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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 130

RIN 0906-AB13

Removing Outmoded Regulations Regarding the Ricky Ray Hemophilia Relief Fund Program

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Final rule.

SUMMARY: This action removes the outmoded regulations for the Ricky Ray Hemophilia Relief Fund Program. The program and its implementing regulation have been rendered obsolete by the statutory language in the authorizing legislation stating that the Fund should terminate on the expiration of the 5-year period beginning on the date of the enactment of the Act. The statute was enacted on November 12, 1998; thus, the fund expired on November 12, 2003.

DATES: This action is effective **[INSERT 30 DAYS FROM THE DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

FOR FURTHER INFORMATION CONTACT: Sweta Maheshwari J.D., Legislative Analyst, Division of Policy and Shortage Designation, Bureau of Health Workforce, HRSA, 5600 Fishers Lane, Room 11W21A, Rockville, MD 20857, by phone at (301) 945-3527, or by email at smaheshwari@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 130. HHS believes that there is good cause to bypass notice and comment and proceed to a final rule, pursuant to 5 U.S.C. 553(b)(3)(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action is non-controversial, as it merely removes a provision from the CFR that is obsolete.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.

Background

The Ricky Ray Hemophilia Relief Fund Act of 1998 (Public Law 105-369) established the Ricky Ray Hemophilia Relief Fund Program designed to provide payments to individuals with blood-clotting disorders, such as hemophilia, who contracted HIV through the use of antihemophilic factor administered between July 1, 1982, and December 31, 1987. The Act also provided for payments to certain persons who contracted HIV from an individual as described above and certain specified survivors.

HHS promulgated 42 CFR part 130 to establish the proper regulatory framework for program implementation. The regulation can be conceptualized as four parts: the process for payment, the documentation required to prove eligibility, the petition process, and the reconsideration process. The Ricky Ray Hemophilia Relief Fund was authorized with a directive to pay \$100,000 in compensation to eligible individuals. At that time, however, no funds were appropriated to implement this statute. In FY 2000, Congress appropriated \$75 million and, in FY 2001, Congress appropriated \$580 million, for a total of \$655 million. The appropriated amounts provided sufficient funding to make compassionate payments on all eligible petitions received by the program. The program received over 6,000 petitions resulting in approved payments over \$550 million.

The statutory language in the authorizing legislation stated that the “Fund shall terminate upon the expiration of the 5-year period beginning on the date of the enactment of this Act.” The statute was enacted on November 12, 1998; thus, the fund expired on November 12, 2003. The program is no longer in effect or funded. The repeal of this regulation should not create any

challenges for other programs, as the regulation was strictly for the implementation of the Ricky Ray Hemophilia Relief Fund program, which has not been in operation for almost 14 years.

Executive Orders 12866, 13563, 13771, and 13777

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13771 directs agencies to categorize all impacts which generate or alleviate costs associated with regulatory burden and to determine the actions net incremental effect.

Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) having an annual effect on the economy of \$100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or Tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). HHS submits that this final rule is not “economically significant” as measured by the \$100 million threshold, and hence not a major rule under the Congressional Review Act. This rule has not been designated as a “significant

regulatory action” under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

Executive Order 13771, titled “Reducing Regulation and Controlling Regulatory Costs,” was issued on January 30, 2017. HHS identifies this final rule as a deregulatory action (removing an obsolete rule from the Code of Federal Regulations). For the purposes of Executive Order 13771, this final rule is not a substantive rule; rather it is administrative in nature and provides no cost savings.

Executive Order 13777, titled “Enforcing the Regulatory Reform Agenda,” was issued on February 24, 2017. As required by Section 3 of this Executive Order, HHS established a Regulatory Reform Task Force (HHS Task Force). Pursuant to Section 3(d)(ii), the HHS Task Force evaluated this rulemaking and determined that these regulations are “outdated, unnecessary, or ineffective.” Following this finding, the HHS Task Force advised the HRSA Administrator to initiate this rulemaking to remove the obsolete regulations from the Code of Federal Regulations.

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.

Dated: June 4, 2018.

George Sigounas,

Administrator,

Health Resources and Services Administration.

Approved: June 21, 2018.

Alex M. Azar II,

Secretary,

Department of Health and Human Services.

List of Subjects in 42 CFR Part 130

Health care, Hemophilia, HIV/AIDS.

PART 130--[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 130.

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