Dated: May 5, 2022.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 88

[Docket No. CDC–2022–0052; NIOSH–347]

RIN 0920–AA82

World Trade Center (WTC) Health Program; Addition of Uterine Cancer to the List of WTC-Related Health Conditions

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of proposed rulemaking.

SUMMARY: Title I of the James Zadroga 9/11 Health and Compensation Act of 2010 amended the Public Health Service Act (PHS Act) to establish the World Trade Center (WTC) Health Program. The WTC Health Program (Program), which is administered by the Director of the National Institute for Occupational Safety and Health (NIOSH), within CDC, provides medical monitoring and treatment to eligible responders to the September 11, 2001, terrorist attacks in New York City, at the Pentagon, and in Shanksville, Pennsylvania, and to eligible survivors of the New York City attacks. In accordance with the WTC Health Program's regulations, which establish procedures for adding a new condition to the list of health conditions covered by the Program, this proposed rule would add malignant neoplasms of corpus uteri and uterus, part unspecified (uterine cancer) to the List of WTC-Related Health Conditions (List).

DATES: Comments must be received by June 24, 2022.

ADDRESSES: You may submit comments identified by Docket No. CDC–2022–0052 and NIOSH–347 by either of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* NIOSH Docket Office, Robert A. Taft Laboratories, MS C–34, 1090 Tusculum Avenue, Cincinnati, Ohio 45226–1998.

Instructions: All written submissions received in response to this document must include the agency name and docket number (CDC–2022–0052; NIOSH–347) for this action. All relevant comments, including any personal information provided, will be posted without change to *https://www.regulations.gov.* Do not submit comments by email. CDC does not accept comments by email.

FOR FURTHER INFORMATION CONTACT: Rachel Weiss, Program Analyst, National Institute for Occupational Safety and Health, 1090 Tusculum Avenue, MS: C–46, Cincinnati, OH 45226; telephone (855) 818–1629 (this is a toll-free number); email *NIOSHregs@cdc.gov.*

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

A. Purpose of Regulatory Action

With this rulemaking, the Administrator of the WTC Health Program (Administrator) and the Secretary of HHS propose the addition of uterine cancer [1] to the List. The Administrator received requests from WTC responders and survivors as well as a September 2020 letter from five of the WTC Health Program Clinical Centers of Excellence (CCEs) asking the Administrator to add ''uterine cancer'' to the List. The Administrator subsequently directed the WTC Health Program's Science Team to review the available scientific evidence for adding uterine cancer to the List under existing Program policy and procedures. A white paper issued by the Program's Science Team in September 2021 (White Paper) found that the available scientific evidence provided sufficient support to add uterine cancer to the List but only for Program members who have a certified WTC-related estrogen-secreting tumor. The Administrator asked the WTC Health Program Scientific/Technical Advisory Committee (STAC) for a recommendation on whether a reasonable basis exists for adding uterine cancer to the List. Between September and November 2021, the STAC reviewed the White Paper and other available scientific information, considered public comment, and deliberated on whether there is a reasonable basis to recommend the addition of uterine cancer to the List. Ultimately, the STAC recommended that uterine cancer be added to the List and provided the Administrator its recommendation and rationale. Upon review, the Administrator decided that the STAC provided a reasonable basis for its recommendation to add uterine cancer to the List. Based on the STAC's recommendation and the scientific literature, including the White Paper, the Administrator has determined that the available information provides a sufficient evidentiary basis to propose the addition of uterine cancer to the List.

B. Summary of Major Provisions

This rule proposes the addition of malignant neoplasms of corpus uteri and uterus, part unspecified (uterine cancer) to the List of WTC-Related Health Conditions in 42 CFR 88.15(d).

C. Costs and Benefits

The addition of uterine cancer to the List through this rulemaking is estimated to cost the WTC Health Program from $1,718,691 to $2,199,808 annually, between 2022 and 2025. All of the costs to the WTC Health Program are transfers.[2] Benefits to current and future

[1] For the purposes of this action, the WTC Health Program defines the term ''uterine cancer'' as ICD–10 code C54, including the following specific malignant neoplasms: Isthmus uteri (C54.0), endometrium (C54.1), myometrium (C54.2), fundus uteri (C54.3), overlapping sites of corpus uteri (C54.8), and corpus uteri, unspecified (C54.9); and ICD–10 code C55, including only a single sub-category, malignant neoplasm of uterus, part unspecified.

[2] Due to the implementation of the Affordable Care Act in 2014, and as required under the authorizing statute for the WTC Health Program, all current and future Program members are assumed to have or have access to medical insurance

Continued

WTC Health Program members are expected to include improved access to care and better treatment outcomes than members would have in the absence of Program coverage.

II. Public Participation

Interested persons or organizations are invited to participate in this rulemaking by submitting written views, opinions, recommendations, and data. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Comments are invited on any topic related to this proposed rule. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

Comments submitted electronically or by mail should be titled ''Docket No. CDC–2022–0052; NIOSH–347'' and should identify the author(s) and contact information in case clarification is needed. Written comments can be submitted to the address provided in the **ADDRESSES** section, above. All communications received on or before the closing date for comments will be fully considered by the Administrator.

Upon publication of this notice of proposed rulemaking, the Administrator has requested an independent peer review from three subject-matter experts of the scientific and technical evidence that comprises the basis of this action.[3] The peer reviews will be posted, without attribution, in the rulemaking docket 30 days after the publication of this proposed rulemaking.

To provide interested parties adequate time to review the proposed rule, supporting scientific literature, and peer reviews, and to submit written comments to the docket, the Administrator has determined that good cause exists to extend the 30-day comment period required by the Program's authorizing statute[4] to 45 days.

III. Background

In this action, the Administrator and the Secretary of HHS propose to amend 42 CFR 88.15 to add malignant neoplasms of corpus uteri and uterus, part unspecified (uterine cancer)[5] to the List.

A. WTC Health Program Statutory Authority

Title I of the James Zadroga 9/11 Health and Compensation Act of 2010 (Pub. L. 111–347, as amended by Pub. L. 114–113 and Pub. L. 116–59), added Title XXXIII to the PHS Act[6] establishing the WTC Health Program within HHS. The WTC Health Program provides medical monitoring and treatment benefits to eligible firefighters and related personnel, law enforcement officers, and rescue, recovery, and cleanup workers who responded to the September 11, 2001, terrorist attacks in New York City, at the Pentagon, and in Shanksville, Pennsylvania (responders), and to eligible persons who were present in the dust or dust cloud on September 11, 2001 or who worked, resided, or attended school, childcare, or adult daycare in the New York City disaster area (survivors).

All references to the Administrator in this document mean the Director of NIOSH, within CDC, or his or her designee. Section 3312(a)(6) of the PHS Act requires the Administrator to conduct rulemaking to propose the addition of a health condition to the List codified in 42 CFR 88.15.

B. Methods Used by the Administrator To Determine Whether To Add Cancers to the List of WTC-Related Health Conditions

In accordance with the Program's authorizing statute as well as regulations in 42 CFR part 88, the Administrator may decide to propose the addition of a health condition to the List in response to a petition from an interested party[7] or at his or her own discretion.[8] Under 42 CFR 88.16, the Administrator has established a process by which health conditions may be considered for addition to the List in § 88.15. Pursuant to sec. 3312(a)(6)(D) of the PHS Act, whenever the Administrator determines that a condition should be proposed for addition to the List, the Administrator is required to publish a notice of proposed rulemaking and allow interested parties to comment on the proposed rule.

The Program also developed the *Policy and Procedures for Adding Types of Cancer to the List of WTC-Related Health Conditions* (*Policy and Procedures*) to describe the evaluation of evidence of a causal association between 9/11 exposures and a type of cancer. Pursuant to these procedures, a type of cancer may be proposed for addition to the List if the available evidence meets at least one of the following four methods:[9]

Method 1. Epidemiologic Studies of September 11, 2001-Exposed Populations.

The peer-reviewed, published epidemiologic studies of 9/11-exposed populations are assessed by applying the following criteria extrapolated from the Bradford Hill criteria,[10] as appropriate:

a. Strength of the association between a 9/11 exposure and a type of cancer (including the precision of the risk estimate);[11]

b. Consistency of the findings across multiple studies. If only a single published epidemiologic study is available for assessment, the consistency of findings cannot be evaluated, and more emphasis will be placed on evaluating the strength of the association and the precision of the risk estimate;

c. Biological gradient, or dose-response relationships between 9/11 exposures and the type of cancer; and

d. Plausibility and coherence with known facts about the biology of the type of cancer.

Method 2. Established Causal Associations.

A type of cancer may be added to the List if there is well-established scientific support published in multiple peer-reviewed epidemiologic studies for a causal association between a condition already on the List and that cancer.

Method 3. Review of Evaluations of Carcinogenicity in Humans.

A type of cancer may be added to the List under Method 3 only if both of the following criteria are satisfied:

3A. *Published Exposure Assessment Information.* A 9/11 agent[12] included in

coverage other than through the WTC Health Program; therefore, all projected treatment costs to be paid by the WTC Health Program are considered transfers.

[3] *See* Public Health Service Act, sec. 3312(a)(6)(F).

[4] *See* Public Health Service Act, sec. 3312(a)(6)(D)(ii).

[5] *See supra* note 1.

[6] Title XXXIII of the PHS Act is codified at 42 U.S.C. 300mm to 300mm–61. Those portions of the Zadroga Act found in Titles II and III of Public Law 111–347 do not pertain to the WTC Health Program and are codified elsewhere.

[7] PHS Act, sec. 3312(a)(6)(B); 42 CFR 88.16(a).

[8] PHS Act, sec. 3312(a)(6)(A); 42 CFR 88.16(b).

[9] John Howard, Administrator of the WTC Health Program, *Policy and Procedures for Adding Types of Cancer Conditions to the List of WTC-Related Health Conditions,* revised Nov. 18, 2021, *https://www.cdc.gov/wtc/pdfs/policies/WTCHP_PP_Addn_Cancer_11182021-508.pdf.*

[10] *See* Hill AB [1965], *The Environment and Disease: Association or Causation?* Proc R Soc Med 58:295–300.

[11] Precision of the risk estimate describes the uncertainty inherent in estimating the strength of association (the effect size) between exposure and health effect from observational data. It is often expressed as a confidence interval illustrating a range of values that contains the true effect size. A narrow confidence interval indicates a more precise measure of the effect size and a wider interval indicates greater uncertainty.

[12] Chemical, physical, biological, or other hazards reported in a published, peer-reviewed exposure assessment study of responders, recovery workers, or survivors who were present in the New York City disaster area, or at the Pentagon site, or the

the Inventory of 9/11 Agents [13] is identified; and

3B. *Evaluation of Carcinogenicity in Humans from Scientific Studies.* NTP [the National Toxicology Program] has determined that the 9/11 agent is *known to be a human carcinogen* or is *reasonably anticipated to be a human carcinogen,* and the IARC [the World Health Organization's International Agency for Research on Cancer] has determined that there is *sufficient* or *limited* evidence in humans that the 9/11 agent causes the type of cancer.

Method 4. Review of Information by the WTC Health Program Scientific/Technical Advisory Committee (STAC).

A type of cancer may be added to the List if the STAC recommends the addition and provides a reasonable basis for the recommendation.[14] To assist the Administrator in understanding whether the STAC's recommendation has a reasonable basis, the STAC must describe in detail the basis for its recommendation and, if applicable, any evidentiary sources it has used to support its recommendation.

C. History and Scope of Rulemaking

In September 2012, the Administrator published a final rule adding most types of cancer to the List,[15] codified at 42 CFR 88.15(d). The 2012 rulemaking added malignant neoplasm of the ovary (ovarian cancer) to the List pursuant to Method 3, described above; rare cancers were also added to the List pursuant to Method 4. In a follow-up rulemaking conducted in February 2014,[16] the Program clarified the definition of ''rare cancers'' to include any type of cancer that occurs in less than 15 cases per 100,000 persons.[17] As a result of this rulemaking other—but not all—types of malignant neoplasms of female genital organs,[18] including cervix uteri (invasive cervical cancer) and uterine sarcomas, were found to meet the revised definition of rare cancers.[19] Uterine cancer [20] was not added to the List because the scientific evidence available at the time of the 2012 and 2014 rulemakings did not provide sufficient support for its inclusion; nor did it meet the definition of rare cancer.

Since 2012, the WTC Health Program has received eight submissions requesting the addition of endometrial or uterine cancer to the List. Only one of these submissions, Petition 023, received in 2019 and requesting the addition of ''endometrial cancer,'' [21] was determined to be a valid petition.[22] In response, the Program conducted a literature search and identified and evaluated seven published, peer-reviewed, epidemiologic studies about uterine cancer, including endometrial cancer, in the 9/11-exposed population. Ultimately, in 2019, the Administrator determined that the evidence was insufficient to support adding uterine cancer, including endometrial cancer, to the List.[23]

On September 11, 2020, the Administrator received a submission from five of the Program's CCEs, requesting the addition of uterine cancer to the List. Although the Program determined that the submission was not a valid petition, the Administrator thought that it raised important questions about the potential association between endocrine disrupting chemicals (EDCs) and hormone-related tumors such as endometrial cancer. The CCEs noted that the WTC Health Program's scientific literature evaluation conducted for Petition 023 did not include consideration of the relationship between EDCs and uterine cancer, despite some EDCs being included in the *Inventory of 9/11 Agents.*[24] The CCEs argued that research that has emerged since 2012 suggests EDCs may have a role in the development of estrogen-related diseases such as endometrial cancer. Moreover, the CCEs noted the low numbers of female [25] WTC responders in the occupational studies of the health effects of 9/11 exposure and expressed concern that this may lead to gaps in the research.

The Administrator determined that a more thorough evaluation of the scientific information regarding uterine cancer available since 2012 was needed and asked the WTC Health Program Science Team (Science Team) to conduct a review of the available scientific evidence to determine whether it might now support adding uterine cancer to the List. The Science Team conducted a literature review and issued a White Paper (discussed below) documenting its findings in September 2021. The White Paper describes the

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Shanksville, Pennsylvania site, as those locations are defined in 42 CFR 88.1, as well as those hazards not identified in a published, peer-reviewed exposure assessment study, but which are reasonably assumed to have been present at any of the three sites. WTC Health Program, *Development of the Inventory of 9/11 Agents,* published Jul. 17, 2018, *https://wwwn.cdc.gov/ResearchGateway/Content/pdfs/Development_of_the_Inventory_of_9-11_Agents_20180717.pdf.*

[13] The *Inventory of 9/11 Agents* is composed of those agents identified in Tables 1–4 of the document, *Development of the Inventory of 9/11 Agents. Id.*

[14] The STAC may base its recommendation and reasonable basis on criteria other than those outlined in Methods 1–3.

[15] WTC Health Program final rule, *Addition of Certain Types of Cancer to the List of WTC-Related Health Conditions,* 77 FR 56138 (Sept. 12, 2012).

[16] WTC Health Program interim final rule, *Amendments to List of WTC-Related Health Condition; Cancer; Revision,* 79 FR 9100 (Feb. 18, 2014).

[17] A cancer is considered to be on the List if it meets the definition of rare cancers in 42 CFR 88.15(d)(24), which is any type of cancer * that occurs in less than 15 cases per 100,000 persons per year in the United States.

* Based on 2005–2009 average annual data age-adjusted to the 2000 U.S. population. *See* Glenn Copeland, Andrew Lake, Rick Firth, *et al.* (eds), *Cancer in North America: 2005–2009. Volume One: Combined Cancer Incidence for the United States, Canada and North America,* Springfield, IL: North American Association of Central Cancer Registries, Inc., June 2012.

See also the Administrator's *Policy and Procedures for Rare Cancers, https://www.cdc.gov/wtc/pdfs/policies/WTCHP_PP_RareCancers05052014-508.pdf.*

[18] Although the List does not identify health condition medical diagnostic codes, the Program uses ICD–10 codes internally to track certified conditions. Malignant neoplasms of female genital organs comprise ICD–10 codes C51–C58 and include malignant neoplasms of the female genital organs: Vulva (C51), vagina (C52), cervix uteri (C53), corpus uteri (C54), uterus, part unspecified (C55), ovary (C56), other and unspecified female genital organs (C57), and placenta (C58). Uterine sarcomas are included in ICD–10 C55. ICD–10 codes C54 and C55 are not currently considered WTC-related health conditions. World Health Organization (WHO) [1997], *International Classification of Diseases, Tenth Edition.*

[19] *See supra* note 17.

[20] *See supra* note 1.

[21] The endometrium is the layer of tissue that lines the uterus. National Cancer Institute, *Dictionary of Cancer Terms, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/endometrium. Endometrial cancer accounts for nearly 90 percent of uterine cancer cases. See also* American Society of Clinical Oncology [2021], *Uterine Cancer: Statistics, https://www.cancer.net/cancer-types/uterine-cancer/statistics.*

[22] Interested parties may petition the Administrator to add health conditions to the List. To be considered a valid petition, a submission must meet the criteria established in 42 CFR 88.16(a)(1) and further described in the *Policy and Procedures for Handling Submissions and Petitions to Add a Health Condition to the List of WTC-Related Health Conditions, https://www.cdc.gov/wtc/pdfs/policies/WTCHPPPPetitionHandlingProcedures14May2014-508.pdf.*

[23] WTC Health Program **Federal Register** document, *Petition 023-Uterine Cancer, Including Endometrial Cancer; Finding of Insufficient Evidence,* 84 FR 49954 (Sept. 24, 2019).

[24] *Inventory of 9/11 Agents* means those 9/11 agents identified as being present at a 9/11 site and included in Tables 1–4 of the WTC Health Program publication, *Development of the Inventory of 9/11 Agents,* Jul. 17, 2018, *https://wwwn.cdc.gov/ResearchGateway/Content/pdfs/Development_of_the_Inventory_of_9-11_Agents_20180717.pdf.* EDCs in the *Inventory of 9/11 Agents* include persistent organic pollutants and other industrial substances such as cadmium, dioxins, perfluoroalkyl and poly fluoroalkyl substances (PFAS), phthalates, polybrominated diphenyl ethers (PBDE), and polychlorinated biphenyls (PCB). None of these 9/11 agents have been found by NTP or IARC to be known to cause or reasonably anticipated to cause uterine cancer.

[25] Although this rulemaking refers to uterine cancer in females, the WTC Health Program recognizes that some individuals who identify as male may also be at risk for uterine cancer.

Science Team's conclusion that insufficient evidence exists to support a decision to add uterine cancer to the List under Methods 1 or 3 of the *Policy and Procedures* described above; evidence considered under Method 2 supports adding uterine cancer to the List, but only for those Program members who have a certified WTC-related estrogen-secreting tumor.

Pursuant to Method 4 of the *Policy and Procedures,* the Administrator exercised his discretion to request a recommendation from the STAC [26] regarding whether the available evidence provides a reasonable basis exists for adding uterine cancer to the List. The Administrator convened the STAC on September 28–29, 2021, and gave the Committee the following charge:

> As you are aware, the WTC Health Program currently covers all major types of cancer, except for uterine cancer. I welcome the Committee's evaluation and recommendation on whether there is a reasonable scientific basis to support adding uterine cancer to the List of WTC-Related Health Conditions.[27]

At the September 2021 meeting, the Science Team presented the White Paper describing the available scientific evidence for an association between uterine cancer and 9/11 exposures. The STAC heard public comment and deliberated on the evidence presented in the White Paper. The Committee ultimately decided to create a workgroup to ''write a report describing the committee's conclusion, scientific rationale, and supporting evidence for adding uterine cancer as a WTC-related health condition.'' [28] At a follow-up meeting on November 18, 2021, the workgroup presented their draft report to the Committee. Following deliberation, the 12 STAC members present [29] voted unanimously to approve the report and recommend that the Administrator add uterine cancer to the List. Both the White Paper and the STAC recommendation are discussed below.

D. Review of Evidence Supporting the Proposed Addition of Uterine Cancer to the List

1. WTC Health Program Science Team Review

As discussed above, the Administrator asked the Science Team to assess the scientific evidence currently available to determine whether a basis exists under the *Policy and Procedures* for proposing the addition of uterine cancer to the List. The Science Team reported its findings in the White Paper entitled, *Scientific Considerations for Potential Addition of Uterine Cancer to the List of Covered Conditions by the World Trade Center Health Program (Revised): Preliminary Assessment for the World Trade Center Health Program Scientific/Technical Advisory Committee.*[30] The White Paper describes the scope of the Science Team's query as well as the literature search and inclusion criteria, and summarizes the studies identified that describe the available evidence on causal relationships between 9/11 exposures and uterine cancer.

Pursuant to Method 1, the Science Team conducted a literature search in April 2021. As described in the White Paper, the Science Team identified and summarized nine studies: Six which were previously evaluated in the Petition 023 **Federal Register** document,[31] one that recapitulated the results of two of those previously evaluated studies, and two additional studies published since the Petition 023 literature search and evaluation were conducted. Ultimately, five studies were found to be relevant for further evaluation, including some of the earlier studies which have been recently updated by their authors.[32] With regard to Method 1, the Science Team concluded:

> Five relevant peer-reviewed, published, epidemiologic studies were identified and reviewed. The studies do not provide consistent evidence of elevated uterine cancer incidence or mortality among WTC responders and survivors. The studies also do not report a dose-response relationship between 9/11 exposures and uterine cancer and the study designs may be susceptible to selection bias. As a result, collectively, these studies do not demonstrate a potential to provide a basis for a decision on whether to add uterine cancer to the List.[33]

Pursuant to Method 2, the Science Team explored whether a causal association exists between uterine cancer and a health condition already on the List. The Science Team found that uterine cancer may be medically associated with estrogen-secreting tumors, which are considered rare cancers in the Program. Studies reviewed by the Science Team demonstrate support for a causal association between granulosa cell tumors of the ovary (the most common type of estrogen-secreting tumor) and uterine cancer.[34] With regard to Method 2, the Science Team concluded:

> A thorough review of the scientific literature found that estrogen-secreting tumors are associated with endometrial cancer, but that these estrogen-secreting tumors are rare. Because estrogen-secreting tumors fall under the category of ''rare cancers'' in the List, uterine cancer [may be considered a medically associated condition and thus] . . . added to the List only for members who have a certified estrogen-secreting tumor.[35]

Pursuant to Method 3, the Science Team considered the evaluations of carcinogenicity published by NTP and IARC of those EDCs that are 9/11 agents identified in the *Inventory of 9/11 Agents.* With regard to Method 3, the Science Team concluded:

> Four EDCs listed in the Inventory of 9/11 Agents are considered carcinogenic to humans by NTP or IARC: (1) 2,3,7,8-tetrachlorodibenzodioxin (TCDD); (2) 2,3,4,7,8-pentachlorodibenzofuran; (3) polychlorinated biphenyls (PCB); and (4) cadmium. None of these agents is considered to have sufficient or even limited evidence of uterine carcinogenicity [based on IARC's *Monographs*]. Further review of epidemiologic studies published after . . . [IARC's *Monographs*] did not identify additional evidence of carcinogenicity to the uterus.[36]

In addition, since Method 4 allows a cancer to be proposed for addition to the List if the STAC provides a reasonable basis, the Science Team presented

[26] *See* PHS Act, sec. 3312(a)(6)(A).

[27] *Administrator's Charge to the World Trade Center Health Program Scientific/Technical Advisory Committee, https://www.cdc.gov/wtc/pdfs/stac/STAC_AdmCharge_Revised20210928-P.pdf.*

[28] World Trade Center Health Program Scientific/Technical Advisory Committee, *Executive Summary of Meeting, September 28–29, 2021, https://www.cdc.gov/wtc/pdfs/stac/WTCHP_STACmeetingMinutes_20210928-29.pdf.*

[29] Per STAC bylaws, a quorum consists of a majority of the committee's membership. Based on the membership at the time of the meeting, the required number of members for a quorum was nine. Four members were unable to attend the November 18, 2021, meeting, however 12 members were in attendance and quorum was maintained throughout the meeting.

[30] WTC Health Program [2021], *Scientific Considerations for Potential Addition of Uterine Cancer to the List of Covered Conditions by the World Trade Center Health Program (Revised): Preliminary Assessment for the World Trade Center Health Program Scientific/Technical Advisory Committee.* The Science Team's White Paper is available in the docket for this rulemaking and on the WTC Health Program website, at *https://www.cdc.gov/wtc/pdfs/stac/ScientificConsiderationsUterineCancer_STAC_20210928.pdf.*

[31] A seventh study was evaluated in the Petition 023 review but was not considered in the Science Team's evaluation for reasons described in the White Paper, *id.* at 8.

[32] *See* full discussion of the Science Team's literature review and findings regarding Method 1 in the White Paper, *id.* at 8–17.

[33] *Id.* at 6–7.

[34] *See* full discussion of the Science Team's review of the scientific literature and findings regarding Method 2 in the White Paper, *supra* note 30, at 17–18.

[35] *Id.* at 7.

[36] *Id.* at 7.

supplementary evidence that was reviewed but found not to be applicable to Methods 1, 2, or 3 for the STAC's consideration. First, the Science Team described the commonalities between the mechanisms of development for uterine cancer and other types of cancer, including ''estrogen, an abnormal mismatch repair (MMR) system, genetic abnormalities, and aberrant methylation of DNA and microRNA.'' [37] Next, the Science Team presented evidence from studies in non-9/11-exposed populations that demonstrate associations between uterine cancer and the 9/11 agents TCDD, PCBs, cadmium, and asbestos (known EDCs). Additionally, the Science Team noted that most studies of EDC exposure are conducted among occupational cohorts, including few or no women. Finally, the Science Team presented evidence that some EDCs in the *Inventory of 9/11 Agents,* including 2,3,7,8-tetrachlorodibenzodioxin and PCBs, are considered by NTP and IARC to be known or probable human carcinogens associated with types of cancer other than uterine cancer (*e.g.,* melanoma, breast cancer, lymphoma, and leukemia), supporting the inference that some EDC 9/11 agents may also be linked to uterine cancer.

2. WTC Health Program Scientific/Technical Advisory Committee Review

After being presented with the White Paper at the September 28–29, 2021, STAC meeting, the Committee created a workgroup to ''write a report describing the committee's conclusion, scientific rationale, and supporting evidence for adding uterine cancer as a WTC-related health condition.'' [38] Following the deliberation of the full committee at the November 18, 2021, meeting, the STAC voted to recommend that uterine cancer be added to the List. The Chair of the STAC sent a letter with the Committee's formal recommendation and rationale to the Administrator, which he received on November 29, 2021.[39]

The STAC recommendation is grounded in evidence and principles first developed by the STAC in its 2012 recommendation to the Administrator concerning the addition of cancers to the List.[40] The 2021 STAC recommendation quotes the 2012 STAC recommendation, which described those principles as including an understanding that ''exposures resulting from the collapse of the World Trade Center were unlike any other exposures in intensity and variety in history. . . . Compounding the uniqueness of the exposures is the absence of any data on air contaminant levels or the composition of the dust and fumes in the first four days after the attack, and the presence of multiple and complex exposures.'' [41] Further, the STAC found in 2012 that ''both responder populations and area residents and workers had potential for significant exposures to toxic and carcinogenic components of WTC dust and smoke.'' [42]

The STAC also revisited the arguments presented in the 2012 STAC recommendation for the addition of all cancer types, adding that:

> . . . we believe that the arguments for adding all cancers can apply to the question of whether to include all types of uterine cancer. Other than uterine cancer, all cancer types now are covered as WTC-related conditions. Mechanisms for carcinogenesis resulting from endogenous and exogenous exposures are similar for most cancer types. It is therefore highly implausible that uterine cancer would be the *only* cancer not related to WTC exposures.[43]

In fact, in reviewing the literature, the STAC found that uterine cancer ''shares many of the same genetic mechanisms with cancers already included in [the] List of WTC-Related Health Conditions.'' [44] Because exposure to endogenous and exogenous estrogen is strongly associated with both endometrial [45] and breast cancer, the STAC found exposure to EDCs in WTC dust to be ''particularly relevant.'' Noting that the 2012 STAC recommendation did not review evidence supporting an association between EDCs and cancer types, the November 2021 recommendation summarized the STAC's understanding of exposures to EDCs and their possible association with uterine cancer.[46]

The STAC acknowledged that ''[s]tudying the potential health effects of exposure to EDCs is inherently challenging and much remains unknown despite decade[s] of research,'' and quoted a recent review which described EDCs' multiple mechanisms of action, acting ''simultaneously at the level of the receptor, hormone synthesis, and hormone degradation.'' [47]

The STAC noted that the *Inventory of 9/11 Agents* includes certain 9/11 agents which are recognized as EDCs. Specifically, the STAC noted that elevated levels of polychlorinated dibenzo-para-dioxins and polychlorinated dibenzofurans (PCDD/F) were found on window surfaces from locations in lower Manhattan and Brooklyn six weeks after September 11, 2001. Other EDCs were found in WTC dust and smoke samples and in runoff samples from Rector Street on September 14 and 20, 2001. Two biomonitoring studies demonstrated significantly elevated levels of EDCs in 9/11-exposed cohorts: A study of perfluorochemicals in plasma from WTC responders working near Ground Zero between September 11 and December 23, 2001 found levels of perfluorooctanoic acid (PFOA) and perfluorohexanesulfonate (PFHxS) twice as high as in the U.S. general population; and a study comparing 9/11-exposed adolescents to non-9/11-exposed adolescents found that PCDD/F levels were statistically significantly higher among the 9/11-exposed cohort.[48] The STAC found that PBDEs, high levels of which were found in WTC dust, in particular have been shown to ''interfere with estrogen- . . . mediated processes'' and that ''some toxicologic studies provide indirect evidence'' for an association between PBDE exposures and uterine cancer.[49]

The STAC found that EDC exposure-related imbalances in sex steroid hormones are a ''plausible mechanism'' for the development of uterine cancer among WTC responders and survivors. Hormone-related cancers thought to be caused by EDC exposure include thyroid cancer, breast cancer, testicular and prostate cancers, and all female reproductive organ cancers, all of which are included on the List with the exception of uterine cancer.

[37] *Id.* at 27.

[38] WTC Health Program STAC, Executive Summary of Meeting, September 28–29, 2021, *https://www.cdc.gov/wtc/stac_meeting.html,* at 2.

[39] Letter from Dr. Elizabeth Ward, Chair of the STAC, to the Administrator, regarding the STAC's resolution on the addition of uterine cancer to the List of WTCHP Covered Conditions, received November 29, 2021. The letter from Dr. Ward, including the STAC's recommendation is available in the docket for this rulemaking and on the WTC Health Program website, at *https://www.cdc.gov/wtc/pdfs/stac/STAC.Recommendation.Received.29.November.2021.pdf.*

[40] Letter from Dr. Elizabeth Ward, Chair of the STAC, to the Administrator, regarding the STAC's resolution on the addition of cancer to the List of WTC-Related Health Conditions, received Apr. 2, 2012, *https://www.cdc.gov/niosh/docket/archive/pdfs/NIOSH-248/0248-040212-Letter.pdf.*

[41] *Supra* note 39, at 6.

[42] *Id.* at 7.

[43] *Id.* at 2.

[44] *Id.*

[45] In footnote 1 of its recommendation, the STAC clarifies that ''endometrial'' and ''uterine'' cancer are used synonymously and that most of the literature reviewed by the STAC relates specifically to endometrial cancer. The STAC recommendations pertain to all types of uterine cancer, including endometrial cancer.

[46] *See supra* note 39, at Attachment 1.

[47] *Id.* at 8.

[48] *See* full discussion of the STAC's review of the scientific literature and findings in Attachment 1, sec. 2 of the STAC recommendation, *supra* note 39.

[49] *Id.* at 10.

The STAC also commented on the likely inability of existing and future epidemiologic studies in the 9/11-exposed responder population—the most studied 9/11-exposure cohort—to accurately capture uterine cancer incidence because of the small number of female responders. Moreover, the STAC noted that studies of carcinogens reviewed by IARC and other authoritative bodies typically represent industrial cohorts, which often include few or no females, making finding an association between a 9/11 agent and uterine cancer highly unlikely and thus potentially foreclosing Method 3 as a basis for adding uterine cancer to the List.

Finally, the STAC considered public comment as well as the strong support of the WTC Health Program CCEs for the addition of uterine cancer to the List, noting that many Program members and advocates feel the exclusion of uterine cancer from the List is ''illogical and unfair and may cause tangible harm.'' The STAC cited a recent study [50] supporting the argument that WTC responders and survivors diagnosed with uterine cancer will experience better cancer survival if uterine cancer is covered by the Program due to treatment coverage and high-quality care.

After reviewing the available evidence and hearing comment from both the public and the WTC Health Program's CCEs, the STAC concluded that:

> In view of the strong rationale for adding all types of uterine cancer to the list of WTC-related cancers and the potential benefits to affected WTC responders, WTC survivors, and providers caring for these patients, we recommend that all types of uterine cancer be added to the list of WTC-related cancers and urge the Administrator to make all feasible efforts to do so as quickly as policies and procedures allow.[51]

E. Administrator's Decision Regarding Uterine Cancer

After reviewing the available body of scientific evidence describing the causal relationship between 9/11 exposures and uterine cancer, including certain 9/11 agents which are known EDCs, as well as evaluating the STAC's comprehensive rationale and recommendation, the Administrator concludes that the totality of available information provides a sufficient evidentiary basis to propose adding uterine cancer [52] to the List.

In accordance with the Program's *Policy and Procedures,* the Administrator evaluated the available information under the four methods developed for determining whether to add a type of cancer to the List. First, he assessed whether there was sufficient evidence in peer-reviewed, published, epidemiologic studies of 9/11-exposed populations to support adding uterine cancer to the List under Method 1. The Administrator concurs with the Science Team's evaluation of the literature pursuant to Method 1 and finds that the available literature does not provide sufficient support for the addition of uterine cancer to the List under Method 1.

Next, he looked at Method 2 which permits an addition to the List if multiple peer-reviewed epidemiologic studies establish a causal association between a condition already on the List and that cancer. The Administrator agrees with the Science Team's finding that there is evidence of a causal association between estrogen-secreting tumors, which are considered rare cancers in the Program, and uterine cancer. Thus, the Administrator finds that uterine cancer may be proposed for addition to the List pursuant to Method 2, but such an addition would be limited to only those Program members who have a certified WTC-related estrogen-secreting tumor.

The Administrator also examined NTP and IARC evaluations of carcinogenicity under Method 3, which permits an addition to the List if NTP has determined that a specific 9/11 agent is known to be a human carcinogen or is reasonably anticipated to be a human carcinogen, and IARC has determined that there is sufficient or limited evidence in humans that the 9/11 agent causes the type of cancer. The Administrator reviewed the NTP and IARC evaluations of those EDCs that are on the *Inventory on 9/11 Agents* (*i.e.,* TCDD, 2,3,4,7,8-pentachlorodibenzofuran, PCB, and cadmium) and concurs with the Science Team's finding that there is insufficient support for the addition of uterine cancer pursuant to Method 3.

Finally, the Administrator reviewed the recommendation of the STAC to determine if uterine cancer could be added to the List pursuant to Method 4, which permits an addition where the STAC recommends such an addition and provides a reasonable basis for the recommendation. The Administrator finds that the STAC's recommendation provides a reasonable basis for the addition of uterine cancer under Method 4 and this recommendation is further supported by the supplemental information presented by the Science Team in the White Paper.

Specifically, the Administrator agrees with the STAC's finding that mechanisms of initiation and progression of uterine cancer are similar to those for several other cancers on the List.[53] In particular, the evidence showing similar gene mutations and abnormal mismatch repair proteins among many cancers, including uterine cancer, strongly supports shared etiology and pathogenesis between uterine cancer and other cancer types on the List. For example, gene mutations found in low-grade, endometrioid endometrial cancer (which accounts for 80 percent of all endometrial cancers) include those in *PTEN* (phosphatase and tensin homolog deleted on chromosome 10), *CTNNB1* (β-catenin), and *K–RAS. PTEN* inactivation is similarly found in malignant melanoma, brain tumors, and ovarian, thyroid, breast, and prostate cancers, while *CTNNB1* and *K–RAS* mutations are found in a variety of human cancers. High-grade endometrial cancers are associated with mutations in oncogene *ERBB2* (HER–2/neu) and tumor suppressor gene *TP53. ERBB2* gene mutations are also found in breast and ovarian cancers; likewise, *TP53* is frequently mutated in a variety of human cancers, including high-grade serous ovarian and basal-like breast cancers.[54] Finally, studies have shown that several microRNAs (miRNAs), including miR–152 which plays a role as a tumor suppressor, can be epigenetically silenced by hyper-methylation of their respective DNA locus in endometrial cancer.[55] Aberrant methylation of miR–152 has also been reported for other cancers, including acute lymphoblastic leukemia, gastrointestinal cancer, and cholangiocarcinoma. Recent pan-cancer molecular studies [56] have found shared

[50] *See* full discussion of the STAC's review of the scientific literature and findings in Attachment 1, sec. 2 of the STAC recommendation, *supra* note 39.

[51] *Id.* at 5.

[52] ICD–10 codes C54 and C55. *See supra* note 1.

[53] Banno K, Yanokura M, Iida M, Masuda K, Aoki D [2014], *Carcinogenic Mechanisms of Endometrial Cancer: Involvement of Genetics and Epigenetics,* J Obstet Gynaecol Res 40(8):1957–1967; Urick ME and Bell DW [2019], *Clinical Actionability of Molecular Targets in Endometrial Cancer,* Nat Rev Cancer 19, 510–521.

[54] Levine DA and the Cancer Genome Atlas Research Network [2013], *Integrated Genomic Characterization of Endometrial Carcinoma,* Nature 497(7447):67–73.

[55] Favier A, Rocher G, Larsen AK, Delangle R, Uzan C, Sabbah M, Castela M, Duval A, Mehats C, Canlorbe G [2021], *MicroRNA as Epigenetic Modifiers in Endometrial Cancer: A Systematic Review,* Cancers (Basel) 6;13(5):1137.

[56] Pan-cancer molecular studies examine the similarities and differences among the genomic and cellular alterations found across diverse tumor types. Weinstein JN, Collisson EA, Mills GB, Mills Shaw KR, Ozenberger BA, Ellrott K, Shmulevich I, Sander C, Stuart JM [2013]. *The Cancer Genome*

molecular features among invasive breast carcinoma and several gynecologic tumors, such as high-grade serous ovarian cystadenocarcinoma, uterine corpus endometrial carcinoma, cervical squamous cell carcinoma and endocervical adenocarcinoma, and uterine carcinosarcoma.[57] The Administrator agrees with the STAC's finding that the shared etiology and pathogenesis described in the scientific literature suggest it would be unlikely that uterine cancer would be the only cancer type not related to 9/11 exposures.

The Administrator also finds that an association between exposure to EDCs in WTC dust and uterine cancer risk is plausible. EDCs can mimic endogenous hormones and interfere with endogenous hormone homeostasis, which may lead to a variety of adverse health outcomes, including cancer (*e.g.,* estrogen imbalances are a key risk factor for uterine cancer). There is extensive evidence from human studies of an etiologic role of estrogens in cancer. However, finding a causal association between an EDC 9/11 agent and uterine cancer is highly unlikely given the potentially long latency between exposure and disease. Moreover, the low number of women included in epidemiologic studies examining EDC carcinogenic risks in occupational cohorts increases the difficulty in finding conclusive evidence of a causal association with uterine cancer. Given the growing body of scientific evidence suggesting that exposure to EDCs may be a risk factor for female reproductive organ cancers (*e.g.,* breast, ovarian, and endometrial cancers), it is reasonable to assume that exposure to EDCs in WTC dust may contribute to uterine cancer risk.

Finally, the Administrator recognizes that the disproportionally low representation of women in the most studied cohorts of exposed responders makes it epidemiologically unlikely that a definitive association between 9/11 exposures and the occurrence of uterine cancer will be identified during the lifetime of even the most highly exposed Program members.

The Administrator has determined that the available scientific evidence and rationale provided by the STAC in its recommendation, supported by the supplemental information presented by the Science Team in the White Paper, offers a plausible rationale for an association between uterine cancer and EDCs in the *Inventory of 9/11 Agents.* Moreover, the cohorts relevant to understanding uterine cancer in the 9/11-exposed population are too small to allow a definitive decision about whether uterine cancer is causally associated with 9/11 exposure. For these reasons, the Administrator finds that a reasonable basis has been provided by the STAC under Method 4 and, accordingly, proposes to add uterine cancer to the List of WTC-Related Health Conditions.

IV. Summary of Proposed Rule

For the reasons discussed above, the Administrator proposes to amend 42 CFR 88.15 by adding a new paragraph (d)(15) to include malignant neoplasms of corpus uteri and uterus, part unspecified [58] on the List of WTC-Related Health Conditions. The existing paragraph (d)(15)—malignant neoplasm of the ovary—and the remainder of the cancer types identified in existing paragraphs (d)(16) through (24)—rare cancers—are renumbered paragraphs (d)(16) through (25), accordingly. Adding uterine cancer to the List would allow the WTC Health Program to offer treatment services to members whose uterine cancers are certified as WTC-related.

V. Required Regulatory Analyses

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

Executive Orders (E.O.) 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, reducing costs, harmonizing rules, and promoting flexibility.

This proposed rule has been determined not to be a significant regulatory action under sec. 3(f) of E.O. 12866, and therefore has not been reviewed by the Office of Management and Budget (OMB). The addition of uterine cancer proposed by this rulemaking is estimated to cost the WTC Health Program between $1,718,691 and $2,199,808 per annum for 2022–2025.[59] All costs to the WTC Health Program will be transfers due to the implementation of provisions of the Patient Protection and Affordable Care Act (Pub. L. 111–148) in 2014 and as required under the authorizing statute for the WTC Health Program.[60] The rule would not interfere with state, local, or tribal governments in the exercise of their governmental functions.

Population Estimates

The WTC Health Program has, as of September 30, 2021, enrolled approximately 82,000 WTC responders and approximately 32,000 survivors, or approximately 114,000 individuals in total. Of that total population, approximately 60,000 individuals were participants in previous WTC medical programs and were enrolled as ''Legacy'' members in the WTC Health Program established by Title XXXIII of the PHS Act. For the purpose of calculating a baseline estimate of cancer prevalence only, the Administrator assumed that a steady rate of enrollment would continue, based on the trend in enrollees through September 2021.

According to WTC Health Program data, 12 percent of the current responder members (approximately 10,000 individuals) and 50 percent of survivor members (approximately 16,000 individuals) are female.[61] The Administrator acknowledges that some uterine cancer cases in this population may not have been caused by 9/11 exposures. The certification of individual cancer diagnoses will be conducted on a case-by-case basis, as required by the Zadroga Act. For the purpose of this economic analysis, however, the Administrator assumes that all diagnosed uterine cancers will be certified for treatment by the WTC Health Program. Finally, because there are no existing data on cancer rates related to 9/11 exposures at either the Pentagon or in Shanksville, Pennsylvania, the Administrator has

Atlas Pan-Cancer analysis project, Nature Genetics. 45 (10): 1113–1120.

[57] Berger AC *et al.* [2018], A *Comprehensive Pan-Cancer Molecular Study of Gynecologic and Breast Cancers,* Cancer Cell 33(4):690–705.

[58] *See supra* note 1.

[59] As discussed in this section, NIOSH estimated lower and upper bound estimates to reflect the uncertainty in the Agency's ability to predict the expected number of cancer cases in three years after this rulemaking. The low bound reflects the general U.S. population cancer rate and uses undiscounted costs for 2022 and costs for 2023–2025 discounted at the 7% discount rate. The upper bound reflects the U.S. population cancer rate + 21%, based on a study by Li *et al.* [2021], *infra* note 69, and uses undiscounted rates for 2022 and costs for 2023–2025 discounted at the 3% discount rate. Although, if added to the List, uterine cancer would be considered a covered condition for the duration of the WTC Health Program (currently authorized through FY 2090), the dates 2022–2025 were chosen in order to provide a snapshot of uterine cancer costs in the coming years.

[60] Because sec. 3331(c)(3) of the PHS Act requires WTC Health Program members to maintain minimum essential insurance coverage all treatment costs to be paid by the WTC Health Program are considered transfers.

[61] *See supra* note 25.

used only data from studies of individuals who were responders or survivors in the New York City disaster area.

Cost of Uterine Cancer Treatment

The Administrator estimated the treatment costs associated with covering uterine cancer in this rulemaking. The costs of treatment are divided into three treatment phases: The first year of treatment following diagnosis; the intervening years or continuing treatment after the first year; and treatment during the last year of life. The first-year costs of cancer treatment are higher due to the initial need for aggressive medical care (*e.g.,* radiation or chemotherapy) and surgical care. The costs during the last year of life are often dominated by increased hospitalization costs.[62] Therefore, three different treatment phase costs were used to provide a best estimate of treatment costs in conjunction with expected incidence and long-term survival rates for uterine cancer. Average treatment costs for uterine cancer are in Table A, below.

TABLE A—AVERAGE COSTS OF TREATMENT FOR UTERINE CANCER, 2021$

Stage of treatment:	
Initial (first 12 months after diagnosis)	$39,638
Continuing (annual)	2,066
Last year of life (last 12 months of life)	118,058

These cost figures were based on a study of cancer patients from the Surveillance, Epidemiology, and End Results (SEER) program maintained by the National Cancer Institute and using Medicare files.[63] The average costs of treatment described above are given in 2021 prices adjusted using the Medical Consumer Price Index for all urban consumers.[64]

Incident Cases of Cancer

The Administrator estimated the expected number of cases of cancer that would be observed in a cohort of responders and survivors followed for cancer incidence after September 11, 2001, using U.S. population cancer rates. Demographic characteristics of the cohort were assigned since the actual data are not available for individuals in the responder and survivor populations who have not yet enrolled in the WTC Health Program. Sex and age (at the time of exposure) distributions for responders and survivors were assumed to be the same as current members in the WTC Health Program. Because uterine cancer occurs only in females,[65] all calculations only consider female WTC Health Program members.

The Administrator assumed race and ethnic origin distributions for responders and survivors, respectively, according to distributions in the WTC Health Registry cohort: [66] 57 percent non-Hispanic white, 15 percent non-Hispanic black, 21 percent Hispanic, and 8 percent other race/ethnicity for responders; 50 percent non-Hispanic white, 17 percent non-Hispanic black, 15 percent Hispanic, and 18 percent other race/ethnicity for survivors. Registry follow-up for cancer morbidity for each person began on January 1, 2002, or age 15 years, whichever was later. Age 15 was considered because the cancer incidence rate file did not include rates for persons less than 15 years of age. Follow-up ended on December 31, 2016, or the estimated last year of life, whichever was earlier. The estimated last year of life was used since not all persons would be expected to remain alive at the end of 2016. The estimated last year of life was based on U.S. gender, race, age, and year-specific death rates from CDC WONDER.[67] A life-table analysis program, LTAS.NET, was used to estimate the expected number of incident cancers for uterine cancer.[68] The Administrator calculated cancer incidence rates using data through 2018 from the SEER Program and estimated rates for 2002–2025.[69] The Program applied the resulting gender, race, age, and year-specific cancer incidence rates to the estimated person-years at risk to estimate the expected number of cancer cases for uterine cancer starting from year 2002, the first full year following the September 11, 2001, terrorist attacks, to 2025.

Prevalence of Cancer

To determine the potential number of persons in the responder and survivor populations with cancer, the Administrator used the number of incident uterine cancer cases described above for each year starting with 2002 and estimated the prevalence of uterine cancer using survival rate statistics for each incident cancer group through 2025.[70] Using the incident cases and survival rate statistics, the Administrator estimated the prevalence (number of persons living with cancer) of cases during the 23-year period (2002–2025) since September 11, 2001. For the purposes of illustrating an upper bound incidence rate and prevalence estimate, the Administrator assumed that the rate of cancer in the WTC Health Program exceeds the general U.S. population rate by 21 percent due to 9/11 exposures. The peer-reviewed literature supports the use of a 21 percent excess risk of cancer in the 9/11-exposed population over the U.S. population cancer rate; a 2021 study by Li *et al.*[71] reported an adjusted hazard ratio of 1.21 (95 percent CI: 1.12, 1.31) for all cancer sites and used a within-cohort comparison less affected by healthy worker selection bias. The resulting Table B summarizes those results for each year from 2022 through 2025, the number of new cases occurring in that year (incidence), the number of persons surviving up to 23 years beyond their first diagnosis (prevalence), and the number of individuals who might be expected to die from their cancer in that year.[72]

[62] Yabroff KR, Lamont EB, Mariotto A, Warren JL, Topor M, Meekins A, Brown ML [2008], *Cost of Care for Elderly Cancer Patients in the United States,* J Natl Cancer Inst 100(9):630–41.

[63] Surveillance, Epidemiology, and End Results (SEER) Program (*www.seer.cancer.gov*) SEER*Stat Database: Incidence—SEER 9 Regs Research Data, Nov 2020 Sub (1975–2018), National Cancer Institute, DCCPS, Surveillance Research Program, Surveillance Systems Branch, released Apr. 2021, based on the Nov. 2020 submission. Although patients who are Medicare members are age 65 and older, cancer treatment costs are not expected to vary with age.

[64] Bureau of Labor Statistics, *Consumer Price Index, https://fred.stlouisfed.org.* Accessed on Apr. 28, 2021.

[65] *See supra* note 25.

[66] Jordan HT, Brackbill RM, Cone JE, Debchoudhury I, Farfel MR, Greene CM, Hadler JL, Kennedy J, Li J, Liff J, Stayner L, Stellman SD [2011], *Mortality Among Survivors of the Sept 11, 2001, Word Trade Center Disaster: Results from the World Trade Center Health Registry Cohort,* Lancet 378:879–887. Note: percentages may not sum to 100 percent due to rounding.

[67] Centers for Disease Control and Prevention, National Center for Health Statistics, Compressed Mortality File 1999–2016 on CDC WONDER Online Database, released June 2017. Data are from the Compressed Mortality File 1999–2016 Series 20 No. 2U, 2016, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program. *http://wonder.cdc.gov/cmf-icd10.html.* Accessed May 29, 2021.

[68] Schubauer-Berigan MK, Hein MJ, Raudabaugh WM, Ruder AM, Silver SR, Spaeth S, Steenland K, Petersen MR, and Waters KM [2011], *Update of the NIOSH Life Table Analysis System: A Person-Years Analysis program for the Windows Computing Environment,* Am J Ind Med 54:915–924.

[69] *See supra* note 62.

[70] *Id.*

[71] Li J, Yung J, Qiao B, Takemoto E, Goldfarb DG, Zeig-Owens R, Cone JE, Brackbill RM, Farfel MR, Kahn AR, Schymura MJ, Shapiro MZ, Dasaro CR, Todd AC, Kristjansson D, Prezant DJ, Boffetta P, Hall CB [2021], *Cancer Incidence in World Trade Center Rescue and Recovery Workers: 14 Years of Follow-Up,* J Natl Cancer Inst *https://doi.org/10.1093/jnci/djab165.*

[72] The 23-year survival limit is imposed based on the analytic time horizon.

TABLE B—ESTIMATED INCIDENCE AND PREVALENCE OF UTERINE CANCER
[2022–2025]

	2022	2023	2024	2025
Responders (based on ~10,000 female members)				
New cases	6.69	6.92	7.14	7.27
Live cases from previous years	29.46	30.78	32.09	33.33
Deaths	5.09	5.37	5.61	5.90
Total cases	36.15	37.70	39.23	40.60
Survivors (based on ~16,000 female members)				
New cases	10.91	10.91	10.91	10.91
Live cases from previous years	53.70	54.72	55.49	56.17
Deaths	9.60	9.90	10.17	10.31
Total cases	64.61	65.63	66.40	67.08
Total (based on ~26,000 female WTC responder and survivor members)				
New cases	17.6	17.83	18.05	18.18
Live cases from previous years	83.16	85.50	87.58	89.50
Deaths	14.69	15.27	15.78	16.21
Total cases	100.76	103.33	105.63	107.68

Cost Computation

To compute the costs for uterine cancer, the Administrator assumes that the individuals diagnosed with uterine cancer will be certified by the WTC Health Program for treatment and monitoring services. The treatment costs for the first year of treatment (Table A, year adjusted) were applied to the predicted newly incident (Year 1) cases for each year. Likewise, the costs of treatment for the last year of life were applied in each year to the number of people predicted to die from their cancer in that year. The costs of continuing treatment from Table A were applied to the number of prevalent cases who had survived their cancers beyond their year of diagnosis, for each year of survival (Year 2–23).

The estimated treatment costs for responders and survivors were re-computed under the following two assumptions: (1) The rate of cancer in the WTC Health Program is equal to the rate of cancer observed in the general U.S. population; and (2) the rate of cancer in the WTC Health Program exceeds the general U.S. population rate by 21 percent, as discussed above. Costs for future years are discounted at both 7 percent and 3 percent to reflect net present value.[73]

The sum of the annual costs in the table for the years 2022 through 2025 represents the estimated treatment costs to the WTC Health Program for coverage of uterine cancer for the 12 percent of approximately 82,000 WTC responders who are female and the 50 percent of approximately 32,000 WTC survivors who are female.

Summary of Costs

Because HHS lacks data to account for recoupment from workers' compensation insurance or primary payment by either private health insurance or Medicare/Medicaid payments, the estimates offered here are reflective of estimated WTC Health Program costs only and assume the Program is the primary payer. This analysis offers an assumption about the number of individuals who might enroll in the WTC Health Program and estimates the impact of both a low rate of cancer (U.S. population average rate) and an increased rate (21 percent greater than the U.S. population average) on the number of cases and the resulting estimated treatment costs to the WTC Health Program. This analysis does not include administrative costs associated with certifying additional WTC-related uterine cancers that might result from this action.

Since the implementation of provisions of the Affordable Care Act on January 1, 2014, all members and future members are assumed to have or have access to medical insurance coverage other than through the WTC Health Program.[74] Therefore, all treatment costs to be paid by the WTC Health Program from 2022 through 2025 are considered transfers.

TABLE C—MEDICAL TREATMENT COST FOR UTERINE CANCER CASES DURING 2022–2025, 2021$

	2022 costs, undiscounted, 2021$		2023–2025 costs,* 7% discount rate	2023–2025 costs, 3% discount rate
	Cancer rate		Cancer rate	
	U.S. average	U.S. average + 21%	U.S. average	U.S. average + 21%
Responders	$749,741	$907,187	$2,145,844	$2,801,474

[73] *See* OMB Circular A–94, *Guidelines and Discount Rates for Benefit-Cost Analysis of Federal Programs. https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A94/a094.pdf.*

[74] Sec. 3331(c)(3) of the PHS Act requires WTC Health Program members to maintain minimum essential insurance coverage.

TABLE C—MEDICAL TREATMENT COST FOR UTERINE CANCER CASES DURING 2022–2025, 2021$—Continued

Survivors	1,067,098	1,291,189	2,912,084	3,799,381
Total	1,816,839	2,198,376	5,057,928	6,600,855

* Since this table summarizes the lowest and highest cost estimates for treatment of uterine cancer, values representing 2023–2025 costs at the 7% discount rate and at the increased cancer rate and 2023–2025 costs at the 3% discount rate and at the U.S. population average rate were not included.

The Administrator found the cost estimate range by adding the low 2023–2025 estimate in Table C (7 percent discount rate, U.S. cancer rate average) and the low estimate for 2022 (U.S. cancer rate average) and dividing the sum by four to find the annual low-cost estimate (*i.e.,* $1,718,691). The same calculation was done for the annual high-cost estimates, adding the higher numbers in Table C (3 percent discount rate, U.S. cancer rate average +21 percent) to the high estimate for 2022 (U.S. cancer rate average +21 percent) and dividing the sum by four (*i.e.,* $2,199,808).

Examination of Benefits (Health Impact)

This section qualitatively describes the potential benefits of this rulemaking to add uterine cancer to the List of WTC-Related Health Conditions in terms of the expected improvements in the health and health-related quality of life of potential uterine cancer patients treated through the WTC Health Program, compared to not conducting the rulemaking.

The Administrator does not have information on the health of the population that may have experienced 9/11 exposures and is not currently enrolled in the WTC Health Program. In addition, the Administrator has only limited information about health insurance and healthcare services for uterine cancers potentially caused by 9/11 exposures and suffered by any population of responders and survivors, including responders and survivors currently enrolled in the WTC Health Program and responders and survivors not enrolled in the Program. For the purposes of this analysis, the Administrator assumes that all unenrolled responders and survivors are now covered by health insurance due to access provided by the Affordable Care Act and may be receiving treatment outside the WTC Health Program.

Although the Administrator cannot quantify the benefits associated with the WTC Health Program, members with uterine cancer are expected to experience better treatment outcomes as Program members than non-members. A recent study found that ''WTC-exposed responder cancer patients enrolled in the MMTP [WTC Medical Monitoring and Treatment Program, a predecessor to the WTC Health Program] had higher survival rates compared with those not enrolled in the MMTP.'' [75] Moreover, under other insurance plans, patients would have deductibles and copays, which impact access to care and, particularly, its timeliness.[76] WTC Health Program members have first-dollar coverage and hence are likely to seek care sooner, when indicated, resulting in improved treatment outcomes.

Finally, during public meetings, Program members have expressed that the lack of social and clinical support, and lack of recognition that their diagnosed uterine cancer is a WTC-related health condition, have had a significant negative impact on their morale and quality of life.

Limitations

The analysis presented here was limited by the dearth of verifiable data on the uterine cancer status of responders and survivors who have yet to apply for enrollment in the WTC Health Program. Because of the limited data, the Administrator was not able to estimate benefits in terms of averted healthcare costs; nor was the Administrator able to estimate administrative costs, or indirect costs, such as averted absenteeism, short- and long-term disability, and productivity losses averted due to premature mortality.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), 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 Administrator certifies that this proposed rule has ''no significant economic impact upon a substantial number of small entities'' within the meaning of the RFA.

C. Paperwork Reduction Act

The Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* requires an agency to invite public comment on, and to obtain OMB approval of, any regulation that requires 10 or more people to report information to the agency or to keep certain records. The Administrator has determined that this rulemaking does not contain any new information collection requirements or recordkeeping requirements; thus, the PRA does not apply to this rulemaking. Data collection and recordkeeping requirements for the WTC Health Program are approved by OMB under ''World Trade Center Health Program Enrollment, Appeals & Reimbursement'' (OMB Control No. 0920–0891, exp. December 31, 2021, currently under OMB review).

D. 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.,* HHS will report the promulgation of this rule to Congress prior to its effective date.

E. 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 proposed rule does not include any Federal mandate that may result in increased annual expenditures in excess of $100 million in 1995 dollars by state, local, or tribal governments in the aggregate, or by the private sector.

F. Executive Order 12988 (Civil Justice)

This proposed 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

[75] Goldfarb DG, Zeig-Owens R, Kristjansson D, Li J, Brackbill RM, Farfel MR, Cone JE, Kahn AR, Qiao B, Schymura MJ, Webber MP, Dasaro CR, Lucchini RG, Todd AC, Prezant DJ, Hall CB, Boffetta P [2021], *Cancer Survival among World Trade Center Rescue and Recovery Workers: A Collaborative Cohort Study,* Am J Ind Med 64(10):815–826.

[76] Wharam JF, Galbraith AA, Kleinman KP, Soumerai SB, Ross-Degnan D, Landon BE [2008], *Cancer Screening before and after Switching to a High-Deductible Health Plan,* Ann Intern Med 148(9):647–655.

been reviewed carefully to eliminate drafting errors and ambiguities.

G. Executive Order 13132 (Federalism)

The Administrator has reviewed this proposed 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.''

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

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

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

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

J. 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. The Administrator has attempted to use plain language in promulgating the proposed rule consistent with the Federal Plain Writing Act guidelines and requests public comment on this effort.

List of Subjects in 42 CFR Part 88

Aerodigestive disorders, Appeal procedures, Cancer, Healthcare, Mental health conditions, Musculoskeletal disorders, Respiratory and pulmonary diseases.

For the reasons discussed in the preamble, the Administrator and HHS Secretary propose to amend 42 CFR part 88 as follows:

PART 88—WORLD TRADE CENTER HEALTH PROGRAM

■ 1. The authority citation for part 88 is revised to read as follows:

Authority: 42 U.S.C. 300mm to 300mm–61.

■ 2. Amend § 88.15 as follows:
■ a. Redesignate paragraphs (d)(15) through (24) as paragraphs (d)(16) through (25).
■ b. Add new paragraph (d)(15).
■ c. In newly redesignated paragraph (d)(24), remove ''*Childhood cancers:*'' and add ''Childhood cancers:'' in its place.
■ d. In newly redesignated paragraph (d)(25), remove ''*Rare cancers:*'' and add ''Rare cancers:'' in its place.

The addition reads as follows:

§ 88.15 List of WTC-Related Health Conditions.

* * * * *

(d) * * *

(15) Malignant neoplasms of corpus uteri and uterus, part unspecified.

* * * * *

John J. Howard,

Administrator, World Trade Center Health Program and Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Department of Health and Human Services.

Xavier Becerra,

Secretary, Department of Health and Human Services.

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FEDERAL MARITIME COMMISSION

46 CFR Part 520

[Docket No. 21–03]

RIN 3072–AC86

Carrier Automated Tariffs

AGENCY: Federal Maritime Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Federal Maritime Commission (Commission) is seeking public comment on proposed modifications to its rules governing Carrier Automated Tariffs through this notice of proposed rulemaking (NPRM). The proposed rule would remove the option for ocean common carriers to charge a fee to access their tariff; allow non-vessel operating common carriers (NVOCCs) to cross reference certain aspects of other carriers' terms in their tariffs; clarify the ability for NVOCCs to reflect increases in certain charges passed-through by other entities without notice; update the definition of co-loading to apply only to less than container loads; require that documentation be annotated with the names of all NVOCCs involved in a shipping transaction; and make other miscellaneous updates and clarifications to the regulation.

DATES: Submit comments on or before June 9, 2022.

ADDRESSES: You may submit comments by email to *secretary@fmc.gov.* For comments, include in the subject line: ''Docket No. 21–03, Comments on Carrier Automated Tariffs Rulemaking.'' Comments should be attached to the email as a Microsoft Word or text-searchable PDF document.

Instructions: For detailed instructions on submitting comments, including requesting confidential treatment of comments, and additional information on the rulemaking process, see the Public Participation heading of the Supplementary Information section of this document. Note that all comments received will be posted without change to the Commission's website unless the commenter has requested confidential treatment.

Docket: For access to the docket to read background documents or comments received, go to the Commission's Electronic Reading Room at: *https://www2.fmc.gov/readingroom/proceeding/21-03/.*

FOR FURTHER INFORMATION CONTACT: William Cody, Secretary; Phone: (202) 523–5725; Email: *secretary@fmc.gov.*

SUPPLEMENTARY INFORMATION:

I. Discussion

On April 8, 2021, the Commission issued an Advance Notice of Proposed Rulemaking (ANPRM) seeking information on how common carriers interpret and apply certain Commission regulations in 46 CFR part 520.[1] In response to the ANPRM, the Commission received three sets of comments from interested parties: The National Customs Brokers and Forwarders Association of America, Inc (NCBFAA); New York New Jersey Foreign Freight Forwarders & Brokers Association, Inc. (NYNJFFF&BA); and the Association of Food Industries, Inc. (AFI). NCBFAA and NYNJFFF&BA are trade associations whose members include non-vessel operating common carriers (NVOCCs), and AFI is a trade association for the U.S. food import industry. These comments are addressed later in this proposed rule.

A. Tariff Access Fees

Before the passage of the Ocean Shipping Reform Act of 1998 (OSRA), which became effective May 1, 1999, vessel operating common carrier (VOCC) and conference tariffs were filed

[1] Advance notice of proposed rulemaking—Carrier Automated Tariffs, 86 FR 18240 (April 8, 2021).