**Billing Code 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**42 CFR Part 9**

**[Docket Number NIH-2019-0001]**

**RIN: 0925-AA66**

Standards of Care for Chimpanzees Held in the Federally Supported Sanctuary System

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Final rule; technical amendments.

**SUMMARY:** This document contains technical amendments to the Health and Human Services (HHS) regulation regarding the Standards of Care for Chimpanzees Held in the Federally Supported Sanctuary System. The regulatory content is being amended to correct references that are made throughout the regulation regarding delegated authorities and activities of the National Center for Research Resources (NCRR) of the National Institutes of Health (NIH). With the abolishment of NCRR in 2011, the Director, NIH, delegated these authorities to the Office of Research Infrastructure Programs (ORIP) within the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI), NIH. The ORIP/DPCPSI now has the lead responsibility for coordinating all efforts on behalf of HHS concerning the sanctuary system for surplus chimpanzees from both federal and non-federal sources. The references to NCRR throughout the regulation are corrected to reflect ORIP/DPCPSI, the definition of National Primate Research Center is corrected to reflect the correct number of currently existing centers, and the office address provided for ORIP/DPCPSI in the regulation is corrected.

**DATES:** Effective on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER.]

**FOR FURTHER INFORMATION CONTACT:** Daniel Hernandez, Acting NIH Regulations Officer, Office of Management Assessment, Division of Management Support, 6011 Executive Boulevard, Suite 601, Rockville, Maryland 20852-7669, telephone 301-435-3343, email dhernandez@od.nih.gov.

**SUPPLEMENTARY INFORMATION:** On December 20, 2000, the United States Congress enacted the Chimpanzee Health Improvement, Maintenance, and Protection Act of 2000 (Pub. L. 106-551, "CHIMP Act"). Section 1 of this law amended the Public Health Service Act by adding section 481C (42 U.S.C.287a-3a). Section 481C requires the Secretary, HHS, to provide for the establishment and operation of a sanctuary system to provide for the lifetime care of chimpanzees that have been used, or were bred or purchased for use, in research conducted or supported by NIH, the Food and Drug Administration (FDA), or other agencies of the Federal Government, and with respect to which it has been determined by the Secretary, HHS, that the chimpanzees are not needed for such research (i.e., surplus chimpanzees).

Section 481C (d) directs the Secretary, HHS, to establish, by regulation, standards of care for operating the sanctuary system to provide for the permanent retirement of surplus chimpanzees. On April 5, 2001, the Secretary, HHS, delegated to the Director, NIH, authorities to establish and operate the sanctuary system. Subsequently, the Director, NIH, delegated the authorities to NCRR. On October 10, 2008, HHS issued a final rule that established the regulation at 42 CFR Part 9 which sets forth the standards of care for chimpanzees held in the federally supported chimpanzee sanctuary system. References are made throughout that regulation regarding delegated authorities and activities of NCRR, NIH.

On September 9, 2011, the Secretary, HHS, approved an organizational change at NIH that included the abolishment of NCRR and the creation of the Office of Research Infrastructure

Programs (ORIP) within the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI). The DPCPSI had been established on May 6, 2008, as a result of provisions of the NIH Reform Act of 2006, Pub. L. 109-482. The Director, NIH, delegated authorities to establish and operate the sanctuary system to ORIP within DPCPSI, NIH. The ORIP/DPCPSI now has the lead responsibility for coordinating all efforts on behalf of HHS concerning the sanctuary system for surplus chimpanzees from both federal and non-federal sources.

Recently, ORIP officials, in collaboration with NIH Regulations Program (NIHRP) officials, completed a review of the regulation codified at 42 CFR Part 9, as part of NIH's efforts to comply with the requirements of the President's Regulatory Reform agenda, as set forth in Executive Order 13777, Enforcing the Regulatory Reform Agenda. One of the outcomes of the review was the determination that the regulation needed to be updated to correct its references regarding the delegated authorities and activities of NCRR and to indicate that ORIP/DPCPSI now has the lead responsibility for coordinating all efforts on behalf of HHS concerning the sanctuary system for surplus chimpanzees.

Since the regulation was issued in 2008, the number of existing National Primate Research Centers has been reduced from eight to seven, as of 2015. This change needs to be made in the definition of National Primate Research Center provided in section 9.2 of the regulation.

Additionally, the office address provided in section 9.4 of the regulation, 1 Democracy Plaza, is corrected to read One Democracy Plaza.

**Matters of Regulatory Procedure**

**Administrative Procedure Act**

Pursuant to 5 U.S.C 553(b) and (d), the Secretary, HHS, has found good cause exists for waiving the general notice of proposed rulemaking, opportunity for public comment and 30-day delay in effectiveness as to these technical updates and correction. The notice, comment and delayed effective date provisions are being waived in part because these minor amendments concern matters of agency organization, practice and procedure. Further, it is in the public interest that correct and up-to-date information be contained in the affected sections of the regulation at 42 CFR Part 9 as soon as possible.

**Executive Orders 12866 and 13563**

Executive Orders 12866, "Regulatory Planning and Review," and 13563, "Improving Regulation and Regulatory Review," 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). Section3(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 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 entitlements, 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) is required for significant and,

economically significant rules with economically significant effects ($100 million or more in any 1 year). It has been determined that this amendatory rulemaking is not significant.

**Executive Order 13771**

Executive Order 13771, "Reducing Regulation and Controlling Regulatory Costs," directs agencies to issue two deregulatory actions for each new significant regulatory action that imposes costs. The incremental costs of a new regulation should be offset by the costs eliminated by the prior regulations. The Secretary, HHS, has determined this amending rulemaking action is not significant and thus is neither regulatory nor deregulatory for the purposes of Executive Order 13771.

**Executive Order 13132**

Executive Order 13132, "Federalism," requires that federal agencies consult with state and local government officials in the development of regulatory policies with federalism implications. The Secretary, HHS, has reviewed this final rule as required under the Executive Order and determined that it will not have federalism implications. The Secretary, HHS, certifies that the final rule will not have effect on the States or on the distribution of power and responsibilities among various levels of government.

**Regulatory Flexibility Act**

The Regulatory Flexibility Act (5 U.S.C. chapter 6) requires agencies to analyze regulatory options that would minimize the significant economic impact of a rule on small entities. The Secretary has determined that this rulemaking will not have a significant economic impact on a substantial number of small entities.

**Unfunded Mandates Reform Act of 1995**

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires agencies to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandates that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually to inflation) in any one year. The current threshold after adjustment for inflation is $154 million, using the most current (2018) Implicit Price Deflator for the Gross Domestic Product. The Secretary, HHS, has determined that this final amendatory rulemaking will not result in an expenditure in any year that meets or exceeds that amount.

**Paperwork Reduction Act**

The Paperwork Reduction Act (44 U.S.C. chapter 35) does not apply, because this amendatory rulemaking does not contain information collection requirements that require the approval of the Office of Management and Budget.

**Congressional Review Act**

The Secretary, HHS, has determined that this amendatory rulemaking is a non-major rule under the Congressional Review Act (5 U.S.C. chapter 8) and has provided a report thereon to the Senate, House of Representatives and General Accounting Office in accordance with that law.

**List of Subjects**

Animal welfare, humane care and treatment of chimpanzees.

Accordingly, under the authority of 42 U.S.C. 216, the Department of Health and Human Services amends 42 CFR Part 9 by making the following correcting amendments:

**Title 42 –Public Health**

**PART 9 – STANDARDS OF CARE FOR CHIMPANZEES HELD IN THE FEDERALLY SUPPORTED SANCTUARY STSTEM**

1. The authority citation for part 9 continues to read as follows:

**Authority:** 42 U.S.C. 216, 287a-3a.

**§ 9.2 [Amended]**

2. Amend § 9.2 by:

a. In the definition of "National Primate Research Center (NPRC)" removing the phrase "National Center for Research Resources" and adding, in its place, the phrase "Office of Research Infrastructure Programs (ORIP) within the Division of Program Coordination, Planning and Strategic Initiatives (DPCPSI)," removing the date "June 2007" and adding, in its place, the date "2015"; and removing the word "eight" and adding, in its place, the word "seven".

b. In the definition of "Sanctuary Contractor" by removing the phrase "NCRR/NIH" and adding, in its place the phrase "ORIP/DPCPSI/NIH."

c. In the definition of "Sanctuary of federally supported chimpanzee system" by removing the phrase "NCRR/NIH/HHS" and adding, in its place, the phrase "ORIP/DPCPSI/NIH/HHS."

**§ 9.3 [Amended]**

3. Amend § 9.3 by:

a. In paragraph (a)(2)(ix) removing the phrase "NCRR" and adding, in its place, the phrase "ORIP/DPCPSI."

b. In paragraph (a)(8) removing the phrase "NCRR/NIH" and adding, in its place, the phrase "ORIP/DPCPSI/NIH."

c. In paragraph (b)(2) removing the phrase “NCRR/NIH” and adding, in its place, the phrase ORIP/DPCPSI/NIH.”

**§ 9.4 [Amended]**

4. In § 9.4, amend paragraph (a) by removing the phrase “NCRR” and adding, in its place, the phrase “ORIP/DPCPSI”, and removing the number “1” in the “1 Democracy Plaza” address and adding, in its place, the word “One” to read “One Democracy Plaza”.

**§ 9.5 [Amended]**

5. Amend § 9.5 by:

a. In paragraph (c)(4) removing the phrase “NCRR/NIH” and adding, in its place, the phrase “ORIP/DPCPSI/NIH.”

b. In paragraph (d)(2) removing the phrase “NCRR” and adding, in its place, the phrase ORIP/DPCPSI/NIH.”

c. In paragraph (e) removing the phrase “NCRR” and adding, in its place, the phrase “ORIP/DPCPSI/NIH.”

**§ 9.6 [Amended]**

6. In § 9.6, amend paragraph (d)(2) by removing the phrase “NCRR” and adding, in its place, the phrase “ORIP/DPCPSI.”

**§ 9.9 [Amended]**

7 In § 9.9, amend paragraph (a) by removing the phrase “NCRR/NIH” and adding, in its place, “ORIP/DPCPSI/NIH.”

**§ 9.12 [Amended]**

8. Amend § 9.12 by:

a. In paragraph (a) removing the phrase “NCRR” and adding, in its place, the phrase “ORIP/DPCPSI”; removing the phrase “NCRR/NIH/HHS” and adding, in its place, the phrase ORIP/DPCPSI/NIH/HHS”; and removing the phrase “NIH/NCRR Project Officer” and adding, in its place, the phrase “ORIP/DPCPSI/NIH Project Officer.”

b. In paragraph (b) removing the phrase “NCRR/NIH/HHS” and adding, in its place, “ORIP/DPCPSI/NIH/HHS”; removing the phrase “NCRR” and adding, in its place, the phrase “ORIP/DPCPSI”; and removing the phrase “NCRR/NIH” and adding, in its place, the phrase “ORIP/DPCPSI/NIH.”

Dated: July 21, 2020.

Francis S. Collins,
Director,
National Institutes of Health.

Alex M. Azar II,
Secretary,
Health and Human Services.

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