



Billing Code: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. CDC-2014-0004; NIOSH-268]

42 CFR Part 88

RIN 0920-AA50

World Trade Center Health Program; Amendments to List of WTC-Related Health Conditions; Cancer; Revision

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

ACTION: Interim final rule.

SUMMARY: On September 12, 2012, the Administrator of the WTC Health Program (Administrator) published a final rule in the **Federal Register** adding certain types of cancer to the List of World Trade Center (WTC)-Related Health Conditions (List) in the WTC Health Program regulations; an additional final rule was published on September 19, 2013 adding prostate cancer to the List. Through the process of implementing the addition of cancers to the List and integrating cancer coverage into the WTC Health Program, the Administrator has identified the need to amend the rule to remove the ICD codes and specific cancer sub-sites, clarify the definition of "childhood cancers," revise the definition of "rare cancers," and notify stakeholders that the Administrator is revising WTC Health Program policy

related to coverage of cancers of the brain and the pancreas. No types of cancer covered by the WTC Health Program will be removed by this action; four types of cancer -- malignant neoplasms of the brain, the cervix uteri, the pancreas, and the testis -- are newly eligible for certification as WTC-related health conditions as a result of this action.

DATES: This interim final rule will be effective [INSERT DATE OF PUBLICATION IN THE **FEDERAL REGISTER**]. The Administrator invites written comments from interested parties on this interim final rule. Comments must be received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**].

ADDRESSES: Written Comments: You may submit comments by any of the following methods:

- Federal eRulemaking Portal:
<http://www.regulations.gov>. Follow the instructions for submitting comments.
- Mail: NIOSH Docket Office, Robert A. Taft Laboratories, MS-C34, 4676 Columbia Parkway, Cincinnati, OH 45226.

Instructions: All submissions received must include the agency name (Centers for Disease Control and Prevention, HHS) and docket number (CDC-2014-0004; NIOSH-268) or Regulation Identifier Number (0920-AA50) for this rulemaking. All relevant comments, including any personal information provided, will be posted without change to <http://www.regulations.gov>. For detailed instructions on submitting public comments, see the "Public Participation" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents, go to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Paul Middendorf, Senior Health Scientist, 1600 Clifton Rd. NE, MS: E-20, Atlanta, GA 30329; telephone (404) 498-2500 (this is not a toll-free number); email pmiddendorf@cdc.gov.

SUPPLEMENTARY INFORMATION:

This rule is organized as follows:

- I. Executive Summary
 - A. Purpose of Regulatory Action
 - B. Summary of Major Provisions
 - C. Costs and Benefits
- II. Public Participation
- III. Background
 - A. WTC Health Program Statutory Authority

- B. Rulemaking History
- C. Need for Rulemaking
 - 1. Table 1
 - 2. Childhood Cancers
 - 3. Rare Cancers
 - 4. Cancers of the Brain and the Pancreas
- IV. Rare Cancers
 - A. STAC Recommendation
 - B. WTC Health Program Rare Cancers Definition and Numeric Threshold Determination
 - 1. Rare Cancers Numeric Threshold
 - 2. Application of Rare Cancers Numeric Threshold
- V. Cancers of the Brain and the Pancreas
 - A. STAC Recommendation
 - B. WTC Health Program Determination
- VI. Effects of Rulemaking on Federal Agencies
- VII. Issuance of an Interim Final Rule with Immediate Effective Date
- VIII. Summary of Interim Final Rule
- IX. Regulatory Assessment Requirements
 - A. Executive Order 12866 and Executive Order 13563
 - B. Regulatory Flexibility Act
 - C. Paperwork Reduction Act
 - D. Small Business Regulatory Enforcement Fairness Act
 - E. Unfunded Mandates Reform Act of 1995
 - F. Executive Order 12988 (Civil Justice)
 - G. Executive Order 13132 (Federalism)
 - H. Executive Order 13045 (Protection of Children from Environmental Health Risks and Safety Risks)
 - I. Executive Order 13211 (Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use)
 - J. Plain Writing Act of 2010

I. Executive Summary

A. Purpose of Regulatory Action

The purpose of this action is to amend regulatory

language added to 42 CFR 88.1 in paragraph (4) of the definition of "List of WTC-related health conditions" by the final rule published in the **Federal Register** on September 12, 2012 (77 FR 56138) and announce a revision to the Administrator's decision to exclude certain types of cancer from WTC Health Program coverage. The Administrator has found that a detailed list of sub-codes unnecessarily constrains the WTC Health Program's ability to appropriately identify which members' cancers are eligible for certification. The Administrator has also identified the need to clarify that childhood cancers are cancers that are first diagnosed in a person under the age of 20 years. The current definition does not clearly indicate that the Administrator has always intended to certify cases of cancer in WTC Program members who were under the age of 20 when they were first diagnosed, even though they may be over the age of 20 when they enter the WTC Health Program. Finally, the Administrator has also identified problems with the definition of "rare cancers" established in §88.1.¹ In application, the definition has proven confusing and imprecise, reflecting neither the intent of the Administrator nor the concern of the WTC Health Program

¹ Rare cancers were defined in Table 1 as, "Any type of cancer affecting the [sic] populations smaller than 200,000 individuals in the Unites [sic] States, i.e., occurring at an incidence rate less than 0.08 percent of the U.S. population. Rare cancers will be determined on a case-by-case basis."

Scientific/Technical Advisory Committee (STAC) that led the STAC to recommend adding such a category of cancers.

In addition, the Administrator has found it appropriate to reconsider and reverse the WTC Health Program policy to deny certification of cases of malignant neoplasms of the brain (brain cancer) and the pancreas (pancreatic cancer) as WTC-Related Health Conditions. With this rulemaking, these two types of cancer become eligible for certification and Program coverage.

B. Summary of Major Provisions

The Administrator is striking the regulatory language indicating that covered cancer types would be specified by medical diagnostic codes (ICD-9² and ICD-10³). The rule is further amended to remove Table 1 in its entirety and to replace it with the narrative list of 24 broadly specified cancer types by body organ or region identified by the September 2012 final rule and in a subsequent final rulemaking published September 19, 2013 adding prostate cancer to the List. Although the codes and subcodes have been removed, all of the specifically identified types of cancers that were included in Table 1 are still covered by

² WHO (World Health Organization) [1978]. International Classification of Diseases, Ninth Revision. Geneva: World Health Organization.

³ WHO (World Health Organization) [1997]. International Classification of Diseases, Tenth Revision. Geneva: World Health Organization.

the Program.

The Administrator is amending the definition of "childhood cancers" to clarify that childhood cancers are any type of cancer diagnosed in a person less than 20 years of age.

The Administrator is amending the definition of "rare cancers" to revise the numeric threshold which determines those cancers which are considered rare. This amendment will result in two additional types of cancer meeting the definition of "rare cancers" and being eligible for coverage -- malignant neoplasm of the cervix uteri (invasive cervical cancer) and malignant neoplasm of the testis (testicular cancer). (See discussion in Section IV.B., below.)

The Administrator also announces that he has reviewed and reversed the policy of considering cancers of the brain and the pancreas ineligible for WTC Health Program coverage. With this rule, the Administrator establishes that these two types of cancer will now be considered eligible for coverage as rare cancers.

C. Costs and Benefits

The total costs and benefits resulting from this

regulatory action are due to brain cancer, invasive cervical cancer, pancreatic cancer, and testicular cancer being eligible for coverage by the Program as "rare cancers." The Administrator estimates the costs of medical treatment for the four cancers now considered eligible under the definition of rare cancers, as well as screening costs associated with invasive cervical cancer, to be between \$2,287,933 and \$4,933,280 annually for FY 2014 through FY 2016.

II. Public Participation

Interested persons or organizations are invited to participate in this rulemaking by submitting written views, opinions, recommendations, and/or data. Comments are invited on any topic related to this interim final rule. In addition, the Administrator invites comments specifically on the following question related to this rulemaking:

1. What incidence per 100,000 persons per year in the United States ("incidence rate") should be used by the WTC Health Program as the threshold for determining whether a type of cancer is rare in relation to the incidence rates for all types of cancer in the U.S. population? Please

provide a justification for the suggested incidence rate.

Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. The Administrator will consider the comments submitted and may revise the final rule as appropriate.

III. Background

A. WTC Health Program Statutory Authority

Title I of the James Zadroga 9/11 Health and Compensation Act of 2010 (Pub. L. 111-347), amended the Public Health Service Act (PHS Act) to add Title XXXIII⁴ establishing the WTC Health Program within the Department of Health and Human Services (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 (responders) who responded to the September 11, 2001, terrorist attacks in New York City, at the Pentagon,

⁴ 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.

and in Shanksville, Pennsylvania, and to eligible persons (survivors) 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.

All references to the Administrator of the WTC Health Program in this rule mean the National Institute for Occupational Safety and Health (NIOSH) Director 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 of WTC-Related Health Conditions (List) codified in 42 CFR 88.1.

B. Rulemaking History

On September 7, 2011, the Administrator received a written petition to add a health condition to the List of WTC-Related Health Conditions (Petition 001). Petition 001 requested that the Administrator "consider adding coverage for cancer" to the List of WTC-Related Health Conditions specified in §88.1. On October 5, 2011, the Administrator formally exercised his option to request a recommendation from the STAC regarding the petition.⁵ The Administrator requested that the STAC "review the available information

⁵ PHS Act, sec. 3312(a)(6)(B)(i); 42 CFR 88.17(a)(2)(i).

on cancer outcomes associated with the exposures resulting from the September 11, 2001, terrorist attacks, and provide advice on whether to add cancer, or a certain type of cancer, to the List specified in the Zadroga Act.”⁶ In response, the STAC submitted its recommendation on April 2, 2012. After considering the STAC’s recommendation, the Administrator issued a notice of proposed rulemaking on June 13, 2012 (77 FR 35574). On September 12, 2012, the Administrator published a final rule in the **Federal Register** adding certain types of cancer⁷ to the List of WTC-Related Health Conditions in 42 CFR 88.1 (77 FR 56138).⁸ On May 2, 2013, the Administrator received a written petition to add prostate cancer to the List (Petition 002). After considering the petition, the Administrator published a notice of proposed rulemaking on July 2, 2013 (78 FR 39670) and a final rule on September 19, 2013 (78 FR 57505) adding prostate cancer to the List.

C. Need for Rulemaking

1. Table 1

The final rule adding certain types of cancer to the

⁶ 77 FR 35574, 35576 (June 13, 2012).

⁷ Including a categorical definition of childhood cancers, which includes any type of cancer diagnosed in an individual under the age of 20 years.

⁸ On October 12, 2012, the Administrator published a **Federal Register** notice to correct errors in Table 1 of the final rule (the list of cancers covered by the Program) (77 FR 62167).

List became effective on October 12, 2012 (the addition of prostate cancer became effective October 21, 2013). Since that time, the WTC Health Program has worked to develop guidelines and procedures to incorporate those types of cancers into existing Program health condition certification practices. However, during the first year of implementation, the Program discovered that the complex process of translating the ICD-9 codes to ICD-10 codes has resulted in confusion among Program medical staff and Clinical Centers of Excellence (CCEs) and Nationwide Provider Network physicians. The Administrator finds that the detailed list of ICD codes in Table 1, including sub-codes, is inappropriately restrictive and often results in coding errors. For instance, CCE physicians have at times submitted requests for certification using a different ICD code for the listed cancer type than the Administrator used in Table 1. ICD codes are highly nuanced and, for some cancers, choosing the precise code may be a matter of professional judgment on the part of the physician making a health condition determination. When a physician submits an ICD code that differs from codes included in Table 1, the Administrator must then determine whether the specific code chosen by the physician references a type of cancer that

was actually intended to be covered by the Program or could be otherwise correctly characterized. In some instances, the determining physician used a different or more-specific subcode than was included in the List; however, after review, the Administrator agreed that the type of cancer submitted by the physician fits within the intent of the final rule on cancer. A detailed list of sub-codes is unnecessary, confusing to providers, and limits the WTC Health Program's ability to appropriately identify which members' cancers are eligible for certification, therefore, the Administrator is replacing Table 1 with a narrative list of cancer categories.

2. Childhood Cancers

The Administrator has also identified the need to clarify that childhood cancers are cancers that are first diagnosed in a person under the age of 20 years. The current definition does not clearly indicate that the Administrator has always intended to certify cases of cancer in WTC Health Program members who were under the age of 20 when they were first diagnosed, even though they may be over the age of 20 when they enter the WTC Health Program. The existing language could be interpreted to mean

that only a WTC Health Program member under the age of 20 years can be certified for treatment of a WTC-related childhood cancer. The revised language clarifies that a childhood cancer is defined based on age at diagnosis rather than the current age of the WTC Health Program member.

3. Rare Cancers

In addition to the detailed list of ICD codes, the Program has also identified problems with the definition of "rare cancers" established in §88.1.⁹ In application, the definition has proven confusing and imprecise, reflecting neither the intent of the Administrator nor the STAC's concern regarding difficulties identifying associations between exposure and some cancers in epidemiologic studies.

The Administrator has identified several problems with the definition of rare cancers for the purpose of identifying such conditions for WTC Health Program coverage as specified in 42 CFR 88.1. First, the original definition was derived from the Rare Diseases Act of 2002, which states that, "[r]are diseases and disorders are those which affect small patient populations, typically populations

⁹ Rare cancers were defined in Table 1 as, "Any type of cancer affecting the [sic] populations smaller than 200,000 individuals in the United States, i.e., occurring at an incidence rate less than 0.08 percent of the U.S. population. Rare cancers will be determined on a case-by-case basis."

smaller than 200,000 individuals in the United States."¹⁰

The Rare Diseases Act addresses the rarity of disease as considered against all possible types of diseases, which is different than the Administrator's intent to define the rarity of a type of cancer as considered against all types of cancer only.

Second, the Rare Diseases Act establishes the threshold for the number of cases qualifying a disease as rare using "prevalence" (i.e., the number of persons in the United States living with a particular disease) instead of "incidence" (i.e., the number of persons in the United States that acquire a particular disease over a given time period). Because life expectancy varies greatly across cancer types, some cancers occur infrequently but have a high survival rate and therefore a high prevalence. Similarly, cancers that occur more frequently but have a high mortality rate have a low prevalence. As a result, the prevalence of a type of cancer varies substantially depending on the life expectancy associated with the cancer type. Therefore, the Administrator finds that incidence is a more useful and appropriate indicator to select a rarity threshold for cancer.

Third, the "case-by-case basis" text is misleading.

¹⁰ Pub. L. 107-280, sec. 2(a)(1); 42 U.S.C. 283h(c).

There is no case-specific approach to "determine" which cancers would qualify as rare cancers. Rare cancers will be determined based on their incidence as specified in this rule.

4. Cancers of the Brain and the Pancreas

In the preamble to the September 12, 2012 final rule, the Administrator concurred with the STAC's decision to not recommend malignant neoplasms of the brain and the pancreas for inclusion on the List of WTC-Related Health Conditions (77 FR 56138, 56147), indicating that no compelling evidence was found to support their inclusion:

The issue of whether to recommend the addition of cancers of the ... brain and pancreas to the List of WTC-Related Health Conditions was considered and discussed by the STAC in the open meeting on March 28, 2012. In those discussions, the STAC considered the available evidence for recommending the addition of cancers of the ... brain and pancreas, including the epidemiologic evidence and the NTP [NIH's National Toxicology Program] and IARC reviews. Following its deliberation on the matter, the STAC voted not to include ... brain or pancreatic cancer in its recommendation. [See STAC (World Trade Center Health Program Scientific/Technical Advisory Committee) Letter from Elizabeth Ward, Chair, to John Howard, MD, Administrator [2012].] The Administrator concurs with the decision of the STAC and is not adding these cancers to the List of WTC-Related Health Conditions at this time. The addition of these cancers may be reconsidered if additional information on the association of 9/11 exposures and those cancer outcomes becomes available.¹¹

¹¹ 77 FR 56138, 56147 (September 12, 2012).

As a result of that determination, the WTC Health Program denied certification of cancers of the brain and the pancreas, even though they were found to meet the numeric threshold in the definition of rare cancers. After review, the Administrator has reconsidered that decision and determined, for the reasons discussed below, that cancers of the brain and the pancreas will be considered eligible for certification as rare cancers. With this rulemaking, a WTC Health Program member whose 9/11 exposure is found substantially likely to be a significant factor in aggravating, contributing to, or causing the individual's brain and/or pancreatic cancer, will be certified for WTC Health Program treatment services. The WTC Health Program will review and reassess cases of brain and pancreatic cancer that were denied certification prior to this rulemaking.

IV. Rare Cancers

A. STAC Recommendation

As noted above, the Administrator asked the STAC to deliberate and develop recommendations on a petition to add cancers to the List of WTC-Related Health Conditions. The

STAC met on three occasions between November 2011 and March 2012, and offered its final recommendation to the Administrator on April 2, 2012.¹² The STAC expressed a sense that insufficient exposure data from the WTC terrorist attack site limited the Committee's ability to identify specific cancers definitively linked to the terrorist attacks.¹³ The STAC further noted the difficulty of detecting excesses of rare cancers in epidemiologic studies, concluding that rare cancers should be covered on a precautionary basis.¹⁴ As the Administrator understands the STAC's basis for recommending inclusion of a rare cancers category, the STAC intended for the WTC Health Program to establish a category of types of cancers that are sufficiently rare that such cancers are difficult to evaluate in epidemiologic studies in general, and 9/11 cohorts in particular.

¹² The STAC premised its recommendation on evidence from four main sources: carcinogens present at the New York City attack site with limited or sufficient evidence of carcinogenicity in humans based on the International Agency for Research on Cancer (IARC) Monographs on the Evaluation of Carcinogenic Risks to Humans; cancers arising from regions of the respiratory and digestive tracts where inflammatory conditions have been documented; cancers for which epidemiologic studies have found some evidence of increased risk in WTC responder and survivor populations; and findings from other sources of information relevant to 9/11 exposures and the potential occurrence of cancer, including the expert judgment and personal experiences of STAC members, and comments from the public. The STAC evaluated the only peer-reviewed study available at the time of its deliberations, an epidemiologic study of Fire Department of New York (FDNY) firefighters conducted by Rachel Zeig-Owens and colleagues, which was published in *The Lancet* in September 2011. [Zeig-Owens R, Webber MP, Hall CB, Schwartz T, Jaber N, Weakley J, Rohan TE, Cohen HW, Derman O, Aldrich TK, Kelly K, Prezant DJ [2011]. Early Assessment of Cancer Outcomes in New York City Firefighters After the 9/11 Attacks: An Observational Cohort Study. *The Lancet*. 378(9794):898-905.] This was also the only study available to the Administrator at the time of the Petition 001 rulemaking in June and September, 2012.

¹³ STAC (World Trade Center Health Program Scientific/Technical Advisory Committee) [2012]. Letter from Elizabeth Ward, Chair, to John Howard MD, Administrator at 1-2. NIOSH Docket 257. <http://www.cdc.gov/niosh/docket/archive/docket257.html>.

¹⁴ *Id.* at 25.

In its April 2, 2012 letter to the Administrator, the STAC formally recommended that the Administrator add rare cancers to the List of WTC Related Health Conditions.

According to the STAC:

Excesses in rare cancers are difficult to detect in epidemiologic studies. Even large studies may have very low numbers of expected cases of rare cancers, and thus very low statistical power to detect any but very large effects. In addition, most cancer studies analyze data by organ site, and not by site and histology. This can result in inability to detect rare site and histology combinations, such as angiosarcoma of the liver, associated with vinyl chloride monomer exposure, and small cell carcinoma of the lung, associated with bischloromethyl ether. Cancers can also be defined as rare based on the patient's gender (male breast cancer), age (prostate cancer in men under 40) or race (melanoma in African Americans). Since customary study methods are unlikely to identify increased risks for rare cancers among WTC-exposed populations unless they occur in sizable clusters. Nonetheless, given the sizable number of carcinogens (and related cancer sites) present in WTC smoke and dust, it is reasonable to consider the possibility that an increased risk of specific rare cancers may occur or that the incidence of common cancers would be increased at younger ages in WTC-exposed populations. One approach that has been used is to consider rare cancers as cancers with age-adjusted incidence rates less than 15 per 100,000, which would result in defining 25% of all adult cancers in the US as rare. Additional definitions -- 10 cases per million per year, or 1 case per million per year -- have also been examined.¹⁵ [citations omitted]

Further, the STAC specifically referenced an incidence rate of less than 15 cases per 100,000 population to

¹⁵ STAC (World Trade Center Health Program Scientific/Technical Advisory Committee) [2012]. Letter from Elizabeth Ward, Chair to John Howard, MD, Administrator, at 25. This letter is included in NIOSH Docket 257, <http://www.cdc.gov/niosh/docket/archive/docket257.html>.

characterize the cancer rate among children as rare.¹⁶ Based on the reference to an incidence rate of 15 cases per 100,000 persons per year in the United States, the Administrator concludes that the STAC sought to identify types of cancer that are rare relative to other types of cancer rather than identifying cancers that are rare diseases compared to the universe of all diseases.

B. WTC Health Program Rare Cancers Definition and Numeric Threshold Determination

1. Rare Cancers Numeric Threshold

In the preamble to the September 2012 final rule, the Administrator developed a four-part methodology for evaluating whether to add a type of cancer to the List.¹⁷ The definition of "rare cancers" was established under Method 4, which requires that the STAC provide a reasonable basis for the inclusion of a type or category of cancer. The Administrator found the STAC's recommendation to develop a categorical definition of rare cancers to be reasonable, and at that time thought it appropriate to establish a numeric threshold derived from the Rare

¹⁶ STAC (World Trade Center Health Program Scientific/Technical Advisory Committee) [2012]. Letter from Elizabeth Ward, Chair to John Howard, MD, Administrator, at 6. This letter is included in NIOSH Docket 257, <http://www.cdc.gov/niosh/docket/archive/docket257.html>.

¹⁷ 77 FR 56138, 56143.

Diseases Act of 2002.¹⁸ However, in hindsight, the definition of rare cancers created in the September 2012 WTC Health Program final rule established a numeric threshold that reflected neither the Administrator's nor the STAC's intent.

In order to revise the definition of "rare cancers" and develop a threshold better suited to WTC Health Program purposes, the Administrator reconsidered the STAC's recommendation, and evaluated the incidence rates used by research organizations in the United States and Europe, including the North American Association of Central Cancer Registries (NAACCR), the National Institutes of Health (NIH), the International Rare Cancers Initiative (IRCI), the European Society for Medical Oncology (ESMO), and RARECARE.

There is no single, universally agreed-upon, quantitative definition of "rare cancers." A rarity threshold is a matter on which informed experts differ; established rarity thresholds also depend on the purpose for which the definition is applied. The different thresholds used by the various organizations were developed to stimulate epidemiologic studies and clinical research on rare cancer therapeutics; the Administrator was unable to

¹⁸ 77 FR 35574, 35592 (June 13, 2012).

identify any incidence rate used by any other organizations for purposes similar to the WTC Health Program. The European organizations IRCI, ESMO, and RARECARE use lower incidence thresholds for rare cancers than do researchers in the United States: IRCI uses a threshold of less than or equal to 2 cases per 100,000 persons per year;¹⁹ ESMO uses a threshold of less than or equal to 5 cases per 100,000 persons per year;²⁰ and RARECARE uses a threshold of less than or equal to 6 cases per 100,000 persons per year.²¹ By contrast, the incidence rate employed by NAACCR is less than 15 cases per 100,000 persons per year.²² This rate of less than 15 cases per 100,000 persons per year is also used by NIH's Office of Rare Diseases (ORD) and the National Cancer Institute's Epidemiology and Genomics Research Program (EGRP).²³ During a May 2007 ORD/EGRP workshop, "Synergizing Epidemiologic Research on Rare Cancers," meeting participants noted:

[r]are cancers were defined as those cancers for which the incidence rate is less than 15 cases per 100,000 population or fewer than 40,000 new cases per year in the United States. Although these numbers are relatively small, all rare cancers combined account

¹⁹ International Rare Cancers Initiative. <http://www.irci.info/abouttheinitiative/>.

²⁰ European Society for Medical Oncology. Improving Rare Cancer Care in Europe; Recommendation on Stakeholder Actions and Public Policies. http://www.rarecancerseurope.org/IMG/pdf/ESMO_Rare_Cancers_RECOMMENDATIONS_FINAL.pdf.

²¹ RARECARE. <http://www.rarecare.eu/rarecancers/rarecancers.asp>.

²² Greenlee RT, Goodman MT, Lynch CF, Platz CE, Havener LA, Howe HL [2010]. The Occurrence of Rare Cancers in U.S. Adults, 1995-2004. Public Health Reports 125:28-43.

²³ NCI Epidemiology and Genomics Research Program. Synergizing Epidemiologic Research on Rare Cancers, May 10-11, 2007, Bethesda, MD. <http://epi.grants.cancer.gov/Synergizing/>.

for 27 percent of cancers diagnosed each year and 25 percent of cancer-related deaths, and the morbidity and mortality that they cause are increasing.²⁴

The Administrator has determined that the incidence rate used by U.S. researchers -- less than 15 cases per 100,000 persons per year in the United States -- is most representative of his intent and that of the STAC. The Administrator has further determined that, because incidence rates change from year-to-year, rare cancers will be identified using average annual data from the 2005-2009 period which has been age-adjusted²⁵ to the U.S. population in 2000.²⁶ In other words, the Administrator will identify each rare cancer type based on its average incidence rate during the years 2005-2009; therefore, for each rare cancer type, the incidence rate is static and will not be adjusted to reflect current incidence rates. Accordingly, the threshold incidence rate for rare cancers will be less than 15 cases per 100,000 persons per year in the United States.

2. Application of Rare Cancers Numeric Threshold

All types of cancer that are not listed in 42 CFR 88.1

²⁴ Id.

²⁵ An age-adjusted incidence rate is a weighted average of the age-specific rates, where weighted in proportion to the number of individuals in the corresponding age groups of a standard population. The potential confounding effect of age is reduced when comparing age-adjusted rates computed using the same standard population.

²⁶ Copeland G, Lake A, Firth R, Wohler B, Wu XC, Stroup A, Russell C, Boyuk K, Schymura M, Hofferkamp J, Kohler B (eds) [2012]. 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.

and that meet the threshold of less than of 15 cases per 100,000 persons per year (based on age-adjusted 2005-2009 average annual data)²⁷ will be considered rare cancers and eligible for certification by the Program; members whose cancers are certified by the WTC Health Program will receive medical treatment and services.

The revised numeric threshold in the definition of rare cancers will result in two types of cancer becoming newly eligible for consideration as rare cancers. Under the former numeric threshold in the definition of rare cancers (prevalence of fewer than 200,000 persons), malignant neoplasms of the cervix uteri (invasive cervical cancer) and the testis (testicular cancer) were not eligible for coverage because their respective prevalence estimates are greater than the threshold of 200,000 persons in the United States with these conditions. Both invasive cervical cancer and testicular cancer, however, will be considered rare cancers under the new definition because their incidence rates are less than 15 cases per 100,000 persons per year in the United States based on age-adjusted 2005-2009 average annual data.²⁸ Moreover, all types of cancer which

²⁷ Copeland G, Lake A, Firth R, Wohler B, Wu XC, Stroup A, Russell C, Boyuk K, Schymura M, Hofferkamp J, Kohler B (eds) [2012]. 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.

²⁸ Id.

are considered rare under the former prevalence-based definition based on the Rare Diseases Act definition are also considered rare under the new incidence-based definition.

V. Cancers of the Brain and the Pancreas

A. STAC Recommendation

During a meeting held on March 28, 2012, STAC members discussed evidence of associations between 9/11 exposures and cancers of the brain and the pancreas, and voted to not recommend cancers of the brain or the pancreas for inclusion as specifically-identified cancers on the List of WTC-Related Health Conditions. The Committee Chair acknowledged that coverage of brain cancer as a rare cancer would depend on the categorical definition of rare cancer adopted by the Administrator; however, the matter of whether brain and pancreatic cancers should be eligible for consideration as "rare cancers" was not brought to a formal vote.²⁹ The Administrator understands that the STAC was distinguishing between the standard for a specific cancer type to be named to the List, and the relatively lower

²⁹ STAC (World Trade Center Health Program Scientific/Technical Advisory Committee) March 28, 2012 meeting transcript at 102. NIOSH Docket 248. <http://www.cdc.gov/niosh/docket/archive/docket248.html>.

standard for a cancer type to fall under the definition of rare cancers, which is predicated on the condition that those cancers occur so infrequently that epidemiologic study would be difficult and usually inconclusive.

B. WTC Health Program Determination

When applying the Administrator's four-part methodology established in the September 12, 2012 final rule, neither cancers of the brain nor the pancreas were found to satisfy any of the four methods.³⁰ Additionally, although the STAC voted specifically not to recommend adding malignant neoplasms of either the brain or the pancreas to the List of WTC-Related Health Conditions, the STAC did recommend that the Administrator establish a definition of rare cancers (as discussed above, rare cancers were added to the List using Method 4, which requires that the STAC provide a reasonable basis for inclusion).³¹ Considering the numeric thresholds in both the former and revised definitions of rare cancers, malignant neoplasms of both the brain and the pancreas meet the definition of rare cancers. As discussed below, after reconsideration of the STAC recommendation and re-evaluation of the available scientific evidence, the

³⁰ 77 FR 56138 (September 12, 2012).

³¹ Id. at 56144 (September 12, 2012).

Administrator finds it appropriate to revise his prior decision to exclude cancers of the brain and the pancreas from consideration under the rare cancers category and allow these two cancers to be recognized as "rare," for the purposes of the WTC Health Program, and therefore eligible for certification.

The rationale provided by the STAC for the inclusion of rare cancers as a category on the List was that there is large uncertainty in associating a rare cancer to a specific exposure. Most rare cancers have not been adequately investigated in epidemiologic studies and the relatively small number of cases of such cancers may preclude epidemiologic study in the future. Moreover, future epidemiologic study of the small number of expected cancer cases in the 9/11-exposed population would be of little help in determining an association between 9/11 exposures and most types of cancer. Although malignant neoplasms of the brain and the pancreas qualify as rare cancers under various numeric thresholds,³² the Administrator determined, pursuant to the September 2012 final rulemaking, that neither type of cancer would be considered a rare cancer within the WTC Health Program.

³² Brain and pancreatic cancers each meet both the previous prevalence-based numeric threshold and the new incidence-based numeric threshold established in this interim final rule to be considered rare within the WTC Health Program.

That determination was premised on the availability of numerous published studies which did not support an association between brain and pancreatic cancers and environmental agents, including certain agents identified in 9/11 exposure assessment studies. In the September 2012 final rule, the Administrator distinguished malignant neoplasms of the brain and the pancreas from other rare cancers for which evidence of causation by environmental or occupational exposure is lacking and for which there is little likelihood that statistically significant evidence of association with 9/11 exposures can be obtained through epidemiologic studies. Other rare cancers were considered WTC-related health conditions because limitations in the available information did not allow their relationships to the September 11, 2001, terrorist attacks to be adequately studied in the published epidemiologic studies and are not likely to be adequately studied in the near future.

At the time of the September 2012 final rulemaking, in accordance with the STAC's stated basis for recommending the inclusion of a rare cancers category (see prior discussion, Section IV.A.), the Administrator had interpreted the presence of many studies addressing brain and pancreatic cancer as an indication that they could be

studied, and that associations would be identified if present; he originally determined that those studies indicate that neither cancers of the brain nor the pancreas are associated with the exposures experienced by WTC responders and survivors, and therefore they could not be considered WTC-related.

In the process of revising the definition of rare cancers, the Administrator re-visited the STAC's rationale for including the category of rare cancers. During its March 2012 meeting, the STAC considered the exposure data collected in the days following the September 11, 2001, terrorist attacks, and found it extremely limited. STAC members acknowledged the difficulties in attempting to identify associations between 9/11 exposures and specific cancer types. This sentiment was clearly expressed by the STAC Chair, who stated, "we know something but we don't know everything" with regard to 9/11 exposures.³³ Following his review of the STAC's findings, the Administrator has reconsidered his previous determination. He concurs with concerns expressed by the STAC, including one STAC member's recognition that for many types of cancer, such as brain cancer, there are difficulties in identifying associations

³³ STAC (World Trade Center Health Program Scientific/Technical Advisory Committee) February 15, 2012 meeting transcript at 160. NIOSH Docket 248. <http://www.cdc.gov/niosh/docket/archive/docket248.html>.

with environmental and occupational exposures.³⁴ Upon further reflection, the Administrator finds it appropriate to take a more cautious approach when excluding rare cancers from WTC Health Program coverage.

The Administrator now finds that while brain cancer or pancreatic cancer may be evaluated in a number of epidemiologic studies, the limitations of those studies are substantial, leading the Administrator to conclude that the uncertainties surrounding the causes of brain and pancreatic cancers are not unlike the uncertainties surrounding other rare cancers. The Administrator reviewed epidemiologic studies of brain and pancreatic cancers involving some of the carcinogens involved in 9/11 exposures and identified five significant study limitations: (1) the low frequency of and difficulty in diagnosing cancers of the brain and pancreas;³⁵ (2) the

³⁴ STAC (World Trade Center Health Program Scientific/Technical Advisory Committee) March 28, 2012 meeting transcript at 45. NIOSH Docket 248. <http://www.cdc.gov/niosh/docket/archive/docket248.html>.

³⁵ Anntila A, Pukkala E, Sallmen M, Hernberg S, Hemminki K [1995]. Cancer incidence among Finnish workers exposed to halogenated hydrocarbons. *JOEM* 37:797-806; Blair A, Grauman DJ, Lubin JH, Fraumeni JF [1983]. Lung cancer and other causes of death among licensed pesticide applicators. *JNCI* 71:31-37; Davis JR, Brownson, Garcia, R, Bentz BJ, Turner A [1993]. Family pesticide use and childhood brain cancer. *Arch Environ Contam Toxicol* 24:87-92; Garabrant DH, Held J, Langholz B, Bernstein L [1988]. Mortality of aircraft manufacturing workers in Southern California. *Am J Ind Med* 13:683-693; IARC (International Agency for Research on Cancer) [2009]. IARC monographs on the evaluation of carcinogenic risks to humans. Vol 100 Part C: Arsenic, metals, fibres and dusts. Lyon, France; Li J, Cone JE, Kahn AR, Brackbill RM, Farfel MR, Greene CM, Hadler JL, Stayner LT, Stellman ST [2012]. Association between World Trade Center exposure and excess cancer risk. *JAMA* 308:2479-2488; Pesatori AC, Sontag JM, Lubin JH, Consonni D, Blair A [1994]. Cohort mortality and nested case-control study of lung cancer among structural pest control workers in Florida (United States). *Cancer Cause Control* 5:310-318; Spirtas R, Steward PA, Lee JS, Marano DE, Forbes, CD, Grauman DJ, Pettigrew HM, Blair A, Hoover RN, Cohen JL [1991]. Retrospective cohort mortality study of workers at an aircraft maintenance facility. I Epidemiologic results. *Br J Ind Med* 48:515-530; Stroup NE, Blair

difficulty in identifying appropriate referent populations (ideally, referent populations would have very similar demographic characteristics and exposures except for the agent being studied);³⁶ (3) the difficulty of conducting studies of brain or pancreatic cancers, which typically have long latency periods, before disease symptoms might manifest in exposed individuals;³⁷ (4) inaccurate or inconsistent exposure assessment;³⁸ and (5) observations of multiple health effects which may identify statistically significant increases in brain or pancreatic cancers by chance.³⁹ The limitations identified in this review are consistent with the findings from other reviews of rare cancers.⁴⁰

Upon re-evaluation of these studies, the Administrator

A, Erikson GE [1986]. Brain cancer and other causes of death in anatomists. *JNCI* 77:1217-1224; Zeig-Owens R, Webber MP, Hall CB, Schwartz T, Javer N, Weakley J, Rohan TE, Cohen HW, Derman O, Aldrich TK, Kelly K, Prezant DJ [2011]. Early assessment of cancer outcomes in New York City firefighters after the 9/11 attacks: an observational cohort study. *The Lancet* 378:898-905.

³⁶ Blair et al. [1983]; Stroup et al. [1986]; Zeig-Owens et al. [2011].

³⁷ Garabrant et al. [1988]; Hauptman M, Lubin JH, Stewart PA, Hayes R, Blair A [2004]. Mortality from cancers among workers in formaldehyde industries. *Am J Epidemiol* 159:1117-1130; Solan S, Wallenstein S, Shapiro M, Teitelbaum SL, Stevenson L, Kochman A, Kaplan J, Dellenbaugh C, Kahn A, Biro FN, Crane M, Crowley L, Gabrilove J, Gonsalves L, Harrison D, Herbert R, Luft B, Markowitz SB, Moline J, Niu X, Sacks H, Shukla G, Udasin I, Lucchini RG, Boffetta P, Landrigan PJ. [2013] Cancer incidence in World Trade Center rescue and recovery workers, 2001-2008. *Environ Health Perspect* 121(6):699-704; Zeig-Owens et al. [2011].

³⁸ Anntila et al. [1995]; Blair et al. [1983]; Coggon D, Harris EC, Poole J, Palmer KT [2003]. Extended follow-up of a cohort of British chemical workers exposed to formaldehyde. *JNCI* 95:1608-1615; Davis JR, Brownson, Garcia, R, Bentz BJ, Turner A [1993]. Family pesticide use and childhood brain cancer. *Arch Environ Contam Toxicol* 24:87-92; Hauptmann et al. [2004]; Pan SY, Ugnat AM, Mao Y [2005]. Canadian Cancer Registries Epidemiology Research Group. Occupational risk factors for brain cancer in Canada. *J Occup Environ Med* 47: 704-717; Solan et al. [2013]; Spirtas et al. [1991].

³⁹ Davis et al. [1993]; Li et al. [2012]; Pan et al. [2005]. The identification of this limitation offers further evidence of the uncertainties associated with identifying causes of brain and pancreatic cancer.

⁴⁰ Charbotel B, Fervers B, Droz JP [2013]. Occupational exposures in rare cancers: a critical review of the literature. *Crit Rev Oncol/Hematol*.

<http://dx.doi.org/10.1016/j.critrevonc.2013.12.004>

finds that brain or pancreatic cancer may be associated with an exposure, but the studies' limitations prevent adequate evaluation of this association. Accordingly, the Administrator has determined that the availability of numerous studies evaluating the associations between brain and pancreatic cancers and environmental exposures should not be given more weight in his decision-making than the inherent limitations of these studies. While the Administrator previously relied on the lack of an identified association between environmental exposures and brain or pancreatic cancers in these epidemiologic studies to conclude that they should not be considered WTC-related, he now determines that those studies are not likely to identify associations because of study limitations and concludes that, because the uncertainty associated with brain and pancreatic cancers is similar to the uncertainty associated with other rare cancers, they should be similarly eligible for consideration as WTC-related.

For the reasons discussed above, the Administrator has determined that brain and pancreatic cancers are considered rare cancers, and that they are eligible for WTC Health Program certification.

VI. Effects of Rulemaking on Federal Agencies

Title II of the James Zadroga 9/11 Health and Compensation Act of 2010 (Pub. L. 111-347) reactivated the September 11th Victim Compensation Fund (VCF). Administered by the U.S. Department of Justice (DOJ), the VCF provides compensation to any individual or representative of a deceased individual who was physically injured or killed as a result of the September 11, 2001, terrorist attacks or during the debris removal. Eligibility criteria for compensation by the VCF include a list of presumptively covered health conditions, which are physical injuries determined to be WTC-related health conditions by the WTC Health Program. Pursuant to DOJ regulations, the VCF Special Master is required to update the list of presumptively covered conditions when the List of WTC-Related Health Conditions in 42 CFR 88.1 is updated.⁴¹

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

In accordance with the provisions of the Administrative Procedure Act at 5 U.S.C. 553(b)(3)(B), the Administrator

⁴¹ 28 CFR 104.21.

finds good cause to waive the use of prior notice and comment procedures for issuing this interim final rule (IFR), and that the use of such procedures would be contrary to the public interest. This IFR amends 42 CFR 88.1 to remove Table 1 and replace it with a narrative list of covered cancers, clarify the definition of childhood cancers, and revise the definition of rare cancers; it also notifies stakeholders that the Administrator now considers malignant neoplasms of the brain and the pancreas to be eligible for coverage as rare cancers. The Administrator has determined that it is contrary to the public interest to delay these necessary amendments. Postponement of the implementation of these amendments could result in real harm to those individuals who are currently suffering from a subtype of cancer that was inadvertently excluded from the detailed list of cancer codes, or from a rare cancer that was not identified by the former prevalence-based numeric threshold (U.S. population size of 200,000 persons), or from cancer of the brain or the pancreas. Thus, the Administrator is waiving the prior notice and comment procedures in the interest of protecting the health of WTC Health Program members whose cancer may now be eligible for certification.

The amendments to replace Table 1 with a narrative list of covered cancers and clarify the definition of childhood cancers will not result in any substantive change to the types of cancers added to the List of WTC-Related Health Conditions by the final rule published on September 12, 2012 (77 FR 56138) or by the final rule published on September 19, 2013 adding prostate cancer (78 FR 57505); however, changing the numeric threshold for rare cancers will result in of two types of cancer becoming newly eligible for consideration as rare cancers. Additionally, cancers of the brain and the pancreas may now be considered for certification as rare cancers. The Administrator expects that most stakeholders will be supportive of the amendments, because the determinations established in this rulemaking will result in more WTC Health Program members becoming eligible for certification of a WTC-Related Health Condition. Interested parties were given an opportunity to comment on the covered cancers during the June 2012 notice of proposed rulemaking's 30-day public comment period. During the public comment period for the initial notice of proposed rulemaking, no commenters reflected on the proposed definition of "rare cancers."

Under 5 U.S.C. 553(d)(3), the Administrator finds good

cause to make this IFR effective immediately. As stated above, in order to ensure that the WTC Health Program is able to promptly respond to a member WTC responder or survivor who is suffering from a type of cancer that may now be eligible for certification, including individuals who may have been denied certification for brain or pancreatic cancer, it is necessary that the Administrator act quickly to promulgate the amendments discussed above. While the amendments to §88.1 are effective on the date of publication of this IFR, they are interim and will be finalized following the receipt of any substantive public comments. (See Section II.)

VIII. Summary of Interim Final Rule

For the reasons discussed above, the Administrator of the WTC Health Program is amending 42 CFR 88.1, paragraph (4) of the definition of "List of WTC-related health conditions," to strike the former regulatory language indicating that covered cancer types would be specified by ICD-10 and ICD-9 codes. The rule is further amended to remove Table 1 in its entirety and to replace it with the narrative list of 24 broadly specified cancer types by body

organ or region included in both the 2012 notice of proposed rulemaking and final rule preambles, as well as prostate cancer which was added to the List in the September 2013 rulemaking.⁴² Although the codes and subcodes are removed, all of the specifically identified types of cancers that were added to the List of WTC-Related Health Conditions by the September 12, 2012 final rule, and which were identified in Table 1 (as well as prostate cancer, added by the September 19, 2013 final rule), remain covered by the Program. This amendment will have the effect of retaining all of the currently covered cancer types but will allow WTC Health Program staff to administratively determine the corresponding codes for the specific types of cancer covered by the Program, regardless of classification system (ICD-9, ICD-10, etc.).

For the reasons discussed above, the Administrator clarifying the definition of "childhood cancers" to replace the words "occurring in" with "diagnosed in."

Finally, the Administrator is also revising the definition of "rare cancers" to remove the 200,000 persons prevalence and 0.08 percent incidence rate in the former definition and instead reflect the revised incidence rate,

⁴² NPRM 77 FR 35574, 35589-35592 (June 13, 2012); Final rule 77 FR 56138, 56144 (September 12, 2012). A notice of proposed rulemaking proposing to add prostate cancer to the List of WTC-Related Health Conditions was published on July 2, 2013 (78 FR 39670), and a final rule was published on September 19, 2013 (78 FR 57505).

less than 15 cases per 100,000 persons per year in the United States based on 2005-2009 average annual data.⁴³ The phrase "Rare cancers will be determined on a case-by-case basis" is stricken.

IX. Regulatory Assessment Requirements

A. Executive Order 12866 and Executive Order 13563

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 has been determined not to be a "significant regulatory action" under sec. 3(f) of E.O. 12866. The amendments in this rule modify the format of the list of named cancers covered by the WTC Health Program, clarify the definition of "childhood cancers," and modify

⁴³ Copeland G, Lake A, Firth R, Wohler B, Wu XC, Stroup A, Russell C, Boyuk K, Schymura M, Hofferkamp J, Kohler B (eds) [2012]. 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.

the definition of "rare cancers." In addition to amendments to the rule text, in this action the Administrator also recognizes malignant neoplasms of the brain and the pancreas as rare cancers. The revised definition and determinations regarding "rare cancers," have resulted in four additional cancer types being considered eligible for coverage under the Program: brain cancer (malignant neoplasm of the brain), invasive cervical cancer (malignant neoplasm of the cervix uteri), pancreatic cancer (malignant neoplasm of the pancreas), and testicular cancer (malignant neoplasm of the testis). Treatment and monitoring services for these four cancer types is estimated to cost the WTC Health Program between \$2,287,933⁴⁴ and \$4,933,280⁴⁵ annually. All of the costs to the WTC Health Program will be transfers after the implementation of provisions of the Patient Protection and Affordable Care Act (Pub. L. 111-148) on January 1, 2014.

The Administrator did not identify any costs associated with the removal of Table 1 from 42 CFR 88.1.

The rule would not interfere with State, local, and Tribal governments in the exercise of their governmental functions.

⁴⁴ Based on a population of 65,000 at the U.S. cancer rate and discounted at 7 percent.

⁴⁵ Based on a population of 110,000 at 21 percent above the U.S. cancer rate and discounted at 3 percent.

Cost Estimates

The WTC Health Program has, to date, enrolled approximately 58,500 New York City responders and approximately 6,500 survivors, or approximately 65,000 individuals in total. Of that total population, approximately 60,000 individuals were participants in previous WTC medical programs and were 'grandfathered' into the WTC Health Program established by Title XXXIII.⁴⁶ In addition to those grandfathered WTC responders and survivors already enrolled, the PHS Act⁴⁷ sets a numeric limitation on the number of eligible members who can enroll in the WTC Health Program beginning July 1, 2011 at 25,000 new WTC responders and 25,000 new WTC survivors (i.e., the statute restricts new enrollment). For the purpose of calculating a baseline estimate of cancer prevalence only, the Administrator assumed that the gradual rate of enrollment seen in the Program to date would continue, and that Program membership would remain around 58,500 WTC responders and 6,500 WTC survivors. The estimate is further based on the average U.S. cancer prevalence rate and 7

⁴⁶ These grandfathered members were enrolled without having to complete a new member application when the WTC Health Program started on July 1, 2011 and are referred to in the WTC Health Program regulations in 42 CFR Part 88 as "currently identified responders" and "currently identified survivors."

⁴⁷ PHS Act, sec. 3311(a)(4)(A) and sec. 3321(a)(3)(A).

percent discount rate.

As it is not possible to identify an upper bound estimate, the Administrator has modeled another possible point on the continuum. For the purpose of calculating the impact of an increased rate of cancer on the WTC Health Program, this analysis assumes that the entire statutory cap for new WTC responders (25,000) and WTC survivors (25,000) will be filled. Accordingly, this estimate is based on a population of 80,000 responders (55,000 grandfathered + 25,000 new) and 30,000 survivors (5,000 grandfathered + 25,000 new). The upper cost estimate also assumes an overall increase in population cancer rates (for malignant neoplasm of the brain [brain cancer], malignant neoplasm of the cervix uteri [invasive cervical cancer], malignant neoplasm of the pancreas [pancreatic cancer], malignant neoplasm of the testis [testicular cancer]) of 21 percent due to 9/11 exposure,⁴⁸ and costs were discounted at 3 percent. The choice of a 21 percent increase in the risk of cancer of the rate found in the unexposed population is based on findings presented in the first published epidemiologic study of September 11, 2001 exposed

⁴⁸ Zeig-Owens R, Webber MP, Hall CB, Schwartz T, Jaber N, Weakley J, Rohan TE, Cohen HW, Derman O, Aldrich TK, Kelly K, Prezant DJ [2011]. Early Assessment of Cancer Outcomes in New York City Firefighters after the 9/11 Attacks: An Observational Cohort Study. *The Lancet*. 378(9794):898-905.

populations.⁴⁹ Given the challenges associated with interpreting the Zeig-Owens findings,⁵⁰ this analysis uses 21 percent as a possible outcome rather than asserting the probability that 21 percent is a "likely" outcome.

The Administrator acknowledges that some cancer cases are not likely to have been caused by 9/11 exposures. The certification of individual cancer diagnoses will be conducted on a case-by-case basis. However, for the purpose of this analysis, the Administrator has estimated that all diagnosed cancers added to the List or meeting the definition of rare cancer 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 used only data from studies of individuals who were responders or survivors in the New York City disaster area.

Costs of Cancer Treatment

The Administrator estimated the treatment costs associated with covering malignant neoplasm of the brain,

⁴⁹ Id.

⁵⁰ As Zeig-Owens et al. point out, the time interval since 9/11 is short for cancer outcomes, the recorded excess of cancers is not limited to specific sites, and the biological plausibility of chronic inflammation as a possible mediator between 9/11 exposure and cancer means that the outcomes remain speculative.

malignant neoplasm of the cervix uteri, malignant neoplasm of the pancreas, and malignant neoplasm of the testis in this rulemaking using the methods described below. Costs associated with cancer screening are discussed separately below.

The WTC Health Program obtained data for the cost of providing medical treatment for each cancer type. The costs of treatment for each type of cancer are described in Table A. The costs of treatment are divided into three phases: the costs for the first year following diagnosis, the costs of intervening years or continuing treatment after the first year, and the costs of treatment for the last year of life. The first year costs of cancer treatment are higher due to the initial need for aggressive medical (e.g., radiation, chemotherapy) and surgical care. The costs during last year of life are often dominated by increased hospitalization costs. Therefore, this analysis uses three different treatment phase costs to estimate the costs of treatment to be able to best estimate costs in conjunction with expected incidence and long-term survival for each type of cancer.⁵¹

Table A--Average Costs of Treatment, Male and Female (2011)

⁵¹ 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. Journal: J Natl Cancer Inst 100(9):630-41.

Type of Cancer	Initial (first 12 months after diagnosis)	Continuing (annual)	Last year of life (last 12 months of life)
Brain	\$87,319	\$6,372	\$101,372
Pancreas	\$74,205	\$5,270	\$84,809
Cervix Uteri	\$33,945	\$1,072	\$36,503
Testis ⁺	\$13,696	\$2,754	\$43,481

+ Approximated by the costs of other tumor sites

These cost figures were based on a study of elderly cancer patients from the Surveillance, Epidemiology, and End Results (SEER) program maintained by the National Cancer Institute using Medicare files.⁵² The average costs of treatment described above are given in 2011 prices adjusted using the Medical Consumer Price Index for all urban consumers.⁵³

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 for the four cancer types considered eligible for coverage under the Program pursuant to this rulemaking. Demographic

⁵² Surveillance, Epidemiology, and End Results (SEER) Program (www.seer.cancer.gov) Research Data (1973-2006), National Cancer Institute, DCCPS, Surveillance Research Program, Surveillance Systems Branch, released April 2009, based on the November 2008 submission.

⁵³ Bureau of Labor Statistics. Consumer Price Index <https://research.stlouisfed.org/fred2/series/CPIMEDSL/downloaddata?cid=32419>. Accessed April 23, 2012.

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. Gender and age (at the time of exposure) distributions for responders and survivors were assumed to be the same as current enrollees in the WTC Health Program. According to WTC Health Program data, males comprise 88 percent of the current responder enrollees and 50 percent of survivor enrollees. Because invasive cervical cancer occurs only in females and testicular cancer only occurs in males, the calculations take into account the applicable gender of the WTC Health Program members for the respective cancer type. The age distribution for current enrollees by gender and responder/survivor status is presented in Table B.

Table B--Percentiles of Current Age (on April 11, 2012) for Current Enrollees in the WTC Health Program by Gender and Responder/Survivor Status

Group	Age percentile (years)								
	Min	1	10	30	50	70	90	99	Max
Male responders	28	32	39	44	49	54	62	74	92
Female responders	28	30	38	44	49	54	62	76	92
Male survivors	12	23	35	46	52	58	67	81	99
Female survivors	12	21	38	49	54	60	68	84	95

The Administrator assumed race and ethnic origin distributions for responders and survivors according to

distributions in the WTC Health Registry cohort:⁵⁴ 57 percent non-Hispanic white, 15 percent non-Hispanic black, 21 percent Hispanic, and 8 percent other race/ethnicity for responders and 50 percent non-Hispanic white, 17 percent non-Hispanic black, 15 percent Hispanic, and 18 percent other race/ethnicity for survivors. 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 individuals 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 individuals 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 (since rates are currently available through 2008, the rate from 2008 was applied to 2009 and later).⁵⁵ A life-table analysis program, LTAS.NET, was used to estimate the expected number of

⁵⁴ 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, World Trade Center Disaster: Results from the World Trade Center Health Registry Cohort. *The Lancet* 378:879-887. Note: percentages may not sum to 100 percent due to rounding.

⁵⁵ Centers for Disease Control and Prevention, National Center for Health Statistics. Compressed Mortality File 1999-2008. CDC WONDER Online Database, compiled from Compressed Mortality File 1999-2008 Series 20 No. 2N, 2011. <http://wonder.cdc.gov/cmfile.html>. Accessed February 15, 2012.

incident cancers for cancer types added.⁵⁶ The Administrator calculated cancer incidence rates using data through 2006 from the Surveillance Epidemiology and End Results (SEER) Program, and estimated rates for 2007-2016.⁵⁷ 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 each cancer type starting from year 2002, the first full year following the September 11, 2001, terrorist attacks, to 2016, the last year for which this Program is currently funded.

Prevalence of Cancer

To determine the potential number of individuals in the responder and survivor populations with cancer, the Administrator used the number of incident cases described above for each year starting with 2002 and estimated the prevalence of cancer using survival rate statistics for each incident cancer group through 2016.⁵⁸

Using the incident cases and survival rate statistics for each cancer type, the Administrator has estimated the

⁵⁶ 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. *American Journal of Industrial Medicine* 54:915-924.

⁵⁷ National Cancer Institute, Surveillance Epidemiology and End Results (SEER). <http://seer.cancer.gov/>. Accessed May 27, 2012.

⁵⁸ Id.

prevalence (number of individuals living with cancer) of cases during the 15 year period (2002-2016) since September 11, 2001. The resulting table provides for each year from 2002 through 2016, the number of new cases occurring in that year (incidence), the number of individuals who died from their cancer in that year, and the number of individuals surviving up to 15 years beyond their first diagnosis (prevalence).⁵⁹ For example, in 2002 there are 6.82 projected new cases of testicular cancer, which would be listed as incident cases for that year. The survival rate for testicular cancer in the first year of diagnosis is 94.68 percent.⁶⁰ Therefore the number of deceased individuals in 2002 would be $6.82 \times (1 - 0.9468) = 0.36$. For the testicular cancer prevalence table, in year 2003, the number of incident cases would be 6.61 cases. In addition to 6.61 newly diagnosed cases in 2003, there would be the one-year survivors from 2002 which would be $6.82 - 0.36$ (or 6.82×0.9468) = 6.46 cases. This computation process can be repeated for each year through year 2016. A portion of the brain, invasive cervical, pancreatic, and testicular cancers prevalence tables are provided in Table

⁵⁹ The 15-year survival limit is imposed based on the analytic time horizon established between the triggering events of September 11, 2001 and the authorization of the WTC Health Program through 2016.

⁶⁰ National Cancer Institute, Surveillance Epidemiology and End Results (SEER). <http://seer.cancer.gov/>. Accessed May 27, 2012.

C1, C2, C3, and C4 respectively.

Prevalence tables were created for each type of covered cancer and the results are summarized in Tables E and G.

This analysis considers cancers diagnosed in 2002 through 2016.

Table C1-- Prevalence Table for Brain Cancer [Based on 80,000 responders]							
Year	Years since exposure to 9/11 agents			Years covered by WTC Health Program			
New/Surv.	2002	2003	2012	2013	2014	2015	2016
1	4.38	4.54	6.18	6.43	6.70	6.94	7.20
2		2.73	3.69	3.85	4.01	4.18	4.32
3			2.58	2.68	2.80	2.91	3.04
4			2.24	2.34	2.43	2.53	2.64
5			2.02	2.11	2.20	2.28	2.38
6			1.85	1.93	2.01	2.10	2.18
7			1.72	1.79	1.87	1.95	2.03
8			1.58	1.64	1.71	1.78	1.86
9			1.59	1.56	1.63	1.69	1.76
10			1.48	1.54	1.52	1.58	1.65
11			1.39	1.44	1.50	1.47	1.54
12				1.36	1.41	1.47	1.45
13					1.32	1.37	1.42
14						1.30	1.35
15							1.25
Live cases from previous years			20.15	22.25	24.39	26.61	28.85
Prevalence			26.32	28.68	31.09	33.55	36.05
Last year of life	1.65	2.46	4.07	4.29	4.49	4.70	4.91

Table C2-- Prevalence Table for Invasive Cervical Cancer [Based on 80,000 responders]						
Year	Years since 9/11 exposures			Years covered by WTC Health Program		
New/Surviving	2002	2003	2012	2014	2015	2016
1	1.17	1.21	1.24	1.23	1.22	1.22
2		1.06	1.12	1.12	1.12	1.11
3			1.01	1.01	1.00	1.00
4			0.95	0.95	0.95	0.95

5			0.91	0.92	0.92	0.92
6			0.87	0.89	0.89	0.89
7			0.86	0.88	0.88	0.89
8			0.83	0.86	0.87	0.87
9			0.87	0.84	0.85	0.86
10			0.84	0.82	0.83	0.84
11			0.81	0.86	0.82	0.83
12				0.83	0.85	0.81
13				0.80	0.82	0.85
14					0.80	0.82
15						0.79
Live cases from previous years			9.06	10.76	11.60	12.42
Prevalence	1.17	2.27	10.30	12.00	12.82	13.63
Last year of life	0.11	0.23	0.38	0.40	0.41	0.41

Table C3-- Prevalence Table for Pancreatic Cancer [Based on 80,000 responders]							
Year	Years since exposure to 9/11 agents			Years covered by WTC Health Program			
New/Surv.	2002	2003	2012	2013	2014	2015	2016
1	3.43	3.80	8.93	9.73	10.56	11.34	12.21
2		0.98	2.34	2.56	2.79	3.03	3.26
3			0.99	1.08	1.18	1.29	1.40
4			0.56	0.61	0.67	0.73	0.80
5			0.42	0.46	0.51	0.55	0.61
6			0.31	0.34	0.38	0.41	0.45
7			0.26	0.29	0.31	0.35	0.38
8			0.22	0.24	0.27	0.30	0.32
9			0.20	0.22	0.24	0.27	0.30
10			0.17	0.19	0.20	0.23	0.25
11			0.14	0.15	0.17	0.18	0.20
12				0.13	0.14	0.16	0.17
13					0.12	0.13	0.15
14						0.12	0.13
15							0.11
Live cases from previous years			5.60	6.27	6.98	7.74	8.51
Prevalence	3.43	4.78	14.53	15.87	17.28	18.67	20.17
Last year of life	2.45	3.24	8.25	9.02	9.80	10.57	11.39

Table C4-- Prevalence Table for Testicular Cancer [Based on 80,000 responders]						
Year	Years since 9/11 exposures			Years covered by WTC Health Program		
New/Surviving	2002	2003	2012	2014	2015	2016
1	6.82	6.61	4.23	3.72	3.44	3.20
2		6.46	4.24	3.76	3.52	3.26

3			4.27	3.80	3.56	3.34
4			4.41	3.93	3.71	3.48
5			4.60	4.13	3.89	3.67
6			4.80	4.33	4.10	3.86
7			5.02	4.55	4.32	4.09
8			5.20	4.78	4.54	4.31
9			5.47	5.00	4.77	4.54
10			5.65	5.19	5.00	4.77
11			5.78	5.42	5.14	4.96
12				5.57	5.38	5.11
13				5.73	5.55	5.36
14					5.70	5.53
15						5.66
Live cases from previous years			49.45	56.18	59.19	61.93
Prevalence	6.82	13.07	53.68	59.89	62.63	65.13
Last year of life	0.36	0.68	0.75	0.70	0.70	0.68

Cost Computation

To compute the costs for each type of cancer, the Administrator assumes that all of the individuals who are diagnosed with a cancer type will be certified by the WTC Health Program for treatment 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 2-15).

Using this procedure, a cost table was constructed for each year covered by the WTC Health Program and the results are presented in Tables D1, D2, D3, and D4. The row for Year 1 in each table is the cost of incident cases for that year. Rows for Years 2-15 show the cost from continuing care for individuals surviving n-years beyond the year of diagnosis. Finally, the cost of last year of life treatment is computed by multiplying the cost for last year of life by the number of individuals dying in that year from that type of cancer from Tables C1-C4.

Year	Years covered by the WTC Health Program		
	2014	2015	2016
1	\$364,737	\$377,541	\$391,595
2	\$25,526	\$26,617	\$27,552
3	\$17,833	\$18,569	\$19,363
4	\$15,463	\$16,128	\$16,793
5	\$14,003	\$14,535	\$15,160
6	\$12,812	\$13,365	\$13,872
7	\$11,906	\$12,404	\$12,939
8	\$10,899	\$11,358	\$11,832
9	\$10,369	\$10,786	\$11,240
10	\$9,661	\$10,080	\$10,485
11	\$9,543	\$9,384	\$9,791
12	\$9,015	\$9,367	\$9,211
13	\$8,391	\$8,710	\$9,050
14		\$8,261	\$8,574
15			\$7,967
Prevalent care	\$520,157	\$547,103	\$567,459
Last year of life care	\$454,701	\$476,561	\$497,829
Total	\$974,859	\$1,023,664	\$1,065,288

Table D2--Cost per 80,000 Responders for Invasive Cervical Cancer, 2011\$

Year	Years covered by the WTC Health Program		
	2014	2015	2016
1	\$37,922	\$37,599	\$37,379
2	\$1,200	\$1,198	\$1,188
3	\$1,078	\$1,075	\$1,073
4	\$1,021	\$1,022	\$1,019
5	\$984	\$983	\$984
6	\$951	\$957	\$956
7	\$938	\$944	\$951
8	\$919	\$928	\$933
9	\$902	\$911	\$920
10	\$880	\$894	\$903
11	\$917	\$875	\$889
12	\$893	\$916	\$873
13	\$858	\$883	\$906
14		\$853	\$878
15			\$843
Prevalent care	\$49,464	\$50,039	\$49,854
Last year of life care	\$14,485	\$14,806	\$15,008
Total	\$63,949	\$64,845	\$64,862

Table D3--Cost per 80,000 Responders for Pancreatic Cancer, 2011\$

Year	Years covered by the WTC Health Program		
	2014	2015	2016
1	\$224,967	\$241,545	\$260,083
2	\$14,713	\$15,977	\$17,155
3	\$6,232	\$6,791	\$7,374
4	\$3,516	\$3,858	\$4,204
5	\$2,671	\$2,908	\$3,190
6	\$1,989	\$2,174	\$2,367
7	\$1,660	\$1,818	\$1,988
8	\$1,411	\$1,556	\$1,705
9	\$1,273	\$1,411	\$1,556
10	\$1,072	\$1,188	\$1,317
11	\$871	\$957	\$1,061
12	\$757	\$836	\$919
13	\$627	\$694	\$767
14		\$627	\$694
15			\$570
Prevalent care	\$261,759	\$282,340	\$304,378
Last year of life care	\$831,446	\$896,398	\$965,711
Total	\$1,093,205	\$1,178,738	\$1,270,089

Table D4--Cost per 80,000 Responders for Testicular Cancer, 2011\$			
	Years covered by the WTC Health Program		
Year	2014	2015	2016
1	\$48,191	\$44,628	\$41,507
2	\$10,348	\$9,691	\$8,974
3	\$10,456	\$9,816	\$9,193
4	\$10,817	\$10,208	\$9,584
5	\$11,373	\$10,705	\$10,102
6	\$11,930	\$11,294	\$10,630
7	\$12,541	\$11,888	\$11,254
8	\$13,152	\$12,512	\$11,859
9	\$13,779	\$13,136	\$12,497
10	\$14,303	\$13,779	\$13,136
11	\$14,918	\$14,167	\$13,649
12	\$15,327	\$14,829	\$14,082
13	\$15,768	\$15,272	\$14,775
14		\$15,711	\$15,217
15			\$15,597
Prevalent care	\$202,903	\$207,634	\$196,458
Last year of life care	\$30,644	\$30,588	\$29,604
Total	\$233,548	\$238,222	\$226,062

The sum of the annual costs in each table for the years 2014 through 2016 represents the estimated treatment costs to the WTC Health Program for coverage of brain, invasive cervical, pancreatic, and testicular cancers, respectively, for 80,000 responders. The cost projections in Tables D1, D2, D3, and D4 are based on an assumed responder population size of 80,000.

The same process described above was applied to the survivor cohort. Based on the incidence rate expected from the survivor cohort, prevalence tables were constructed for each covered type of cancer.

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 population; and (2) the rate of cancer exceeds the general population rate by 21 percent due to their 9/11 exposures.⁶¹

A summary of the estimated prevalence at the U.S. population average for the assumed population of 58,500 responders and 6,500 survivors is provided in Table E. A summary of the estimated treatment costs to the WTC Health Program is provided in Table F.

A summary of the estimated prevalence using cancer rates 21 percent over the U.S. population average for the increased rate of 80,000 responders and 30,000 survivors is given in Table G. A summary of the estimated treatment costs to the WTC Health Program is provided in Table H.

Table E – Estimated prevalence by year and cancer type based on 58,500 and 6,500 responder and survivor population, respectively and assuming cancer rates at U.S. population average			
Cancer type	Prevalence (incident + live cases)		
	2014	2015	2016
Based on 58,500 responder population			

⁶¹ Zeig-Owens R, Webber MP, Hall CB, Schwartz T, Jaber N, Weakley J, Rohan TE, Cohen HW, Derman O, Aldrich TK, Kelly K, Prezant DJ [2011]. Early Assessment of Cancer Outcomes in New York City Firefighters After the 9/11 Attacks: An Observational Cohort Study. The Lancet. 378(9794):898-905. Limitations of the Zeig-Owens study include: limited information on specific exposures experienced by firefighters; short time for follow-up of cancer outcomes; speculation about the biological plausibility of chronic inflammation as a possible mediator between 9/11-exposure and cancer outcomes; and potential unmeasured confounders.

Brain	22.74	24.53	26.36
Cervix Uteri	8.77	9.38	9.97
Pancreas	12.83	13.95	15.16
Testis	43.80	45.80	47.62
Total	88.14	93.66	99.11
Based on 6,500 survivor population			
Brain	2.53	2.73	2.93
Cervix Uteri	0.97	1.04	1.11
Pancreas	1.43	1.55	1.68
Testis	4.87	5.09	5.29
Total	9.79	10.41	11.01

Table F – Estimated treatment costs by year and cancer type based on 58,500 and 6,500 responder and survivor population, respectively and assuming cancer rates at U.S. population average (2011 \$)				
Cancer type	2014	2015	2016	2014-2016
Based on 58,500 responder population				
Brain	\$712,865	\$748,555	\$778,992	\$2,240,412
Cervix Uteri	\$46,763	\$47,418	\$47,430	\$153,115
Pancreas	\$799,406	\$861,952	\$928,753	\$2,590,111
Testis	\$170,782	\$174,200	\$165,308	\$552,115
Total	\$1,729,816	\$1,832,125	\$1,920,482	\$5,482,423
Based on 6,500 survivor population				
Brain	\$76,302	\$79,634	\$82,372	\$238,308
Cervix Uteri	\$32,741	\$33,935	\$33,944	\$108,512
Pancreas	\$116,940	\$124,458	\$132,382	\$373,780
Testis	\$13,130	\$13,333	\$12,728	\$42,417
Total	\$239,113	\$251,360	\$261,426	\$751,898
Total				
Brain	\$789,167	\$828,189	\$861,364	\$2,478,720
Pancreas	\$916,346	\$986,410	\$1,061,135	\$2,963,891
Cervix Uteri	\$79,504	\$81,353	\$81,374	\$261,627
Testis	\$183,911	\$187,533	\$178,036	\$594,532
Total	\$1,968,928	\$2,083,485	\$2,181,909	\$6,298,770

Table G – Estimated prevalence by year and cancer type based on 80,000 and 30,000 responder and survivor population, respectively and assuming incidence of cancer is 21% higher than the U.S. population due to 9/11 exposure	
Cancer type	Prevalence (incident + live cases)

	2014	2015	2016
Based on 80,000 responder population			
Brain	37.62	40.60	43.62
Cervix Uteri	14.52	15.52	16.50
Pancreas	21.23	23.09	25.08
Testis	72.47	75.78	78.80
Total	145.84	154.98	163.99
Based on 30,000 survivor population			
Brain	14.11	15.22	16.36
Cervix Uteri	5.44	5.82	6.19
Pancreas	7.96	8.66	9.40
Testis	27.18	28.42	29.55
Total	54.69	58.12	61.50

Table H – Estimated treatment costs by year and cancer type based on 80,000 and 30,000 responder and survivor population, respectively and assuming incidence of cancer is 21% higher than the U.S. population due to 9/11 exposure (2011 \$)				
Cancer type	2014	2015	2016	2014-2016
Based on 80,000 responder population				
Brain	\$1,199,076	\$1,259,107	\$1,310,304	\$3,768,487
Cervix Uteri	\$78,658	\$79,760	\$79,780	\$238,198
Pancreas	\$1,344,642	\$1,449,848	\$1,562,209	\$4,356,699
Testis	\$287,263	\$293,014	\$278,056	\$858,333
Total	\$2,909,639	\$3,081,728	\$3,230,350	\$9,221,717
Based on 30,000 survivor population				
Brain	\$355,098	\$370,605	\$383,345	\$1,109,048
Cervix Uteri	\$152,371	\$157,927	\$157,972	\$468,270
Pancreas	\$544,220	\$579,209	\$616,087	\$1,739,515
Testis	\$61,103	\$62,050	\$59,234	\$182,387
Total	\$1,112,792	\$1,169,790	\$1,216,638	\$3,499,221
Total				
Brain	\$1,554,174	\$1,629,712	\$1,693,649	\$4,877,535
Cervix Uteri	\$231,029	\$237,686	\$237,752	\$706,468
Pancreas	\$1,888,862	\$2,029,057	\$2,178,296	\$6,096,215
Testis	\$348,366	\$355,063	\$337,290	\$1,040,719
Total	\$4,022,431	\$4,251,519	\$4,446,987	\$12,720,937

Cost of Cancer Screening

Costs of screening have been added to the summary estimates table below. The screening indicated by this rulemaking follows U.S. Preventive Services Task Force

(USPSTF) guidelines. The USPSTF recommends cervical cancer screening but does not recommend screening for brain, pancreatic, or testicular cancer. For cervical cancer, USPSTF recommends that females age 21-65 receive one Pap test every 3 years; females age 30-65, are recommended to receive one HPV screening every 5 years.⁶² Costs for screening were distributed according to these recommended screening rates. The cost for cytology (Pap test) was estimated at between \$26 and \$78 per person and the cost for HPV screening at between \$35 and \$77 per person based on current FECA rates.

Summary of Costs

Because the Administrator lacks data to account for either recoupment by health insurance or workers' compensation insurance or reduction by either health insurance or Medicare/Medicaid payments, the estimates offered here are reflective of estimated WTC Health Program costs only. 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

⁶² U.S. Preventive Services Task Force [2012]. Recommendation: Screening for Cervical Cancer. <http://www.uspreventiveservicestaskforce.org/uspstf/uspscerv.htm>. Accessed June 26, 2013.

(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 diagnoses of cancers that are WTC-related health conditions that might result from this action. Those costs were addressed in the interim final rule that established regulations for the WTC Health Program (76 FR 38914, July 1, 2011).

After the implementation of provisions of the Patient Protection and Affordable Care Act (Pub. L. 111-148) on January 1, 2014, all of the members and future members can be assumed to have or have access to medical insurance coverage other than through the WTC Health Program. Therefore, all treatment and screening costs to be paid by the WTC Health Program from 2014 through 2016 are considered transfers.

Table I describes the allocation of WTC Health Program transfer payments based on 58,500 responders and 6,500 survivors and, alternatively, 80,000 responders and 30,000 survivors.

Table I – Breakdown of estimated annual WTC Health Program costs and transfers, 58,500 and 80,000 responders and 6,500 and 30,000 survivors , 2014-2016, 2011\$	
	Annualized transfers for 2014-2016, 2011\$

	Discounted at 7 percent	Discounted at 3 percent
	Cancer Rate	
	U.S. Average	U.S. + 21%
58,500 Responders	\$1,706,502	
6,500 Survivors	\$234,123	
Cervical cancer screening	\$347,368	
65,000 Total	\$2,287,993	
80,000 Responders		\$2,982,174
30,000 Survivors		\$1,131,770
Cervical cancer screening		\$819,336
110,000 Total		\$4,933,280

Examination of Benefits (Health Impact)

This section describes qualitatively the potential benefits of the interim final rule in terms of the expected improvements in the health and health-related quality of life of potential cancer patients treated through the WTC Health Program, compared to no Program. The assessment of the health benefits for cancer patients uses the number of expected cancer cases that was estimated in the cost analysis section.

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 health care services

for cancers 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 broad trends on demographics and access to health insurance reported by the U.S. Census Bureau and health care services for cancer similar to those reported by Ward et al.⁶³ would apply to the population of general responders (those individuals who are not members of the FDNY and who meet the eligibility criteria in 42 CFR Part 88 for WTC responders) and survivors both within and outside the Program. For the purposes of this analysis, the Administrator assumes that access to health insurance and health care services for FDNY responders within and outside the Program would be equivalent because this population is likely covered by employer-based health insurance.

Although the Administrator cannot quantify the benefits associated with the WTC Health Program, enrollees with cancer would have improved access to care and thereby the Program should produce better treatment outcomes than in its absence. Under other insurance plans, patients would

⁶³ Ward E, Halpern M, Schrag N, Cokkinides V, DeSantis C, Bandi P, Siegel R, Stewart A, Jemal A [2008]. Association of Insurance with Cancer Care Utilization and Outcomes. CA Cancer J Clin 58:9-31.

have deductibles and copays, which impact access to care and particularly its timeliness. WTC Health Program members would have first-dollar coverage and hence are likely to seek care sooner when indicated, resulting in improved treatment outcomes.

Limitations

The analysis presented here was limited by the dearth of verifiable data on the 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

rule has “no significant economic impact upon a substantial number of small entities” within the meaning of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.).

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. 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, 2014). The Administrator has determined that no changes are needed to the information collection request already approved by OMB.

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 interim final 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. However, the rule may result in an increase in the contribution made by New York City for treatment and monitoring, as required by the PHS Act §3331(d)(2). For 2013, the inflation adjusted threshold is \$150 million.

F. Executive Order 12988 (Civil Justice)

This interim final 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.

G. Executive Order 13132 (Federalism)

The Administrator has reviewed this interim final 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 interim final rule on children. The Administrator has determined that the rule would have no environmental health and safety effect on children, although an eligible child who has been diagnosed with any cancer type may seek certification of the condition by the Administrator.

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 interim final 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 interim final 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, Health care, Mental health conditions, Musculoskeletal disorders, Respiratory and pulmonary diseases.

Final Rule

For the reasons discussed in the preamble, the

Department of Health and Human Services amends 42 CFR Part 88 as follows:

PART 88--WORLD TRADE CENTER HEALTH PROGRAM

1. The authority citation for Part 88 continues to read as follows:

Authority: 42 U.S.C. 300mm--300mm-61, Pub. L. 111-347, 124 Stat. 3623.

2. In § 88.1, revise paragraph (4) of the definition of "List of WTC-related health conditions" to read as follows:

§ 88.1 Definitions.

* * * * *

List of WTC-related health conditions * * *

(4) Cancers:

- (i) Malignant neoplasms of the lip, tongue, salivary gland, floor of mouth, gum and other mouth, tonsil, oropharynx, hypopharynx, and other oral cavity and pharynx.
- (ii) Malignant neoplasm of the nasopharynx.
- (iii) Malignant neoplasms of the nose, nasal cavity, middle ear, and accessory sinuses.
- (iv) Malignant neoplasm of the larynx.
- (v) Malignant neoplasm of the esophagus.

- (vi) Malignant neoplasm of the stomach.
- (vii) Malignant neoplasm of the colon and rectum.
- (viii) Malignant neoplasm of the liver and
intrahepatic bile duct.
- (ix) Malignant neoplasms of the retroperitoneum
and peritoneum, omentum, and mesentery.
- (x) Malignant neoplasms of the trachea; bronchus
and lung; heart, mediastinum and pleura; and
other ill-defined sites in the respiratory
system and intrathoracic organs.
- (xi) Mesothelioma.
- (xii) Malignant neoplasms of the peripheral nerves
and autonomic nervous system, and other
connective and soft tissue.
- (xiii) Malignant neoplasms of the skin (melanoma
and non-melanoma), including scrotal cancer.
- (xiv) Malignant neoplasm of the female breast.
- (xv) Malignant neoplasm of the ovary.
- (xvi) Malignant neoplasm of the prostate.
- (xvii) Malignant neoplasm of the urinary bladder.
- (xviii) Malignant neoplasm of the kidney.
- (xix) Malignant neoplasms of the renal pelvis,
ureter and other urinary organs.

- (xx) Malignant neoplasms of the eye and orbit.
- (xxi) Malignant neoplasm of the thyroid.
- (xxii) Malignant neoplasms of the blood and lymphoid tissues (including, but not limited to, lymphoma, leukemia, and myeloma).
- (xxiii) Childhood cancers: any type of cancer diagnosed in a person less than 20 years of age.
- (xxiv) Rare cancers: any type of cancer¹ that occurs in less than 15 cases per 100,000 persons per year in the United States.

* * * * *

Dated: January 8, 2014.

John Howard, M.D.
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

¹Based on 2005-2009 average annual data age-adjusted to the 2000 U.S. population. See, Copeland G, Lake A, Firth R, Wohler B, Wu XC, Stroup A, Russell C, Boyuk K, Schymura M, Hofferkamp J, Kohler B (eds) [2012]. 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.

[FR Doc. 2014-03370 Filed 02/14/2014 at 8:45 am; Publication Date: 02/18/2014]