



DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 102

RIN 0906-AA84

Removing Outmoded Regulations Regarding the Smallpox Vaccine Injury Compensation Program

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Direct final rule.

SUMMARY: This action removes the outmoded regulations for the Smallpox Vaccine Injury Compensation Program. The program and its implementing regulation have been rendered obsolete by the expiration of the Declaration Regarding Administration of Smallpox Countermeasures under the Smallpox Emergency Personnel Protection Act of 2003 and incorporation of the smallpox countermeasure injury coverage under the Public Readiness and Emergency Preparedness Act of 2005 and its authorization of the Countermeasures Injury Compensation Program.

DATE: This action is effective **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]** without further action, unless adverse comment is received by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. If adverse comment is received, HHS will publish a timely withdrawal of the rule in the Federal Register.

FOR FURTHER INFORMATION CONTACT: Questions or comments regarding the

Smallpox Vaccine Injury Compensation Program should be directed to Narayan Nair, M.D., Acting Director, Division of Injury Compensation Programs, Healthcare Systems Bureau, HRSA, 5600 Fishers Lane, Room 08N146B, Rockville, MD 20857, by phone at (301) 443-5287, or by email at nnair@hrsa.gov.

SUPPLEMENTARY INFORMATION: In response to Executive Order 13563, Sec. 6(a), which urges agencies to “repeal” existing regulations that are “outmoded” from the Code of Federal Regulations (CFR), HHS is removing 42 CFR part 102. Notice and comment are not required for this rule, because it affects agency organization, procedure, or practice under 5 U.S.C. 553(b)(A). Furthermore, HHS believes that there is good cause hereby to bypass notice and comment and proceed to a direct final rule, pursuant to 5 U.S.C. 553 (b)(B). The action is non-controversial, as it merely removes a provision from the CFR that is obsolete. This rule poses no new substantive requirements on the public. Accordingly, HHS believes this direct final rule will not elicit any significant adverse comments, but if such comments are received HHS will publish a timely notice of withdrawal in the Federal Register.

I. Background

The Smallpox Emergency Personnel Protection Act of 2003 (SEPPA), (42 U.S.C. 239 *et seq.*) enacted on April 30, 2003, authorized the Secretary of the Department of Health and Human Services (the Secretary), through the establishment of the Smallpox Vaccine Injury Compensation Program (SVICP), to provide benefits and/or compensation to certain persons who sustained covered injuries as a direct result of the administration of covered smallpox countermeasures (including the smallpox vaccine) or as a result of vaccinia contracted through accidental vaccinia contact. The SVICP’s implementing regulation was codified at 42 CFR part

102.

The SVICP provided compensation for unreimbursed medical expenses and/or lost employment income to eligible individuals for covered injuries sustained as a direct result of the smallpox vaccine or accidental vaccinia inoculation, and/or death benefits to certain survivors of these individuals. The Secretary did not extend SEPPA's Declaration Regarding Administration of Smallpox Countermeasures, which expired on January 23, 2008. Vaccine recipients and accidental vaccinia contacts had 1 and 2 years, respectively, to file a request for program benefits. The SVICP ended on January 23, 2010.

Alternatively, based on a credible risk that the threat of exposure to variola virus, the causative agent of smallpox, constitutes a public health emergency, the Secretary issued a Declaration (73 FR 61869-61871) covering smallpox countermeasures under the Public Readiness and Emergency Preparedness Act of 2005 (PREP Act), with an effective date of January 24, 2008. The PREP Act authorizes the establishment and administration of the Countermeasures Injury Compensation Program, whose implementing regulation, at 42 CFR part 110, is based on the SVICP's regulation and provides similar benefits. On December 9, 2015, the PREP Act Declaration was amended and republished (80 FR 76546-76553), extending the effective time period to December 31, 2022, and deleting obsolete language referring to SEPPA.

Executive Order 12866

This action does not meet the criteria for a significant regulatory action as set out under Executive Order 12866, and review by the Office of Management and Budget has accordingly not been required.

Regulatory Flexibility Act

This action will not have a significant economic impact on a substantial number of small entities. Therefore, the regulatory flexibility analysis provided for under the Regulatory Flexibility Act is not required.

Paperwork Reduction Act

This action does not affect any information collections.

List of Subjects in 42 CFR Part 102

Biologics, Immunization, Public health, Smallpox.

PART 102 – [REMOVED]

For reasons set out in the preamble, and under the authority at 5 U.S.C. 301, HHS amends 42 CFR chapter I by removing part 102.

Dated: August 26, 2016

James Macrae,

Acting Administrator,
Health Resources and Services Administration.

Approved: _September 7, 2016_____

Sylvia M. Burwell,

Secretary,
Department of Health and Human Services.

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