40-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 52d

[Docket No. NIH-2025-0034]

RIN: 0925-AA74

Recission of the National Cancer Institute Clinical Cancer Education Program Regulation

AGENCY: National Institutes of Health, Department of Health and Human Services (HHS).

ACTION: Notice of Proposed Rulemaking.

SUMMARY: The Department of Health and Human Services (HHS), in consultation with the National Institutes of Health (NIH), is proposing to rescind the existing regulation concerning grants under the National Cancer Institute (NCI) Clinical Cancer Education Program because the regulation is obsolete and no longer necessary.

DATES: Comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Comments must be submitted in one of the following two ways (please choose only one of the two ways listed):

- Electronically at https://www.regulations.gov. Follow the "Submit a comment" instructions. If you are reading this document on *www.federalregister.gov*, you may use the green "SUBMIT A PUBLIC COMMENT" button beneath this rulemaking's title to submit a comment to the *www.regulations.gov* docket.
- You may mail comments to the following address: Kelly Daughtridge, NIH Regulations Officer, National Institutes of Health, Office of Management Assessment, Rockledge 1, 6701 Rockledge Drive, Suite 601, Bethesda, Maryland

20817 – MSC 7901. Mailed comments must be received by the end of the comment period.

Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments are public records; they are publicly displayed exactly as received, and will not be deleted, modified, or redacted. Comments may be submitted anonymously.

Follow the search instructions https://www.regulations.gov to view public comments.

FOR FURTHER INFORMATION CONTACT: Kelly Daughtridge, NIH Regulations Officer, Office of Management Assessment, NIH, Rockledge 1, 6705 Rockledge Drive, Suite 601, Bethesda, MD 20817 – MSC 7901, by email at Kelly.Daughtridge@nih.gov, or by telephone at 301- 451-8081 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

1. Background

Deregulation is a central objective of the Trump administration. To achieve this objective, the President has issued several executive orders (EOs) to reduce the amount of rulemaking undertaken by Federal agencies and identify and eliminate regulations that are unlawful, anti-competitive, or obsolete and unnecessary, for example EO 14219, Ensuring Lawful Governance and Implementing the President's "Department of Government Efficiency" Deregulatory Initiative, February 19, 2025, and EO 14192, Unleashing Prosperity Through Deregulation, January 31, 2025. In response to these and other deregulatory initiatives announced by the Trump administration, NIH conducted a comprehensive review of 23 HHS regulations that NIH historically has authored for approval and signature by the Secretary, HHS, and/or assisted in maintaining on behalf of the Secretary, HHS. This review identified the HHS regulation codified at 42 CFR Part

52d, National Cancer Institute Clinical Cancer Education Program, as likely obsolete and unnecessary.

Subsequently, NIH Regulations officials and National Cancer Institute (NCI) senior management executives knowledgeable about the scope, history, and intent of the regulation, completed a follow-up review and determined that the regulation had not been updated significantly since 1980. Based on this review, NIH and NCI determined that the program to which the regulation applied has changed over the years and no longer exists in the same form as it did in 1980. Notably, the regulation states at 42 CFR 52d.1 that it applies "to grants under the Clinical Cancer Education Program authorized by section 404(a)(4) of the Public Health Service Act" (PHSA), but section 404 of the PHSA no longer exists. Thus, NIH and NCI concluded the regulation is outdated, no longer necessary, and should be rescinded. Additionally, NIH and NCI concluded that other existing regulations, including 42 CFR Part 52 (Grants for Research Projects) and 2 CFR Part 200 (Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards), would continue to apply to NCI Cancer Education grant programs if the regulation at 42 CFR Part 52d were rescinded. Neither HHS nor NIH anticipate any adverse impact on stakeholders resulting from the recission of the regulation.

Thus, HHS, in consultation with NIH, is issuing this proposed rule to rescind the regulation at 42 CFR Part 52d, National Cancer Institute Clinical Cancer Education Program, because the regulation is obsolete and unnecessary. While it is anticipated that no measurable cost savings will result from this deregulatory action, the recission of the regulation codified at 42 CFR Part 52d aligns with the administration's deregulation objectives and the goals of EOs 14192 and 14219 and other deregulatory initiatives of the President.

Regulatory Impact Analysis

We examined the impact of this proposed rule under Executive Order (E.O.) 12866, Regulatory Planning and Review; E.O. 13563, Improving Regulations and Regulatory Review; E.O. 14192, Unleashing Prosperity Through Deregulation; E.O. 13132, Federalism; the Regulatory Flexibility Act (5 U.S.C. 601-612); and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4).

Executive Orders 12866 and 13563

E.O. 12866, Regulatory Planning and Review, and E.O. 13563, Improving Regulations and Regulatory Review, direct Federal 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) for all significant regulatory actions. Under E.O. 12866 Section 3(f)(1), rules are "economically significant" if they "[h]ave 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." A regulatory impact analysis (RIA) must be prepared for major rules with economic significant effects ($100 million or more in any one year). We believe this proposed rule is not a significant or economically significant regulatory action under Executive Order 12866.

Executive Order 14192

E.O. 14192, Unleashing Prosperity Through Deregulation, requires that any new incremental costs associated with certain significant regulatory actions "shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at

least 10 prior regulations." This proposed rule, if finalized as proposed, is expected to be an Executive Order 14192 deregulatory action.

Executive Order 13132

E.O. 13132, Federalism, requires Federal agencies to consult with State and local government officials in the development of regulatory policies with federalism implications. We reviewed this rule as required under this Order and determined that it will not have a significant potential negative impact on States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government and does not have any federalism implications. The Secretary, HHS, certifies that this rule will not have effect on the States or on the distribution of power and responsibilities among the various levels of government.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601- 612) requires Federal agencies to analyze regulatory options that would minimize any significant impact of the rule on small entities. The Secretary certifies that this rule will not create a significant impact on a substantial number of small entities, and therefore a regulatory flexibility analysis is not required.

Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (UMRA) generally requires that each agency conduct a cost-benefit analysis; identify and consider a reasonable number of regulatory alternatives; and select the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule before promulgating any proposed or final rule that includes a Federal mandate that may result in expenditures of more than $100 million (adjusted for inflation) in at least one year by State, local, and

tribal governments, in the aggregate, or by the private sector. Each agency issuing a rule with relevant effects over that threshold must also seek input from State, local, and tribal governments. The current threshold after adjustment for inflation using the Implicit Price Deflator for the Gross Domestic Product is $193 million. This rule does not meet or exceed that amount.

Paperwork Reduction Act

This proposed rule does not contain any information collection requirements. Therefore, clearance by the Office of Management and Budget is not required.

Financial Assistance Listings

There is no current Financial Assistance Listings program affected by this rule.

List of Subjects in 42 CFR Part 52d

Cancer, Educational study programs, Grant programs-health, Health professions.

PART 52d – [REMOVED AND RESERVED]

For the reasons stated in the preamble, under the authority of sections 215, 301, 402, 405, and 410 of the Public Health Service Act (42 U.S.C. 216, 241, 282, 284, and 285), HHS proposes to amend Subchapter D of Chapter 1 of Title 42 of the Code of Federal Regulations by removing part 52d.

Robert F. Kennedy, Jr.

Secretary, Department of Health and Human Services

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