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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 81

[Docket Number CDC-2019-0050; NIOSH-329]

RIN 0920-AA74

Guidelines for Determining the Probability of Causation under the Energy Employees Occupational Illness Compensation Program Act of 2000; Technical Amendments

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Final rule.

SUMMARY: In August 2019, the Department of Health and Human Services (HHS) published an interim final rule to revise its regulations to update references to the International Classification of Disease (ICD) codes from ICD-9-CM to ICD-10-CM, and remove outdated references to chronic lymphocytic leukemia from Energy Employees Occupational Illness Compensation Program regulations. These technical amendments have no effect on the cancer eligibility requirement under the Program because all cancer types are eligible to receive a dose reconstruction from NIOSH. Thus, no eligible claimant will be adversely impacted by the rulemaking finalized in this document.

DATES: This rule is effective on [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Rachel Weiss, Program Analyst;
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is a toll-free number); email *NIOSHregs@cdc.gov*.

SUPPLEMENTARY INFORMATION:

I. Public Participation

Interested persons or organizations were invited to participate in this rulemaking by submitting written views, arguments, recommendations, and data. Comments were invited on any topic related to this rulemaking.

HHS received one public comment for this rulemaking from a professional organization of health physicists.

II. Review by the Advisory Board on Radiation and Worker Health

As discussed in the August 2019 interim final rule (84 FR 37587), the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA)¹ requires that HHS obtain a review by of that rulemaking the Advisory Board on Radiation and Worker Health. The Board conducted its review and submitted a letter to the docket stating its concurrence with the interim final rule as published.

III. Background

¹ 42 U.S.C. 7384n(c).

As described in the August 2019 interim final rule, EEOICPA was established to provide financial compensation and prospective medical benefits to employees for illness caused by exposure to radiation, beryllium, silica, and toxic substances during their employment at facilities of the Department of Energy, its predecessor agencies, and certain of its contractors and vendors. It is administered by the Department of Labor's Office of Workers' Compensation Programs (OWCP) with radiation dose reconstructions for claims involving radiogenic cancers provided by CDC's National Institute for Occupational Safety and Health (NIOSH). HHS regulations in 42 CFR part 81 govern the NIOSH dose reconstructions.

IV. Summary of Final Rule

In the August 2019 interim final rule, HHS updated the International Classification of Disease (ICD) codes required to identify specific cancer types used in determining the likelihood that an individual's cancer is associated with workplace radiation exposures using a number of factors, including the radiation doses estimated by NIOSH. Both the public commenter and the Board concurred with updating references from ICD-9-CM to ICD-10-CM.

Although supportive of the rulemaking, the public commenter objected to HHS's explanation in the interim final rule preamble that "the definition of the term 'non-radiogenic cancer' is removed because all cancers are considered radiogenic." According to the commenter,

[t]his is a very claimant-favorable policy decision which is not supported by scientific evidence. According to UNSCEAR [citation omitted], ‘...for about 30% of tumour types ... there is only a weak or no relationship between radiation exposure and risk at any age of exposure.’ To be consistent with scientific evidence we recommend a revision to remove the assertion that there are no non-radiogenic [cancers].

HHS agrees that the explanation should properly have stated that the definition is being removed because there are no types of cancer ineligible for NIOSH dose reconstruction; accordingly, the revision is accepted and the explanation for the removal of the definition is revised below. No other changes are made to the rulemaking preamble or regulatory text.

With this final rule, and for the reasons discussed in the August 2019 interim final rule, HHS adopts as final amendments to the regulations in 42 CFR part 81 allowing NIOSH to update references and ICD codes. No substantive changes are made to part 81.

In the existing definitions section, § 81.4, the term “specified cancer” includes a reference to a corresponding DOL regulation (*i.e.*, 20 CFR 30.5(dd)). DOL has recently conducted a rulemaking to revise 20 CFR part 30 that resulted in the reordering of this reference from 20 CFR 30.5(dd) to 20 CFR 30.5(gg).² Therefore, in § 81.4, HHS has revised the reference to read “20 CFR 30.5(gg).” In addition, the definition of the term “non-radiogenic cancer” is removed because there are no longer any types of cancer ineligible for receiving a dose reconstruction from NIOSH. Finally, § 81.4 is revised by adding a new definition of “ICD-10-CM,” to include a reference and web link.

In existing § 81.5(b), the term “ICD-9” is replaced with “ICD-10-CM.” In §§ 81.21, 81.23, and 81.24, all references to ICD-9 codes are changed to ICD-10-CM codes.

² 84 FR 3026 (February 8, 2019).

In §§ 81.21(a) and 81.24(a), outdated references to chronic lymphocytic leukemia are also removed.

Finally, Appendix A is removed in its entirety because it is a glossary of ICD-9 codes and their cancer descriptions, and such reference tables, including tables of ICD-10 codes and their cancer descriptions, are readily available online.

V. Regulatory Assessment Requirements

A. Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)

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). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

This final rule is not being treated as a “significant” action under E.O. 12866. It updates references and ICD codes in existing 42 CFR part 81 to allow better administrative efficiency in the processing of dose reconstruction claims. The rule does not result in costs to the Program, claimants, or any other interested parties. Accordingly, HHS has not prepared an economic analysis and the Office of Management and Budget (OMB) has not reviewed this rulemaking.

The rule does not interfere with State, local, or tribal governments in the exercise of their governmental functions.

B. Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs)

Executive Order 13771 requires executive departments and agencies to eliminate at least two existing regulations for every new significant regulation that imposes costs. HHS has determined that this rulemaking is cost-neutral because it does not require any new action by stakeholders. The rulemaking ensures that the dose reconstructions developed by the Program can be conducted efficiently.

Because OMB has determined that this rulemaking is not significant, pursuant to E.O. 12866, and because it does not impose costs, OMB has determined that this rulemaking is exempt from the requirements of E.O. 13771. Thus it has not been reviewed by OMB.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, requires each agency to consider the potential impact of its regulations on small entities including small businesses, small governmental units, and small not-for-profit organizations. The rule affects only Federal agencies and certain individuals covered by EEOICPA. Therefore, HHS certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

D. Paperwork Reduction Act

The Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, requires an agency to invite public comment on and to obtain OMB approval of any rule of general applicability that requires recordkeeping, reporting, or disclosure requirements.

NIOSH has obtained approval from OMB to collect information from claimants under “Energy Employees Occupational Illness Compensation Program Act Dose Reconstruction Interviews and Forms (EEOICPA)” (OMB Control No. 0920-0530, exp. January 31, 2022), which covers information collected under 42 CFR part 81. This rulemaking does not change the reporting burden on any respondents.

E. Small Business Regulatory Enforcement Fairness Act

As required by Congress under the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*), the Department will report the promulgation of this rule to Congress prior to its effective date. The report will state that the Department has concluded that this rule is not a “major rule” because it is not likely to result in an annual effect on the economy of \$100 million or more.

F. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531 *et seq.*) directs agencies to assess the effects of Federal regulatory actions on State, local, and tribal governments, and the private sector “other than to the extent that such regulations incorporate requirements specifically set forth in law.” For purposes of the Unfunded Mandates Reform Act, this rule does not include any Federal mandate that may result in

increased annual expenditures in excess of \$100 million by State, local, or tribal governments in the aggregate, or by the private sector.

G. Executive Order 12988 (Civil Justice)

This rule has been drafted and reviewed in accordance with Executive Order 12988, “Civil Justice Reform,” and will not unduly burden the Federal court system. This rule has been reviewed carefully to eliminate drafting errors and ambiguities.

H. Executive Order 13132 (Federalism)

The Department has reviewed this rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have “federalism implications.” The rule does not “have substantial direct effects on the 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.”

I. Executive Order 13045 (Protection of Children From Environmental Health Risks and Safety Risks)

In accordance with Executive Order 13045, HHS has evaluated the environmental health and safety effects of this rule on children. HHS has determined that the rule would have no effect on children.

J. Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use)

In accordance with Executive Order 13211, HHS has evaluated the effects of this rule on energy supply, distribution or use, and has determined that the rule will not have a significant adverse effect.

K. Plain Writing Act of 2010

Under Public Law 111–274 (October 13, 2010), executive Departments and Agencies are required to use plain language in documents that explain to the public how to comply with a requirement the Federal Government administers or enforces. HHS has attempted to use plain language in promulgating the final rule consistent with the Federal Plain Writing Act guidelines.

List of Subjects in 42 CFR Part 81

Cancer, Government employees, Nuclear materials, Occupational safety and health, Radiation protection, Radioactive materials, Workers' compensation.

Final Rule

For the reasons discussed in the preamble, the Department of Health and Human Services adopts as final the interim final rule published on August 1, 2019, at 84 FR 37587 and further amends 42 CFR part 81 as follows:

**PART 81—GUIDELINES FOR DETERMINING PROBABILITY OF
CAUSATION UNDER THE ENERGY EMPLOYEES OCCUPATIONAL
ILLNESS COMPENSATION PROGRAM ACT OF 2000**

1. The authority citation for part 81 continues to read as follows:

Authority: 42 U.S.C. 7384n(c); E.O. 13179, 65 FR 77487, 3 CFR, 2000 Comp., p. 321.

Appendix A to Part 81—[Removed]

2. Amend part 81 by removing Appendix A.

Dated: January 10, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

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