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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Parts 22 and 32

RIN 0906-AB20

Removing Outdated Regulations Regarding the National Hansen's Disease Program

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This action removes the outmoded HHS regulations for the National Hansen's Disease Program (NHDP). Due to superseding events and statutory changes, NHDP's regulations are obsolete.

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

FOR FURTHER INFORMATION CONTACT: Jeri Pickett, Director, Division of National Hansen's Disease Programs, 1770 Physicians Park Drive, Baton Rouge, Louisiana 70816, by phone at (225) 756-3774, or by email at jpickett@hrsa.gov.

SUPPLEMENTARY INFORMATION: In response to Executive Order 13563, Section 6(a), which urges agencies to repeal existing regulations that are outmoded from the Code of Federal Regulations (CFR), HHS is removing 42 CFR 22.1 and 42 CFR Part 32. 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)(B). The action is non-controversial, as it merely

removes obsolete provisions from the CFR. This rule poses no new substantive requirements on the public. Thus, we view notice and comment as unnecessary.

Background

Regulations pertaining to the NHDP appear at 42 CFR 22.1, "Hansen's Disease Duty by Personnel Other than Commissioned Officers" and 42 CFR part 32, "Medical Care for Persons with Hansen's Disease and Other Persons in Emergencies." The NHDP regulation at Part 22.1 was originally published at 50 FR 43146 (October 24, 1985) and was superseded by the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA), Pub. L. 99–272 (April 7, 1986). The NHDP regulations under Part 32 were originally published at 40 FR 25816 (June 19, 1975), and later amended by 40 FR 36774 (August 22, 1975), 46 FR 51918 (October 23, 1981), and 48 FR 10318 (March 11, 1983). The NHDP authorizing statute was substantially amended after these regulations were promulgated. *See* 42 U.S.C. 247e; Pub. L. 105-78 (Nov. 13, 1997), *amended by* Pub. L. 107-220 (Aug. 21, 2002).

For the reasons indicated below, the regulations at 42 CFR 22.1 and 42 CFR part 32 are outdated, unnecessary, and/or redundant. First, as noted above, Section 22.1 was superseded by Pub. L. 99-272. Second, Part 32 references a Public Health Service Hospital in Carville, Louisiana, but there is no longer a Public Health Services Hospital in Carville, Louisiana. *See* 42 CFR 32.86 -.87. Third, section 32.1 references "the Director, Bureau of Health Care Delivery and Assistance." This Bureau no longer exists at HRSA, and other terms set forth in section 32.1 are defined elsewhere in the Public Health Service Act. *See* 42 U.S.C. 201. Fourth, the NHDP authorizing statute, 42 U.S.C. 247e, only permits the Secretary to provide short-term care and treatment, including

outpatient care, for Hansen's Disease and related complications at or through the National Hansen's Disease Programs Center, with the limited exception of a small number of patients who were patients of the Gillis W. Long Hansen's Disease Center as of October 1, 1996. However, Part 32 references inpatient care, hospitals, hospitalization, discharge, and hospitalized non-beneficiaries. *See, e.g.* 42 CFR 32.6, 32.86, 32.87, 32.89 32.91, and 32.111. Fifth, section 32.90 contains provisions regarding notification to health authorities but such notifications have been rendered obsolete in light of changes in management of the disease. Lastly, the NHDP can rely upon statutory authority to continue to operate in the absence of the regulations at part 22.1 and 32. In light of the foregoing, we are rescinding the regulations promulgated under 42 CFR 22.1, "Hansen's Disease Duty by Personnel Other than Commissioned Officers" and 42 CFR part 32, "Medical Care for Persons with Hansen's Disease and Other Persons In Emergencies". We will continue to operate the NHDP relying on statutory authority alone.

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).

Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as "any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment,

public health or safety or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in th[e] Executive Order."

A regulatory impact analysis 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 as defined by Executive Order 12866. As such, it has not been reviewed by the Office of Management and Budget.

Executive Order 13771, titled "Reducing Regulation and Controlling Regulatory Costs," was issued on January 30, 2017. Pursuant to Executive Order 13771, HHS identifies this final rule as a deregulatory action (i.e., 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.

On February 24, 2017, the President issued Executive Order 13777 titled "Enforcing the Regulatory Reform Agenda". As required by Section 3 of the Executive Order, HHS established a Regulatory Reform Task Force (HHS Task Force) to review existing regulations and make recommendations regarding their repeal, replacement, or modification. The HHS Task Force evaluated the NHDP regulations at 42 CFR 22.1 and

42 CFR 32 and determined them to be outdated, unnecessary, or ineffective. Thus, the HHS Task force advised initiating this final rule to remove the obsolete regulations from the Code of Federal Regulations.

Regulatory Flexibility Act

This action will not have a significant 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: May 20, 2019.

George Sigounas,

Administrator,

Health Resources and Services Administration.

Approved: June 7, 2019.

Alex M. Azar II,

Secretary,

Department of Health and Human Services.

List of Subjects

42 CFR Part 22

Diseases, Government Employees, Health Professions, Wages

42 CFR Part 32

Diseases, Health Care

For reasons stated in the preamble, 42 CFR parts 22 and 32 are amended as follows:

PART 22—PERSONNEL OTHER THAN COMMISSIONED OFFICERS

1. The authority citation for part 22 continues to read as follows:

Authority: Sec. 208(e) of the Public Health Service Act, 42 U.S.C. 210(e); E.O. 11140, 29 FR 1637.

§ 22.1—[Removed]

2. Section 22.1 is removed.

PART 32—[REMOVED]

3. Under the authority of 5 U.S.C. 301, part 32 is removed.

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