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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: Interim final rule.

SUMMARY: The Department of Health and Human Services (HHS) is revising 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to update references to the International Classification of Disease (ICD) codes from ICD-9-CM to ICD-10-CM, and remove outdated references to chronic lymphocytic leukemia from Energy Employees Occupational Illness Compensation Program regulations.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 this rulemaking.

DATES: This rule is effective on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Comments must be received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by “RIN 0920-AA74,” by any of the following methods:

- *Internet:* Access the Federal e-rulemaking portal at <http://www.regulations.gov>. Follow the instructions for submitting comments to docket CDC-2019-0050.
- *Mail:* NIOSH Docket Office, 1090 Tusculum Avenue, MS C-34, Cincinnati, OH 45226-1998.

Instructions: All submissions received must include the agency name and docket number or Regulation Identifier Number (RIN) for this rulemaking. For detailed instructions on submitting comments and additional information on the rulemaking process, see the “Public Participation” heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and search for CDC-2019-0050.

FOR FURTHER INFORMATION CONTACT: Rachel Weiss, Program Analyst; 1090 Tusculum Ave, MS: C-48, Cincinnati, OH 45226; telephone (855) 818-1629 (this is a toll-free number); email NIOSHregs@cdc.gov.

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I. Public Participation

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

All relevant comments submitted will be available for examination in the docket for this rulemaking both before and after the closing date for comments. All relevant comments will be posted without change to Docket CDC-2019-0050 at <http://www.regulations.gov> including any personal information provided.

All relevant communications received on or before the closing date for comments will be fully considered by HHS.

II. Background

The Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA)¹ 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). For these radiogenic cancer claims, OWCP is responsible for developing a claim file upon receipt of an application for benefits under EEOICPA from a claimant. The claim file includes, among other things, employment history and an International Classification of Disease (ICD) diagnosis code(s) indicating the type and location of a radiogenic cancer for the claimant. After a claim file is developed, OWCP then transmits the claim file to NIOSH, which uses that information to estimate the amount of radiation (radiation "dose") the worker might have received during covered employment. OWCP then makes determinations regarding 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. Existing HHS regulations in 42 CFR part 81 require the use of International Classification of Disease, 9th Revision, Clinical Modification (ICD-9-CM) codes to identify specific cancer types used in making these determinations.

The World Health Organization (WHO) develops diagnostic codes for the identification of health conditions; these ICD codes are periodically updated to reflect advances in health and medicine. WHO developed the 10th version (ICD-10) to replace

¹ 42 U.S.C. 7384n(c).

the 9th in 1999. CDC's National Center for Health Statistics developed the ICD-10-CM classification, which is a "clinical modification" of WHO's ICD-10 codes, for use in coding and classifying disease in the clinical setting. Since the development of the ICD-10-CM codes, health facilities and other organizations, including OWCP, have relied on HHS' Centers for Medicare & Medicaid Services (CMS) to provide "general equivalence mapping" between ICD-9-CM codes and ICD-10-CM codes. However, CMS will discontinue that service on September 30, 2019.² Accordingly, OWCP informed NIOSH in January 2019 that it will be unable to continue providing both ICD-9-CM and ICD-10-CM codes in the claim files without potentially causing delay to claim processing. Therefore, the ICD-9-CM codes in part 81 must be replaced with ICD-10-CM codes to bring the regulations up to date and allow NIOSH to efficiently develop dose estimates and improve the overall efficiency in claim processing.

Updating the ICD codes and references in part 81 will inform the claimant population of the current diagnosis codes used in the compensation program and the dose reconstruction process. This rulemaking will benefit the population of energy workers who submit claims to OWCP for benefits under EEOICPA by allowing NIOSH to complete radiation dose reconstructions in support of OWCP's adjudication of the claims in a timely manner. This technical amendment has no effect on the cancer eligibility requirement under the dose reconstruction program (Program) because all cancer types are eligible to receive a dose reconstruction from NIOSH. Thus, no eligible claimant will be adversely impacted by this rulemaking.

In addition to updating the ICD codes, NIOSH will also remove outdated references to chronic lymphocytic leukemia (CLL) from part 81. Until promulgation of a

² See <https://www.cms.gov/Medicare/Coding/ICD10/2019-ICD-10-CM.html>.

final rule in 2012,³ CLL was not covered under the EEOICPA program. The 2012 final rule removed 42 CFR 81.30, which excluded this cancer, thereby allowing claimants to seek compensation through the dose reconstruction process. That rulemaking mistakenly did not remove other references to this provision found elsewhere in part 81.

Finally, a recent Department of Labor rulemaking renumbered a CFR section that defines the term “specified cancer” used in that part. Because that term is referenced in HHS’ rules in part 81, the citation to the Department of Labor regulations is no longer accurate and should be updated.

III. Issuance of an Interim Final Rule with Immediate Effective Date

Rulemaking under the Administrative Procedure Act (APA) generally requires a public notice and comment period and consideration of the submitted comments prior to promulgation of a final rule (5 U.S.C. 553). However, the APA provides for exceptions to its notice and comment procedures when an agency finds that there is good cause for dispensing with such procedures on the basis that they are impracticable, unnecessary, or contrary to the public interest. In accordance with the provisions in 5 U.S.C. 553(b)(3)(B), HHS finds good cause to waive the use of prior notice and comment procedures when issuing this IFR and to make updates to references and ICD codes in 42 CFR part 81 effective immediately.

This IFR amends 42 CFR part 81 to update references and ICD codes. HHS has determined that it is unnecessary to use prior notice and comment procedures for this IFR

³ Final Rule; *Guidelines for Determining Probability of Causation Under the Energy Employees Occupational Illness Compensation Program Act of 2000; Revision of Guidelines on Non- Radiogenic Cancers*, February 6, 2012 (77 FR 5711).

because HHS has already issued through notice-and-comment rulemaking a requirement that covered entities, such as physicians and hospitals, use ICD-10-CM for covered transactions.⁴ Updating the ICD codes is a technical amendment in which CDC exercises little discretion. Soliciting public comment prior to promulgation of this rulemaking would be unnecessary since mapping between ICD-9 and -10 codes is straightforward and all cancer types are eligible to receive a dose reconstruction from NIOSH. Moreover, notice and comment rulemaking would be impracticable and contrary to the public interest because the rulemaking process may take up to 2 years to complete, resulting in the public not being provided timely information about the updated diagnosis codes as well as a lack of transparency in NIOSH's dose reconstruction process. NIOSH was not notified until January 2019 that OWCP will no longer provide both sets of ICD codes when CMS phases out the general equivalence mapping in September 2019. Thus, there is limited time in which to promulgate this regulation. For similar reasons, HHS has also determined that the need for immediate implementation of the proposed updates to ensure transparency and expediency in the NIOSH dose reconstruction process outweighs the fairness consideration and any need of potential stakeholders to adjust to the use of ICD-10-CM codes. Accordingly, HHS is waiving the prior notice and comment procedures in the interest of regulatory compliance and administrative efficiency.

Under 5 U.S.C. 553(d)(3), HHS finds good cause to make this IFR effective immediately. As stated above, in order to facilitate the complete transition of the Program from ICD-9-CM to ICD-10-CM, it is necessary that HHS act quickly to amend 42 CFR part 81 to allow NIOSH to replace all references to ICD-9-CM codes with ICD-10-CM codes. While amendments to 42 CFR part 81 are effective on the date of publication of

⁴ 45 CFR 162.1002(c)(2).

this IFR, they are interim and a final rule will be published following the receipt and consideration of any substantive public comments.

IV. Technical Review by the Advisory Board on Radiation and Worker Health

EEOICPA requires that HHS obtain a technical review by the Advisory Board on Radiation and Worker Health (the Board) prior to establishing the probability of causation guidelines to be amended through this rulemaking.⁵ HHS interprets this requirement also to apply to any revisions HHS would make to these guidelines. Hence, HHS will obtain a technical review by the Board and consider the findings of this review in promulgating the final regulation.

V. Summary of Interim Final Rule

This interim final rule amends 42 CFR part 81 to allow NIOSH to update references and ICD codes. No substantive changes are being 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).⁶ Therefore, in § 81.4, HHS is revising the reference to “20 CFR 30.5(gg).” In addition, the definition of the term “non-radiogenic cancer” is removed because all cancers are considered radiogenic and there

⁵ 42 U.S.C. 7384n(c).

⁶ 84 FR 3026 (February 8, 2019).

are no longer any non-radiogenic cancers 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. In §§ 81.21(a) and 81.24(a), outdated references to CLL 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.

VI. 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 interim 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 interim 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 No. 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 interim 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.

Interim Final Rule

For the reasons discussed in the preamble, the Department of Health and Human Services 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.

2. Amend § 81.4 as follows:

a. Remove paragraph (l);

b. Redesignate paragraphs (g) through (k) as paragraphs (h) through (l), respectively;

c. Add a new paragraph (g);

d. In paragraph (s), remove the reference “20 CFR 30.5(dd)” and add in its place “20 CFR 30.5(gg)”.

The addition reads as follows:

§ 81.4 Definition of terms used in this part.

* * * * *

(g) *ICD-10-CM* means the International Statistical Classification of Diseases and Related Health Problems, Tenth Revision, Clinical Modification, <https://www.cdc.gov/nchs/icd/icd10cm.htm>.

* * * * *

3. Amend § 81.5 as follows:

a. Add a period at the end of paragraph (a);

- b. Revise paragraph (b); and
- c. Add periods at the ends of paragraphs (c) through (f).

The revision reads as follows:

§ 81.5 Use of personal and medical information.

* * * * *

- (b) Cancer diagnosis (by ICD-10-CM code) for primary and secondary cancers.

* * * * *

- 4. Revise § 81.21 to read as follows:

§ 81.21 Cancers requiring the use of NIOSH-IREP.

- (a) DOL will calculate probability of causation for all cancers using NIOSH-IREP.

(b) Carcinoma in situ (ICD-10-CM codes D00-D09), neoplasms of uncertain behavior (ICD-10-CM codes D37-D44 and D48), and neoplasms of unspecified nature (ICD-10-CM code D49) are assumed to be malignant, for purposes of estimating probability of causation.

(c) All secondary and unspecified cancers of the lymph node (ICD-10-CM codes C77 and C7B.01) shall be considered secondary cancers (cancers resulting from metastasis of cancer from a primary site). For claims identifying cancers of the lymph node, Table 1 in § 81.23(a) provides guidance for assigning a primary site and calculating probability of causation using NIOSH-IREP.

- 5. Amend § 81.23 by revising paragraph (a) to read as follows:

§ 81.23 Guidelines for cancers for which primary site is unknown.

(a) In claims for which the primary cancer site cannot be determined, but a site of metastasis is known, DOL will calculate probability of causation estimates for various likely primary sites. Table 1 of this paragraph (a) indicates the primary cancer site(s) DOL will use in NIOSH-IREP when the primary cancer site is unknown.

TABLE 1 to Paragraph (a)

Primary cancers (ICD-10-CM codes) for which probability of causation is to be calculated, if only a secondary cancer site is known. “M” indicates cancer site should be used for males only, and “F” indicates the cancer site should be used for females only.

| Secondary cancer (ICD-10-CM code) | ICD-10-CM code of likely primary cancers |
|--|--|
| Lymph nodes of head, face and neck (C77.0) | C01, C02, C07(M), C08(M), C09(M), C10(M), C14(F), C32(M), C33, C34, C43, C44, C50(F), C73(F), D03 |
| Intrathoracic lymph nodes (C77.1) | C15(M), C33, C34, C50(F) |
| Intra-abdominal lymph nodes (C77.2) | C15(M), C16(M), C18, C25(F), C33, C34, C50(F), C53(F), C61(M), C64, C65, C66, C68, C82(F), C84(F)(excluding C84.6, C84.7), C85(F), C86(F) (excluding C86.5, C86.6), C91.4(F), C96(F) |
| Lymph nodes of axilla and upper limb (C77.3) | C33, C34, C43, C50(F), D03 |
| Inguinal and lower limb lymph nodes (C77.4) | C19(M), C20(M), C21(M), C33, C34, C43, C44(F), C60(M), C63(M), D03 |
| Intrapelvic lymph nodes (C77.5) | C18(M), C19(F), C20(F), C21(F), C33(M), C34(M), C53(F), C54(F), C61(M), C67 |
| Lymph nodes of multiple sites (C77.8) | C15(M), C16(M), C18(M), C33, C34, C50(F) |
| Lymph nodes, site unspecified (C77.9) | C15(M), C16, C18, C33, C34, C43, C50(F), C61(M), D03 |
| Lung (C78.0) | C18, C33, C34, C43(M), C50(F), C61(M), C67(M), C64, C65, C66, C68, D03(M) |
| Mediastinum (C78.1) | C15(M), C33, C34, C50(F) |
| Pleura (C78.2) | C15(M), C18(M), C33, C34, C50(F), C56(F), C57(F), C61(M), C64(M), C65(M), C66(M), C68(M) |
| Other respiratory organs (C78.3) | C15, C18(M), C32, C33, C34, C44(M), C50(F), C61(M), C73(F) |
| Small intestine, including duodenum (C78.4) | C17, C18, C25, C33, C34, C49, C43(M), C50(F), C56(F), C57(F), C64(M), C65(M), C66(M), C68(M), D03(M) |
| Large intestine and rectum (C78.5) | C18, C19, C20, C21, C33, C34, C50(F), C56(F), C57(F), C61(M) |
| Retroperitoneum and peritoneum (C78.6) | C16, C18, C19(M), C20(M), C21(M), C25, C33(M), C34(M), C49, C50(F), C54(F), C56(F), |

| | |
|---|--|
| | C57(F) |
| Liver, specified as secondary (C78.7) | C16(M), C18, C19(M), C20(M), C21(M), C25, C33, C34, C50(F) |
| Other digestive organs (C78.8) | C15(M), C16, C18, C25, C33, C34, C50(F), C61(M) |
| Kidney (C79.0) | C18, C33, C34, C50(F), C53(F), C61(M), C67, C64, C65, C66, C68, C82(F), C84(F) (excluding C84.6, C84.7), C85(F), C86(F) (excluding C86.5, C86.6), C91.4(F), C96(F) |
| Other urinary organs (C79.1) | C18, C50(F), C53(F), C56(F), C57(F), C61(M), C67, C64(F), C65(F), C66(F), C68(F) |
| Skin (C79.2) | C18, C33, C34, C49(M), C43, C44(M), C50(F), C64(M), C65(M), C66(M), C68(M), D03 |
| Brain and spinal cord (C79.3) | C33, C34, C43(M), C50(F), D03(M) |
| Other parts of nervous system (C79.4) | C33, C34, C43(M), C50(F), C61(M), C82, C84 (excluding C84.6, C84.7), C85, C86 (excluding C86.5, C86.6), C91.4, C96, D03(M) |
| Bone and bone marrow (C79.5) | C33, C34, C50(F), C61(M) |
| Ovary (C79.6) | C18(F), C50(F), C56(F), C57(F) |
| Adrenal gland (C79.7) | C18(F), C33, C34, C50(F) |
| Other specified sites (C79.8) | C18, C33, C34, C43(M), C50(F), C56(F), C57(F), C61(M), C67(M), D03(M) |
| Unspecified sites (C79.9) | C18, C33, C34, C43(M), C50(F), C56(F), C57(F), C61(M), C67(M), D03(M) |
| Carcinoid tumor of distant lymph nodes (C7B.01) | C15(M), C16, C18, C33, C34, C43, C50(F), C61(M), D03 |
| Carcinoid tumor of liver (C7B.02) | C16(M), C18, C19(M), C20(M), C21(M), C25, C33, C34, C50(F) |
| Carcinoid tumor of bone (C7B.03) | C33, C34, C50(F), C61(M) |
| Carcinoid tumor of peritoneum (C7B.04) | C16, C18, C19(M), C20(M), C21(M), C25, C33(M), C34(M), C49, C50(F), C54(F), C56(F), C57(F) |
| Merkel cell carcinoma (C7B.1) | C18, C33, C34, C49(M), C43, C44(M), C50(F), C64(M), C65(M), C66(M), C68(M), D03 |

* * * * *

6. Amend § 81.24 by revising paragraph (a) to read as follows:

§ 81.24 Guidelines for leukemia.

(a) For claims involving leukemia, DOL will calculate one or more probability of causation estimates from up to three of the four alternate leukemia risk models included in NIOSH-IREP, as specified in the NIOSH-IREP Operating Guide. These include: “Leukemia, all types” (ICD-10-CM codes C91-C95), “acute lymphocytic leukemia”

(ICD-10-CM code C91.0), and “acute myelogenous leukemia” (ICD-10-CM codes C92.6 and C92.A).

* * * * *

§ 81.25 [Amended]

7. Amend § 81.25 by redesignating footnote 4 as footnote 3.

Dated: July 25, 2019.

Alex M. Azar II,
Secretary,
Department of Health and Human Services.
[FR Doc. 2019-16347 Filed: 7/31/2019 8:45 am; Publication Date: 8/1/2019]