as tracking, telemetry, and commanding or “TT&C”) on a co-equal basis with stations in the Incumbent Television Broadcast Auxiliary Service (“BAS”), Cable Television Relay Service (“CARS”), and Local Television Transmission Service (“LTTS”). For simplicity, in the remainder of this document the BAS, LTTS, and CARS services collectively will be referred to as BAS. The actions taken in the AWS Seventh Report and Order were specifically designed to facilitate the introduction of new advanced wireless services (“AWS”) in the band 1710–1755 MHz by providing replacement spectrum for clearing that band of incumbent Federal Government operations that would otherwise impede the development of new nationwide AWS services. These actions were consistent with proposals made in the AWS Fourth NPRM, 68 FR 52156, September 2, 2003, and previous actions in this proceeding and with the United States Department of Commerce, National Telecommunications and Information Administration (“NTIA”) 2002 Viability Assessment, which addressed relocation and reaccommodation options for Federal Government operations in the band 1710–1755 MHz.
2. In the Memorandum Opinion and Order, the Commission denied both the MSTV/NAB and the SBE petitions. In this regard, the Commission found that the Petitioners have not raised any new arguments or concerns that were not already considered by the Commission in its adoption of the AWS Seventh Report and Order and that the Commission’s decision properly addressed the relevant facts in order to reach its conclusion that BAS and Federal Government operations will be able to co-exist in the band. The Commission, however, provided additional clarification on a matter raised in the SBE petition.
3. In the AWS Seventh Report and Order, the Commission undertook the specific task of reaccommodating Federal users in order to make the band 1710–1755 MHz available for AWS use. This decision was part of a larger and substantially more complex proceeding designed to make spectrum available for a variety of new and innovative wireless services and involving a variety of bodies, including this Commission, Federal stakeholders represented through NTIA, and Congress.
4. In the AWS Seventh Report and Order decision, the Commission recognized the concerns of the broadcasting community that sharing of the band 2025–2110 MHz (“the 2 GHz band”) by TV BAS stations and DOD TT&C uplink earth stations would be challenging in some instances, given the high power and close proximity of some of these earth stations to nearby cities served by BAS. However, it affirmed its confidence that such sharing is feasible and will promote the public interest, particularly in the ultimate provision of AWS to the public. To maintain its longstanding policy that first-licensed facilities have the right of protection from later-licensed facilities operating in the same band, and to facilitate compatible operations, the Commission required each DOD earth station to coordinate with all potentially affected BAS stations prior to earth station authorization. Additionally, for the rare situation where no reasonable coordination can be negotiated, the Commission stated that the issue may be