DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. CDC–2012–0007; NIOSH–257]

42 CFR Part 88

RIN 0920–AA49

World Trade Center Health Program; Addition of Certain Types of Cancer to the List of WTC-Related Health Conditions

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: Title I of the James Zadroga 9/11 Health and Compensation Act of 2010 amended the Public Health Service Act (PHS Act) to establish the World Trade Center (WTC) Health Program. The WTC Health Program, which is administered by the Director of the National Institute for Occupational Safety and Health (NIOSH), within the Centers for Disease Control and Prevention (CDC), provides medical monitoring and treatment to eligible firefighters and related personnel, law enforcement officers, and rescue, recovery, and cleanup workers who responded to the September 11, 2001, terrorist attacks in New York City, at the Pentagon, and in Shanksville, Pennsylvania, and to eligible survivors of the New York City attacks. In accordance with our regulations, which establish procedures for adding a new condition to the list of health conditions covered by the WTC Health Program, this proposed rule would add certain types of cancer to the List of WTC-Related Health Conditions.

DATES: Comments must be received by July 13, 2012.

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.
- *Facsimile:* (513) 533–8285.

Instructions: All submissions received must include the agency name (Centers for Disease Control and Prevention, HHS) and docket number (CDC–2012–007; NIOSH–257) or Regulation Identifier Number (0920–AA49) 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* or *http://www.cdc.gov/niosh/docket/archive/docket257.html.*

FOR FURTHER INFORMATION CONTACT: Frank J. Hearl, PE, Chief of Staff, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Patriots Plaza, Suite 9200, 395 E St. SW., Washington, DC 20201. Telephone: (202) 245–0625 (this is not a toll-free number). Email: *WTCpublicinput@cdc.gov.*

SUPPLEMENTARY INFORMATION: This notice of proposed rulemaking is organized as follows:

I. Executive Summary

A. Purpose of Regulatory Action

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) establishing the World Trade Center (WTC) Health Program within the Department of Health and Human Services (HHS). The PHS Act requires the WTC Program Administrator (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 whether the Administrator adds a health condition based on the findings from periodic reviews of cancer,[1] based on a request from a petition, or based on a determination made at the Administrator's discretion that a proposed rule adding a condition should be initiated. Following a petition to add cancer or certain types of cancer to the List and a recommendation by the WTC Health Program's Scientific/Technical Advisory Committee (STAC), the Administrator is following the procedures established in 42 CFR 88.17 to add some, but not all types of cancer recommended by the petition.

B. Summary of Major Provisions

This rule modifies the List of WTC-Related Health Conditions in 42 CFR 88.1 to add the following conditions (types of cancer identified by ICD–10 code are specified in the discussion below):

- Malignant neoplasms of the lip, tongue, salivary gland, floor of mouth, gum and other mouth, tonsil, oropharynx, hypopharynx, and other oral cavity and pharynx
- Malignant neoplasm of the nasopharynx
- Malignant neoplasms of the nose, nasal cavity, middle ear, and accessory sinuses
- Malignant neoplasm of the larynx
- Malignant neoplasm of the esophagus
- Malignant neoplasm of the stomach
- Malignant neoplasm of the colon and rectum
- Malignant neoplasm of the liver and intrahepatic bile duct
- Malignant neoplasms of the retroperitoneum and peritoneum, omentum, and mesentery
- Malignant neoplasms of the trachea; bronchus and lung; heart, mediastinum and pleura; and other ill-defined sites in the respiratory system and intrathoracic organs

[1] See PHS Act, Title XXXIII § 3312(a)(5).

- Mesothelioma
- Malignant neoplasms of the soft tissues (sarcomas)
- Malignant neoplasms of the skin (melanoma and non-melanoma), including scrotal cancer
- Malignant neoplasm of the breast
- Malignant neoplasm of the ovary
- Malignant neoplasm of the urinary bladder
- Malignant neoplasm of the kidney
- Malignant neoplasms of renal pelvis, ureter and other urinary organs
- Malignant neoplasms of the eye and orbit
- Malignant neoplasm of the thyroid
- Malignant neoplasms of the blood and lymphoid tissues (including, but not limited to, lymphoma, leukemia, and myeloma)
- Childhood cancers
- Rare cancers

The Administrator developed a hierarchy of methods (detailed in section III.D of this preamble) for determining which cancers to propose for inclusion on the List of WTC-Related Health Conditions. HHS is seeking comments on the proposed methods in this rule.

C. Costs and Benefits

Annual costs, benefits, and transfers of this rule are listed in the table below. This analysis estimates the impact on WTC Health Program costs using the number of persons currently enrolled in the program as responders and survivors and assumes that the rate of cancer in the population will be equal to the U.S. population average rate. An alternative analysis considers the impact on costs if the Program enrolls additional persons up to the Program's statutory limits, and that the expanded population experiences a 21 percent higher rate of cancer than the U.S. population average. The basis for these assumptions is explained in detail in the preamble of this rulemaking.

Although we cannot quantify the benefits associated with the WTC Health Program, enrollees with cancer are expected to experience a higher quality of care than they would in the absence of the Program. Mortality and morbidity improvements for cancer patients expected to enroll in the WTC Health Program are anticipated because barriers may exist to access and delivery of quality health care services for cancer patients in the absence of the services provided by the WTC Health Program. HHS anticipates benefits to cancer patients treated through the WTC Health Program, who may otherwise not have access to health care services, to accrue in 2013. Starting in 2014, continued implementation of the Affordable Care Act will result in increased access to health insurance and improved health care services for the general responder and survivor population that currently is uninsured.

ESTIMATED ANNUAL WTC HEALTH PROGRAM COSTS, BENEFITS, AND TRANSFERS, 55,000 RESPONDERS AND 5,000 SURVIVORS AT U.S. POPULATION CANCER RATE, AND 80,000 RESPONDERS AND 30,000 SURVIVORS AT U.S. POPULATION CANCER RATE + 21 PERCENT, 2013–2016, 2011$

	Societal Costs for 2013, 2011$		Annualized Transfers for 2013–2016, 2011$	
	Based on the 16.3 percent of general responders and survivors who are expected to be uninsured		Discounted at 7 percent	Discounted at 3 percent
	Cancer Rate		Cancer Rate	
	U.S. Average	U.S. + 21%	U.S. Average	U.S. + 21%
55,000 Responders	$1,648,706	.....	$10,172,308	.....
5,000 Survivors	271,427	.....	1,572,907	.....
Colorectal and Breast Screening	204,491	.....	713,321	.....
60,000 Total	2,124,624	.....	12,458,535	.....
80,000 Responders	.....	$2,631,100	.....	$19,912,464
30,000 Survivors	.....	1,970,560	.....	12,124,118
Colorectal and Breast Screening	.....	417,521	.....	1,271,478
110,000 Total	.....	5,019,182	.....	33,308,060

Qualitative benefits:

Although we cannot quantify the benefits associated with the WTC Health Program, enrollees with cancer are expected to experience a higher quality of care than they would in the absence of the Program. Mortality and morbidity improvements for cancer patients expected to enroll in the WTC Health Program are anticipated because barriers may exist to access and delivery of quality health care services for cancer patients in the absence of the services provided by the WTC Health Program. HHS anticipates benefits to cancer patients treated through the WTC Health Program, who may otherwise not have access to health care services, to accrue in 2013. Starting in 2014, continued implementation of the Affordable Care Act will result in increased access to health insurance and improved health care services for the general responder and survivor population that currently is uninsured.

II. Public Participation

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

1. The four methods proposed to evaluate evidence for the addition of types of cancer to the List of WTC-Related Health Conditions;

2. Information or published studies about the type of welding that occurred in the New York City disaster area, at the Pentagon, or at Shanksville, Pennsylvania with regard to metal

cutting not involving exposure to ultraviolet light and welding involving ultraviolet light exposure; and

3. Information or published studies about work hours scheduling or shiftwork occurring in the New York City disaster area, at the Pentagon, or in Shanksville, Pennsylvania.

Comments submitted electronically or by mail should be titled ''Docket No. CDC–2012–0007; NIOSH–257,'' addressed to the ''NIOSH Docket Officer,'' and should identify the author(s) and contact information (such as return address, email address, or phone number), in case clarification is needed. Electronic and written comments can be submitted to the addresses provided in the **ADDRESSES** section, above. All communications received on or before the closing date for comments will be fully considered by the Administrator of the WTC Health Program.

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 XXXIII [2] establishing the World Trade Center (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 who responded to the September 11, 2001, terrorist attacks in New York City, at the Pentagon, and in Shanksville, Pennsylvania, and to eligible survivors of the New York City attacks.

All references to the Administrator of the WTC Health Program (Administrator) in this notice mean the NIOSH Director or his or her designee. Title XXXIII, § 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. Addition of Health Conditions to the List of WTC-Related Health Conditions

Under 42 CFR 88.17, the Administrator has established a process by which health conditions may be considered for addition to the List of WTC-Related Health Conditions in § 88.1. Pursuant to § 3312(a)(6) of Title XXXIII of the PHS Act, the Administrator is required to publish a notice of proposed rulemaking and allow interested parties to comment on the proposed rule. The proposed rule may be initiated by the Administrator whenever he or she determines that a proposed rule should be promulgated to add a health condition (*e.g.,* when a review of WTC Health Program monitoring data reveals the prevalence of a condition not previously identified in Title XXXIII or by the Program), on the basis of the WTC Health Program's periodic review of all available scientific and medical evidence of cancer or a certain type of cancer pursuant to § 3312(a)(5) of Title XXXIII, or in response to a petition submitted by an interested party. Upon receipt of a petition from an interested party to add a condition to the List of WTC-Related Health Conditions, the Administrator is authorized to request a recommendation of the WTC Health Program STAC; or publish a proposed rule to add such health condition; or publish the Administrator's determination not to publish a proposed rule and the basis for that determination; or to publish a determination that insufficient evidence exists to take action.

C. Need for Rulemaking

On September 7, 2011, the Administrator of the WTC Health Program 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 under the Zadroga Act'' to the List in § 88.1. [Maloney, *et al.* 2011]

On October 5, 2011, the Administrator formally exercised his option to request a recommendation from the STAC regarding the petition (PHS Act, Title XXXIII, § 3312(a)(6)(B)(i); 42 CFR 88.17(a)(2)(i)). The Administrator requested that the STAC ''review the available information 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.'' [Howard 2011] The background to this rulemaking and a discussion of the STAC's recommendation are provided below.

D. Addition of Certain Types of Cancer to the List of WTC-Related Health Conditions

To determine whether the scientific evidence is sufficient to support the addition of cancer or types of cancer to the List of WTC-Related Health Conditions, the Administrator considered data from five information sources: (1) Peer-reviewed studies published in the scientific literature, including environmental sampling data, epidemiologic studies on the 9/11 exposed populations, and studies providing evidence of a causal relationship between a type of cancer and a condition already on the List of WTC-Related Health Conditions; (2) findings and recommendations solicited from the WTC Clinical Centers of Excellence and Data Centers, the WTC Health Registry at the New York City Department of Health and Mental Hygiene, and the New York State Department of Health; (3) information from the public solicited through a request for information published in the **Federal Register** on March 8, 2011 and March 29, 2011; (4) the findings of the National Toxicology Program (NTP) in the National Institute of Environmental Health Sciences, HHS, as well as the World Health Organization's International Agency for Research on Cancer (IARC); and (5) findings from other sources of information relevant to 9/11 exposures, including the expert judgment and personal experiences of STAC members, and comments from the public.

NTP, an interagency program that evaluates agents of public health concern using toxicology and molecular biology, publishes the biennial Report on Carcinogens (RoC), which contains a list of human carcinogens, exposure information, and descriptions of Federal exposure limits.[3] The RoC classifies agents in one of two ways: *known to be a human carcinogen,* and *reasonably anticipated to be a human carcinogen;* this classification is determined by an expert panel convened for each candidate substance and is based on an evaluation of the published, peer-reviewed literature and reviews conducted by Federal agencies and IARC. Unlike IARC, NTP does not identify specific types of cancer that have sufficient evidence of carcinogenicity.

IARC, which coordinates and conducts research on the causes of human cancer and the mechanisms of carcinogenesis, maintains a series of

[2] Title XXXIII of the Public Health Service 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 World Trade Center Health Program and are codified elsewhere.

[3] NTP Report on Carcinogens (RoC). *http://ntp.niehs.nih.gov/?objectid=72016262-BDB7-CEBA-FA60E922B18C2540.* Accessed May 9, 2012.

Monographs on the carcinogenic risks to humans caused by chemicals, complex mixtures, occupational exposures, physical agents, biological agents, and lifestyle factors. In the Monographs, carcinogens are categorized according to whether they provide *sufficient* evidence of carcinogenicity in humans for a certain type of cancer (Group 1); or *limited* evidence of carcinogenicity in humans, including agents probably carcinogenic to humans (Group 2A) and agents possibly carcinogenic to humans (Group 2B); whether they are not classifiable as to carcinogenicity in humans (Group 3); or whether there is evidence suggesting lack of carcinogenicity (Group 4).[4] IARC convenes working groups of international experts to develop each Monograph based on reviews of epidemiological, animal, and mechanistic data ''that have been published or accepted for publication in the openly available scientific literature,'' although ''[i]n certain instances, government agency reports that have undergone peer review and are widely available are considered.'' [IARC 2006]

In July 2011, the Administrator released the *First Periodic Review of the Scientific and Medical Evidence Related to Cancer for the World Trade Center Health Program* (*First Periodic Review*). [NIOSH 2011] As required by Title XXXIII, § 3312(a)(5)(A) of the PHS Act, the Administrator reviewed ''all available scientific and medical evidence, including findings and recommendations of Clinical Centers of Excellence, published in peer-reviewed journals to determine if, based on such evidence, cancer or a certain type of cancer should be added to the applicable list of WTC-related health conditions.'' As described in the *First Periodic Review,* environmental sampling identified 287 chemicals and chemical groups as present in the New York City disaster area (referred to herein as ''9/11 agents'' [5]). [COPC 2003] Published exposure assessments reviewed by the Administrator in the *First Periodic Review* ''suggest that responders and others in the nearby area were potentially exposed to one or more of the substances designated by IARC and NTP as known or reasonably anticipated human carcinogens, although generally not in excess of applicable occupational exposure limits.'' [NIOSH 2011]

At the time of publication, the *First Periodic Review* [NIOSH 2011] identified only one peer-reviewed article addressing the association of exposures arising from the September 11, 2001, terrorist attacks and cancer in responders and survivors, and two publications that used models to estimate the risk of cancer among residents in Lower Manhattan. The Administrator used a ''weight of the evidence'' approach to evaluate data derived from information sources (1)–(3), discussed above, and reported that insufficient evidence existed at that time to propose the addition of cancer or certain types of cancer to the List of WTC-Related Health Conditions.

In September 2011, an epidemiologic study was published in *The Lancet.* The study, by Rachel Zeig-Owens and colleagues, ''identified a modest effect of WTC exposure for all cancers combined by comparing the ratios in the exposed group [of Fire Department of New York City firefighters] to those in the non-exposed group.'' [Zeig-Owens, *et al.* 2011] This publication led to the submission of Petition 001.

In the petition, which was received shortly after publication of the Zeig-Owens study, the petitioners stated they ''read with great concern * * * the study conducted by the New York City Fire Department and published last week in *The Lancet* that indicated an elevated risk of melanoma, thyroid and prostate cancer, and non-Hodgkin lymphoma among firefighters who served at ground zero.'' While they ''feel strongly there must be a scientific basis for adding coverage for new conditions under the Zadroga Act,'' petitioners state that ''given the severity of the illnesses reported in *The Lancet,* we also want to make sure that this and other peer-reviewed studies linking cancers to the [September 11, 2001] attacks are evaluated as expeditiously as possible.'' [Maloney, *et al.* 2011]

Title XXXIII, § 3302(a)(1) establishes the STAC, and charges it to ''review scientific and medical evidence and to make recommendations to the Administrator on additional WTC Program eligibility criteria and on additional WTC-related health conditions.'' Accordingly, when asked by the Administrator to provide a recommendation on Petition 001, the STAC established evidentiary criteria and assessed the weight of the available scientific evidence provided by information sources (1), (4), and (5), described above. The STAC found support for including a number of types of cancer based in part on evidence of increased risk reported in Zeig-Owens.[6] The STAC also included a number of types of cancer based on the professional judgment of STAC members with scientific expertise, on the personal experience of some of the STAC members who were themselves WTC responders or survivors, and on comments made by the public.

Unlike the explicit language in Title XXXIII, § 3312(a)(5)(A) of the PHS Act, which prescribes the standard to be used in the periodic reviews of cancer, § 3312(a)(6) does *not* specifically limit the type of sources upon which the Administrator may base his or her determination to propose the addition of cancer or types of cancer to the List of WTC-Related Health Conditions. In this action, the Administrator's determination is based on the information sources used in the *First Periodic Review,* the NTP's RoC, the IARC Monographs, and from all other scientific information provided by the STAC, including the Zeig-Owens study which has been added to the peer-reviewed epidemiologic literature and is discussed below.

As discussed extensively below, the Administrator has adopted a formal methodology to evaluate the available scientific evidence. The formal methodology follows on criteria used by the STAC in its recommendation and is presented below, in section III.D.3.[7]

Based upon the new methodology, the Administrator proposes to add the types of cancer identified in section III.D.4., below, to the List of WTC-Related Health Conditions. The Administrator seeks comment on the methods developed, and the application of those methods, to add cancer or a type of cancer to the List of WTC-Related Health Conditions.

[4] WHO International Agency for Research on Cancer (IARC). *http://monographs.iarc.fr/.* Accessed May 8, 2012.

[5] Several other agents were recommended by the STAC, verified in the published literature, and are also considered 9/11 agents. The agents identified at the Pentagon and in Shanksville, Pennsylvania were reviewed but no additional agents were identified.

[6] 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 WTC-exposure and cancer outcomes; and potential unmeasured confounders.

[7] The Administrator's methodology does not incorporate the standard established in Title XXXIII, § 3312(a)(2) to determine whether an individual can be diagnosed with a WTC-related health condition—that individual standard requires a determination that the terrorist attacks ''were substantially likely to be a significant factor in aggravating, contributing to, or causing the [individual's] illness or health condition.'' The WTC Health Program regulations at 42 CFR 88.1 define the ''List of WTC-related health conditions'' differently than a ''WTC-related health condition'' [in an individual]. For more information on the topic of certification of an individual, see Section III.D.6. below.

1. STAC Recommendations

In response to the Administrator's October 5, 2011 request, the STAC met on three occasions—November 9–10, 2011, February 15–16, 2012, and March 28, 2012—to deliberate and develop recommendations on Petition 001 for the Administrator's consideration. The Administrator received the STAC recommendations on April 2, 2012. [STAC 2012]

In its April 2, 2012 recommendation to the Administrator, the chair of the STAC wrote that the STAC had:

> [R]eviewed available information on cancer outcomes that may be associated with the exposures resulting from the September 11, 2001, terrorist attacks, and believes that exposures resulting from the collapse of the buildings and high-temperature fires are likely to increase the probability of developing some or all cancers. This conclusion is based primarily on the presence of approximately 70 known and potential carcinogens in the smoke, dust, volatile and semi-volatile contaminants identified at the World Trade Center site. Fifteen of these substances are classified by the International Agency for Research on Cancer (IARC) as known to cause cancer in humans, and 37 are classified by the National Toxicology Program (NTP) as reasonably anticipated to cause cancer in humans; others are classified by IARC as probable and possible carcinogens. Many of these carcinogens are genotoxic and it is therefore assumed that any level of exposure carries some risk. [STAC 2012]

In its recommendation, the STAC also noted that ''exposure data are extremely limited.'' The STAC summarized the state of exposure assessment relevant to the terrorist attacks in New York City:

> No data were collected in the first 4 days after the attacks [in New York City], when the highest levels of air contaminants occurred, and the variety of samples taken on or after September 16, 2001 are insufficient to provide quantitative estimates of exposure on an individual or area level. However, the committee considers that the high prevalence of acute symptoms and chronic conditions observed in large numbers of rescue, recovery, cleanup and restoration workers and survivors, as well as qualitative descriptions of exposure conditions in downtown Manhattan, represent highly credible evidence that significant toxic exposures occurred. Furthermore, the salient biological reaction that underlies many currently recognized WTC health conditions—persistent inflammation—is now believed to be an important mechanism underlying cancer through generating DNA-reactive substances, increasing cell turnover, and releasing biologically active substances that promote tumor growth, invasion and metastasis.

In its recommendation to the Administrator, the STAC wrote:

> The committee deliberated on whether to designate all cancers as WTC-related conditions or to list only cancers with the strongest evidence. Some members proposed to include all cancers based on the incomplete and limited epidemiological data available to identify specific cancers, and others argued for the alternative of listing specific cancers based on best available evidence. The committee agreed to proceed by generating a list of cancers potentially related to WTC exposures based on evidence from three sources. [STAC 2012]

The STAC based its Petition 001 recommendation regarding the addition of certain types of cancer on evidence from four sources:

> 1. 9/11 agents (those known and potential carcinogens identified in the New York City disaster area) with *limited* or *sufficient* evidence of carcinogenicity in humans based on International Agency for Research on Cancer (IARC) Monographs on the Evaluation of Carcinogenic Risks to Humans [8];
>
> 2. Cancers arising from regions of the respiratory and digestive tracts where inflammatory conditions, such as gastroesophageal reflux disease (GERD), have been documented;
>
> 3. Cancers for which epidemiologic studies have found some evidence of increased risk in WTC responder and survivor populations; and
>
> 4. 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.

Based on these four evidentiary sources, the STAC recommended to the Administrator that the following 14 cancer groups, encompassing many types of cancer, be added to the List of WTC-Related Health Conditions in 42 CFR 88.1:

> 1. Malignant neoplasms of the respiratory system (including nose, nasal cavity and middle ear, larynx, lung and bronchus, pleura, trachea, mediastinum, and other respiratory organs);
>
> 2. Certain cancers of the digestive system, including esophagus, stomach, colon and rectum, liver and intrahepatic bile duct, retroperitoneum, peritoneum, omentum, and mesentery;
>
> 3. Cancers of the oral cavity and pharynx, including lip, tongue, salivary gland, floor of mouth, gum and other mouth, nasopharynx, tonsil, oropharynx, hypopharynx and other oral cavity, and pharynx;
>
> 4. Soft tissue sarcomas;
>
> 5. Melanoma and non-melanoma skin cancers, including scrotal cancer;
>
> 6. Mesothelioma of the pleura and peritoneum;
>
> 7. Cancer of the ovary;
>
> 8. Cancers of the urinary tract, including urinary bladder, kidney and renal pelvis, ureter, and other urinary organs;
>
> 9. Cancer of the eye and orbit;
>
> 10. Thyroid cancer;
>
> 11. Lymphoma, leukemia, and myeloma;
>
> 12. Breast cancer;
>
> 13. Childhood cancers (all cancers diagnosed in persons less than 20 years old); and
>
> 14. Rare cancers.

In its recommendation to the Administrator, the STAC also made four additional points.

First, the STAC recommended that as new epidemiologic studies of 9/11-exposed populations become available, the studies' findings ''be reviewed and modifications made to the list as appropriate.'' [STAC 2012]

Second, the STAC recommended that the WTC Health Program provide funding and guidelines for medical screening and early detection of cancer and appropriate counseling. [STAC 2012]

Third, the STAC emphasized that although evidence of carcinogenicity of 9/11 agents from animal studies or mechanistic studies exists,

> because there is limited concordance between specific cancer sites affected in humans and in animals, only those substances classified based on human data are informative regarding organ sites of carcinogenicity in humans. [STAC 2012]

Fourth, the STAC noted:

> In addition to the evidence considered by the committee to identify potential WTC-related cancers, arguments in favor of listing cancer as a WTC-related condition include the presence of multiple exposures and mixtures with the potential to act synergistically and to produce unexpected health effects; the major gaps in the data with respect to the range and levels of carcinogens, the potential for heterogeneous exposures and hot spots representing exceptionally high or unique exposures both on the WTC site and in surrounding communities, the potential for bioaccumulation of some of the compounds, limitations of testing for carcinogenicity of many of the 287 agents and chemical groups cited in the first NIOSH Periodic Review, and the large volume of toxic materials present in the WTC towers. [STAC 2012]

Finally, the STAC stated that

> [A]lthough acknowledging some lack of certainty in the evidence for targeting specific organs or organ site groupings as WTC-related, the majority of the committee agreed that recommending the specified cancer sites and site groupings was based on a sound scientific rationale and the best evidence available to date. [STAC 2012]

2. Administrator's Review of Available Scientific Information and the STAC's Recommendations

The Administrator agrees with the STAC that individual exposure assessment information arising from the terrorist attacks is extremely limited and that its absence impairs definitive

[8] See IARC *http://monographs.iarc.fr/ENG/Monographs/PDFs/index.php.*

scientific analysis of the relationship between exposures arising from the attacks and the occurrence of any specific type of cancer. Also absent at the present time are multiple epidemiologic studies of cancer in exposed responders and survivors which definitively support an association between 9/11 exposures and specific types of cancer that would meet generally well-accepted criteria indicating that the association is a causal one.

As noted in the *First Periodic Review:*

> Drawing causal inferences about exposures resulting from the September 11, 2001, terrorist attacks and the observation of cancer cases in responders and survivors is especially challenging since cancer is not a rare disease. In the United States, the probability that a person will develop cancer during their lifetime is one in two for men and one in three for women [ACS 2010]. This 'background' rate of cancer development would be expected in responders and survivors even if the September 11, 2001, terrorist attacks had never occurred. Determining, then, if the September 11, 2001, exposures are contributing to an additional burden of cancer in responders and survivors is a scientific challenge. [NIOSH 2011]

Also noted in the *First Periodic Review,* an important framework used by epidemiologists to assess the causal nature of an observed association is the ''Bradford Hill criteria.'' [Hill 1965] The criteria are not intended to be a rigorous checklist, although they are often viewed in that way. None of the nine Bradford Hill criteria are alone sufficient to establish causation; together they can provide a starting point in evaluating whether an observed association is indeed a causal one. Five of those criteria are used by the Administrator in this rulemaking to evaluate evidence of a causal relationship between 9/11 exposures and a type of cancer: *Strength* of the association reported in the study between exposure agents and the type of cancer; *consistency* of the findings across multiple studies of exposed populations; *biological gradient* or dose-response relationship between exposures and the type of cancer; and *plausibility* and *coherence* of the findings with known facts about the biology of the type of cancer.[9]

Given the limitations of the current peer-reviewed scientific literature on cancer and 9/11 exposures, the Administrator agrees with the approaches the STAC used to recommend cancers for addition to the List of WTC-Related Health Conditions, but seeks additional information or published studies that are informative on the subject of adding certain types of cancer to the List of WTC-Related Health Conditions (Section III.D.5).

First, the STAC approach recommended including types of cancer for which IARC has categorized known 9/11 agents as having *sufficient* (Group 1 carcinogens) or *limited* (Group 2A *probable* carcinogens and Group 2B *possible* carcinogens) evidence for human carcinogenicity. IARC describes the evidence for carcinogenicity in humans as *sufficient* when a causal relationship has been established between exposure to the agent and human cancer. That is, a positive relationship has been observed between the exposure and a type of cancer in studies in which chance, bias, and confounding could be ruled out with reasonable confidence. IARC describes the evidence as *limited* when a positive association has been observed between the exposure and the cancer, and the IARC working group considered a causal interpretation to be credible but could not rule out chance, bias, or confounding with reasonable confidence. The Administrator has made the judgment that an IARC determination that the epidemiologic evidence for a 9/11 agent is *sufficient* or *limited* for a type of cancer qualifies the type for inclusion in the List of WTC-Related Health Conditions. The Administrator has further determined that evidence of exposure to 9/11 agents at any of the three sites—the New York City disaster area, the Pentagon, or Shanksville, Pennsylvania—qualifies for proposing the inclusion of a cancer type. The Administrator has also determined that cancers at sites in close anatomical proximity to sites proposed for inclusion under Method 3 (described in III.D.3., below) may also be added since it is often difficult to distinguish the cancer's anatomical origin especially when cancers from closely proximate sites are histopathologically indistinguishable.

Second, the STAC drew attention to types of cancers which arise in regions of the respiratory and digestive tracts where inflammatory conditions have been documented, some of which are health conditions already on the List of WTC-Related Health Conditions, including WTC-related health conditions of the upper and lower airway, and gastroesophageal reflux disease (GERD). The STAC cited several peer-review scientific publications about current scientific thinking on the relationship between inflammation and cancer.

The Administrator agrees that a type of cancer may be added to the List if there is well-established scientific support for a causal relationship between that cancer and a WTC-related health condition already on the List. For example, when a WTC-related health condition (*e.g.,* GERD) has been determined to be causally associated by means of multiple epidemiologic studies with the development of a particular type of cancer (*e.g.,* esophageal cancer), the cancer type can be added to the List of WTC-Related Health Conditions.

Third, the STAC included types of cancer based on an epidemiologic cohort study that identified a modest effect of WTC exposure for all cancers combined in exposed FDNY firefighters. [Zeig-Owens, *et al.* 2011] The STAC reviewed the Zeig-Owens study, which reported a 32 percent increase in the incidence of cancer among 9/11-exposed firefighters compared with non-exposed firefighters (Standardized Incidence Ratio (SIR) 1.32; 95% Confidence Interval (CI) 1.07–1.62). After correcting for possible surveillance bias, the increase was reduced to 21 percent (SIR 1.21; 95% CI 0.98–1.49). [Zeig-Owens, *et al.* 2011]

The Administrator believes that it is plausible that the overall rate of cancer cases in FDNY firefighters may have increased following those firefighters' exposures to 9/11 agents, but agrees with the authors of the Zeig-Owens study who noted there could be other explanations for the findings:

> We remain cautious in our interpretation of these findings because 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 WTC-exposure and cancer outcomes remains speculative. [Zeig-Owens, *et al.* 2011]

The Administrator notes that the STAC recommended inclusion of five site-specific cancer types based on findings in the Zeig-Owens study when the incidence of certain types of cancer in exposed firefighters was compared to non-exposed firefighters. These cancers are stomach, colon (excluding rectum), melanoma, non-Hodgkin lymphoma, and thyroid. The Zeig-Owens study is

[9] Four Bradford Hill criteria were not considered because, while useful in considering all sources of information, as the NTP and IARC reviews do, they have limited value when considering only the cancer epidemiologic studies of the 9/11-exposed population. *Analogy* establishes that if one exposure causes cancer, then a similar exposure should cause a similar cancer. This criterion is most useful with a large body of evidence. *Specificity* is not useful since many cancers are caused by multiple exposures. *Temporal relationship* establishes that exposure always precedes the outcome. *Experiment* establishes that the condition can be altered (prevented or ameliorated) by an appropriate experimental regimen.

the only published study of a 9/11-exposed population currently available for review and presents the risk estimates in multiple ways. The Administrator agrees with the authors of the Zeig-Owens study, who note that ''[s]ite-specific cancer SIR ratios (exposed versus non-exposed) were not significantly increased, although we noted a trend towards an increase in ten of 15 sites.'' [Zeig-Owens, *et al.,* 2011] The Administrator placed a different emphasis on an interpretation of the statistical significance of the findings than did the STAC, and considered only the cancer risk estimates that were corrected for surveillance bias and that utilized the more similar referent group, unexposed firefighters. The Administrator has made the judgment that only statistically significant findings will be used to support the proposed inclusion of a type of cancer using Method 1, however cancers can be added under Methods 2, 3, 4 (see III.D.3., below). At the same time, the Administrator understands the interpretation of the findings from the Zeig-Owens study about site-specific cancer rates used by the STAC to recommend that stomach, colon (excluding rectum), melanoma, non-Hodgkin lymphoma, and thyroid be included on the List of WTC-Related Health Conditions.

Fourth, the STAC also considered findings from sources of information relevant to 9/11 exposures (including the expert judgment and personal experiences of STAC members, and comments from the public) and the potential occurrence of cancer.

The Administrator considered the approaches used in the *First Periodic Review* and also the approaches used by the STAC to evaluate the available scientific evidence. In order to determine whether to propose a type of cancer for inclusion on the List, the Administrator sought to develop a method that would assist with characterizing 9/11 exposures and the likelihood of developing cancer or a type of cancer. One approach considered was to rely exclusively on a weight of evidence evaluation of the epidemiologic literature. In this approach, accumulated evidence from four types of studies (*i.e.,* cohort, cross sectional, case-control, and case series) would be evaluated to develop insight into historic exposures and the risk of developing cancer or a type of cancer. Utilization of this approach would be consistent with the approach described by the Administrator in the *First Periodic Review* of cancer, a portion of the methodology adopted by the STAC, and Method 1 described in section III.D.3., below. However, evaluation of the epidemiologic literature is limited by both the lack of exposure data available for the days immediately after the collapse of the WTC Towers and the insufficient time for differences in cancer incidence and mortality to be detected in 9/11-exposed populations. Additional approaches were adopted to compensate for both of these limitations. Method 2 recognizes that certain WTC-related health conditions may progress to cancer. Method 3 is a qualitative approach that uses concordance between two authoritative reviews of peer-reviewed literature (NTP and IARC) as a threshold to characterize the likelihood of 9/11 agents to cause cancer in humans. Method 4 relies on the work of the STAC in providing a reasonable basis for adding a type of cancer in addition to those identified under Methods 1–3.

3. Methods Used by the Administrator To Determine Whether To Add Cancer or Types of Cancer to the List of WTC-Related Health Conditions

The Administrator developed the following hierarchy of methods for determining whether to add cancer or types of cancer to the List of WTC-Related Health Conditions in 42 CFR 88.1. In determining whether to propose that a type of a cancer be included on the List, a review of the evidence must demonstrate fulfillment of at least one of the following four methods:

▪ Method 1. Epidemiologic Studies of September 11, 2001 Exposed Populations. A type of cancer may be added to the List if published, peer-reviewed epidemiologic evidence supports a causal association between 9/11 exposures and the cancer type. The following criteria extrapolated from the Bradford Hill criteria will be used to evaluate the evidence of the exposure-cancer relationship:

- *strength* of the association between a 9/11 exposure and a health effect (including the magnitude of the effect and statistical significance);
- *consistency* of the findings across multiple studies;
- *biological gradient,* or dose-response relationships between 9/11 exposures and the cancer type; and
- *plausibility* and *coherence* with known facts about the biology of the cancer type. If only a single published epidemiologic study is available for review, the consistency of findings cannot be evaluated and strength of association will necessarily place greater emphasis on statistical significance than on the magnitude of the effect.

▪ Method 2. Established Causal Associations. A type of cancer may be added to the List if there is well-established scientific support published in multiple epidemiologic studies for a causal association between that cancer and a condition already on the List of WTC-Related Health Conditions.

▪ Method 3. Review of Evaluations of Carcinogenicity in Humans. A type of cancer may be added to the List only if *both* of the following criteria for Method 3 are satisfied:

3A. Published Exposure Assessment Information. 9/11 agents were *reported* in a published, peer-reviewed exposure assessment study of responders or survivors who were present in either the New York City disaster area as defined in 42 CFR 88.1, or at the Pentagon, or in Shanksville, Pennsylvania; and

3B. Evaluation of Carcinogenicity in Humans from Scientific Studies. NTP has determined that the 9/11 agent is *known to be a human carcinogen* or is *reasonably anticipated to be a human carcinogen,* and IARC has determined there is *sufficient* or *limited* evidence that the 9/11 agent causes a type of cancer.

▪ Method 4. Review of Information Provided by the WTC Health Program Scientific/Technical Advisory Committee. A type of cancer may be added to the List if the STAC has provided a reasonable basis for adding a type of cancer and the basis for inclusion does not meet the criteria for Method 1, Method 2, or Method 3.

The Administrator invites comment on this methodology and its implementation. The following schematic illustrates the methodology used in this rulemaking.

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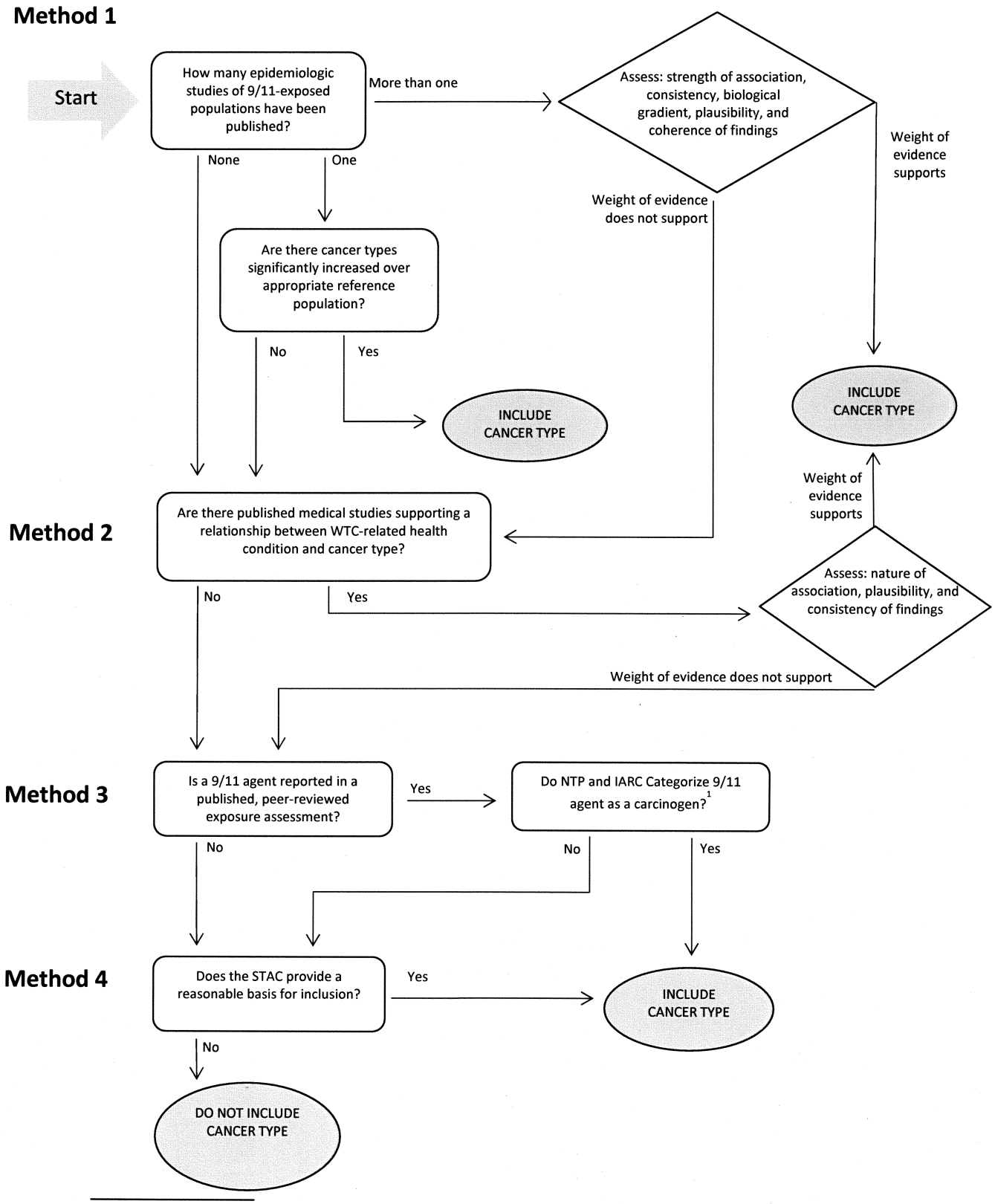

[1] NTP has determined that the 9/11 agent is *known to be a human carcinogen* or *reasonably anticipated to be a human carcinogen*, and IARC has determined there is *sufficient* or *limited* evidence that the 9/11 agent causes a type of cancer.

4. Administrator's Determination Concerning Petition 001

Using the evidentiary standards established above for inclusion of a cancer on the List of WTC-Related Health Conditions in 42 CFR 88.1, the Administrator reviewed the scientific evidence referenced in the *First Periodic Review* [NIOSH 2011], Petition 001, and in the STAC's April 2, 2012 recommendations to the Administrator.[10] Accordingly, the Administrator proposes to add the specific types of cancers in Table A, below, to the List of WTC-Related Health Conditions in 42 CFR 88.1.

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[10] Transcripts and recordings of the STAC meetings are available in NIOSH Docket 248 *http://www.cdc.gov/niosh/docket/archive/docket248.html.* Accessed April 20, 2012.

Table A -- Types of cancer proposed for inclusion in 42 CFR 88.1, List of WTC-Related Health Conditions

Type of cancer	ICD-10 Code	Evidence Used by the Administrator to Add a Type of Cancer				
		Method 1	Method 2	Method 3		Method 4
		9/11 Exposed Population Study	WTC-related health condition	Exposure Agent(s)[1]	IARC Categorization	STAC Recommendation
Head & Neck						
Lip	C00	---	---	Asbestos[2]	Limited	---
Tongue	C01,C02	---	---	Asbestos[2]	Limited	---
Parotid and Salivary gland	C07,C08	---	---	Asbestos[2]	Limited	---
Floor of mouth	C04	---	---	Asbestos[2]	Limited	---
Gum, palate and other mouth	C03,C05 C06	---	---	Asbestos[2]	Limited	---
Tonsil	C09	---	---	Asbestos[2]	Limited	---
Oropharynx	C10	---	---	Asbestos[2]	Limited	---
Piriform sinus and hypopharynx	C12,C13	---	---	Asbestos[2]	Limited	---
Other oral cavity and pharynx	C14	---	---	Asbestos	Limited	---
Nasopharynx	C11	---	---	Formaldehyde	Sufficient	---
Nasal cavity	C30	---	---	Nickel	Sufficient	---
Accessory sinuses	C31	---	---	Nickel	Sufficient	---
Larynx	C32	---	---	Strong inorganic acid mists, Asbestos	Sufficient	---
Digestive System						

Esophagus	C15	---	Gastro-esophageal reflux disease	---	---	---	---
Stomach	C16	---	---	Asbestos	Limited	---	
				Lead	Limited	---	
Colon and rectum	C18, C19, C20 C26.0, C26.8-C26.9	---	---	Asbestos	Limited	---	
Liver and intrahepatic bile duct	C22	---	---	Vinyl chloride	Sufficient	---	
				Arsenic and inorganic arsenic compounds, polychlorinated biphenyls, trichloroethylene	Limited	---	
Retroperitoneum and peritoneum	C48	---	---	Asbestos[2]	Limited	---	
Respiratory System							
Trachea	C33	---	---	Arsenic and inorganic arsenic compounds, Asbestos, Beryllium and beryllium compounds, Cadmium and cadmium compounds, Nickel compounds, Silica dust, crystalline	Sufficient	---	
Bronchus and lung	C34	---	---	Arsenic and inorganic arsenic compounds, Asbestos, Beryllium and beryllium compounds, Cadmium and cadmium compounds, Nickel compounds, Silica dust, crystalline	Sufficient	---	

Heart, mediastinum, and pleura	C38	---	---	Arsenic and inorganic arsenic compounds, Asbestos, Beryllium and beryllium compounds, Cadmium and cadmium compounds, Nickel compounds, Silica dust, crystalline[2]	Sufficient	---
Other and ill-defined sites in the respiratory system and intrathoracic organs	C39	---	---	Arsenic and inorganic arsenic compounds, Asbestos, Beryllium and beryllium compounds, Cadmium and cadmium compounds, Nickel compounds, Silica dust, crystalline[2]	Sufficient	---
Mesothelium						
Mesothelioma	C45	---	---	Asbestos	Sufficient	---
Soft Tissues						
Sarcoma	C47,C49	---	---	2,3,7,8-tetrachlorodibenzeno-para-dioxin	Limited	---
Skin						
Non-melanoma skin cancers including scrotal cancer	C44, C63.2	---	---	Arsenic and inorganic arsenic compounds, Soot	Sufficient	---
Melanoma	C43	---	---	---	---	STAC recommendation
Breast						
Breast	C50	---	---	---	---	STAC recommendation
Female Reproductive Organs						
Malignant neoplasm of ovary	C56	---	---	Asbestos	Sufficient	---

Urinary System						
Urinary bladder	C67	---	---	Arsenic and inorganic arsenic compounds	Sufficient	---
Kidney	C64	---	---	Arsenic and inorganic arsenic compounds, Cadmium and cadmium compounds	Limited	---
Renal pelvis	C65	---	---	Arsenic and inorganic arsenic compounds[2]	Limited	---
Ureter	C66	---	---	Arsenic and inorganic arsenic compounds[2]	Limited	---
Other urinary organs	C68	---	---	Arsenic and inorganic arsenic compounds[2]	Limited	---
Eye and Orbit						
Eye and orbit	C69	---	---	---	---	STAC recommendation
Thyroid						
Thyroid	C73	---	---	---	---	STAC recommendation
Blood and Lymphoid Tissue						
Hodgkin's disease	C81	---	---	1,3-Butadiene	Sufficient	---
Follicular [nodular] non-Hodgkin lymphoma	C82	---	---	1,3-Butadiene	Sufficient	---
Diffuse non-Hodgkin lymphoma	C83	---	---	1,3-Butadiene	Sufficient	---
Peripheral and cutaneous T-cell lymphomas	C84	---	---	1,3-Butadiene	Sufficient	---
Other and unspecified types of non-Hodgkin	C85	---	---	1,3-Butadiene	Sufficient	---

lymphoma							
Malignant immuno-proliferative diseases	C88	---	---	1,3-Butadiene	Sufficient	---	
Multiple myeloma and malignant plasma cell neoplasms	C90	---	---	1,3-Butadiene	Sufficient	---	
Lymphoid leukemia	C91	---	---	1,3-Butadiene, Formaldehyde	Sufficient	---	
Myeloid leukemia	C92	---	---	1,3-Butadiene, Benzene, Formaldehyde	Sufficient	---	
Monocytic leukemia	C93	---	---	1,3-Butadiene, Formaldehyde	Sufficient	---	
Other leukemias of specified cell type	C94	---	---	1,3-Butadiene, Formaldehyde	Sufficient	---	
Leukemia of unspecified cell type	C95	---	---	1,3-Butadiene, Formaldehyde	Sufficient	---	
Other and unspecified malignant neoplasms of lymphoid, hematopoietic and related tissue	C96	---	---	1,3-Butadiene	Sufficient	---	
Childhood Cancers							
Childhood cancers defined as all cancers diagnosed in	Many	---	---	---	---	STAC recommendation	

persons less than 20 years old.[3]						
Rare Cancers						
Rare cancers based on age-specific incidence rates by gender, decade of age, site and histology. Site-histology combinations to be considered as unique cancers should be determined a priori in consultation with appropriate experts.[3]	Many	---	---	---	---	STAC recommendation

1. Each agent listed was categorized as a carcinogen by NTP and IARC
2. Cancers at sites in close anatomical proximity to sites added under Method 3 will also be added since it is often difficult to distinguish the cancer's anatomical origin especially when cancers from closely proximate sites are histopathologically indistinguishable.
3. As described by STAC

5. Explanations for Adding Certain Types of Cancer to the List of WTC-Related Health Conditions

The Administrator's rationale and the method relied upon for inclusion of each type of cancer are offered below. The types of cancer proposed by the Administrator are grouped by anatomical region, for ease of discussion, and are identified by their individual ICD–10 code.[11] [WHO 1997] The ICD–9 codes associated with each specific type of cancer are identified in the regulatory text.

Cancers of the Head and Neck. For the reasons discussed below for each type, the Administrator proposes the inclusion of cancers found in the lip, tongue, salivary gland, floor of mouth, gum and other mouth, tonsil, oropharynx, nasopharynx, hypopharynx, other oral cavity and pharynx, nasal cavity, accessory sinuses, and the larynx.

▪ *Malignant neoplasms of the lip [C00], tongue [C01, C02], salivary gland [C07, C08], floor of mouth [C04], gum and other mouth [C03, C05, C06], tonsil [C09], oropharynx [C10], hypopharynx [C12, C13], other oral cavity and pharynx [C14]:* (Method 3) IARC has determined that there is *limited* evidence that asbestos causes cancer of other oral cavity and pharynx. The review of published exposure assessment studies has not identified any 9/11 exposure agent associated with cancers of the lip, tongue, salivary gland, floor of mouth, gum and other mouth, tonsil, oropharynx, and hypopharynx. The Administrator has determined that the types of cancer proposed to be added in the Head and Neck group under Method 3 share an anatomic continuum and can be included with other head and neck group types of cancer.

▪ *Malignant neoplasm of the nasopharynx [C11]:* (Method 3) The review of published exposure assessment studies identified formaldehyde as present in the New York City disaster area. [COPC 2003] IARC has determined that results of epidemiologic studies of exposure by inhalation to formaldehyde provide *sufficient* epidemiological evidence that formaldehyde causes nasopharyngeal cancer in humans. [IARC 2012c]

▪ *Malignant neoplasms of the nasal cavity [C30] and accessory sinuses [C31]:* (Method 3) The review of published exposure assessment studies identified nickel and hexavalent chromium compounds as present in the New York City disaster area. [Lioy, *et al.* 2002; COPC 2003; Lorber, *et al.* 2007] IARC has determined that results of epidemiologic studies of exposure by inhalation provide *sufficient* epidemiological evidence that nickel compounds cause cancer of the nose and nasal sinuses in humans. [IARC 2012a]

▪ *Malignant neoplasm of the larynx [C32]:* (Method 3) The review of published exposure assessment studies identified asbestos and sulfuric acid as present in the New York City disaster area. [Lioy, *et al.* 2002; COPC 2003; Lorber, *et al.* 2007] IARC has determined that results of epidemiologic studies of exposure by inhalation provide *sufficient* epidemiological evidence that all forms of asbestos (chrysotile, crocidolite, amosite, tremolite, actinolite, and anthophyllite) cause cancer of the larynx in humans. [IARC 2012a] IARC has determined that the results of epidemiologic studies of exposure by inhalation provide *sufficient* epidemiological evidence that strong inorganic acids including sulfuric acid cause cancer of the larynx.

Cancers of the Digestive System. For the reasons discussed below for each site, the Administrator proposes the inclusion of cancers found in the esophagus; stomach; colon and rectum; liver and intrahepatic bile duct; retroperitoneum; and peritoneum.

▪ *Malignant neoplasms of the esophagus [C15]:* (Method 2) There is well-accepted evidence that symptoms of an already-covered WTC-related health condition—gastroesophageal reflux disease (GERD)—increases the risk of developing esophageal cancer. Persons with recurring symptoms of reflux have an eightfold increase in the risk of esophageal adenocarcinoma. [Lagergren, *et al.,* 1999]

▪ *Malignant neoplasm of the stomach [C16]:* (Method 3) The review of published exposure studies identified asbestos and inorganic compounds of lead as present in the New York City disaster area. [COPC 2003] IARC has determined that the results of epidemiologic studies of exposure by inhalation and/or ingestion provide *limited* evidence that all forms of asbestos (chrysotile, crocidolite, amosite, tremolite, actinolite, and anthophyllite) cause cancer of the stomach in humans. [IARC 2012a] IARC has also determined that there is *limited* evidence that exposure to inorganic lead causes cancer of the stomach. [Cogliano, *et al.* 2011; IARC 2006]

▪ *Malignant neoplasms of the colon (and rectum) [C18, C19, C20, C26.0]:* (Method 3) The review of published exposure assessment studies identified asbestos as present in the New York City disaster area. [COPC 2003] IARC has determined that the results of epidemiologic studies of exposure by inhalation provide *limited* epidemiologic evidence that all forms of asbestos (chrysotile, crocidolite, amosite, tremolite, actinolite, and anthophyllite) cause cancer of the colon and rectum in humans. [Cogliano, *et al.* 2011]

▪ *Malignant neoplasms of the liver and intrahepatic bile duct [C22]:* (Method 3) The review of published exposure assessment studies identified vinyl chloride, arsenic and inorganic arsenic compounds, polychlorinated biphenyls, and trichloroethylene as present in the New York City disaster area. [COPC 2003] Arsenic and vinyl chloride are classified as *known human carcinogens* by IARC and NTP. For arsenic, IARC identifies the evidence for causality of cancer of the liver and intrahepatic duct as *limited* and classifies the evidence for carcinogenicity of vinyl chloride as *sufficient* to cause angiosarcomas of the liver and hepatocellular carcinomas. For polychlorinated biphenyls and trichloroethylene exposure, IARC characterizes the evidence as *limited* for causation of cancer of the liver. [Cogliano, *et al.* 2011]

▪ *Malignant neoplasms of the retroperitoneum and peritoneum [C48]:* The review of published exposure assessment studies has not associated any 9/11 agent with cancer of the retroperitoneum, peritoneum, omentum, and mesentery. The Administrator has determined that the types of cancer proposed to be added in the digestive system under Method 3 share an anatomic continuum and can be included together with other added digestive system types of cancer.

Cancers of the Respiratory System. For the reasons discussed below for each site, the Administrator proposes the inclusion of cancers found in the trachea; bronchus and lung; heart; and other and ill-defined sites in the respiratory system and intrathoracic organs.

▪ *Malignant neoplasms of the trachea [C33]; bronchus and lung [C34]; heart, mediastinum and pleura [C38]; and other ill-defined sites in the respiratory system and intrathoracic organs [C39]:* (Method 3) The review of published exposure assessment studies identified arsenic, asbestos, beryllium, cadmium, nickel, and silica as present in the New York City disaster area. [COPC 2003;

[11] The International Classification of Diseases (ICD) is used to code and classify injuries and diseases and their signs, symptoms, and external causes for statistical presentation, disease analysis, hospital records indexing, and medical billing reimbursement.

Lioy, *et al.* 2002; Wallingford and Snyder 2001] IARC has determined that there is *sufficient* evidence in humans for the carcinogenicity of mixed exposure to inorganic arsenic compounds, including arsenic trioxide, arsenite, and arsenate. Inorganic arsenic compounds, including arsenic trioxide, arsenite, and arsenate, cause cancer of the lung and intrathoracic organs. [IARC 2012a] IARC has determined that there is *sufficient* evidence in humans that inhalation exposure to all forms of asbestos (chrysotile, crocidolite, amosite, tremolite, actinolite, and anthophyllite) causes cancer of the lung and intrathoracic organs (including C33, C34, C38, and C39). IARC has determined that results of epidemiologic studies of exposure by inhalation provide *sufficient* epidemiological evidence that beryllium and beryllium compounds cause cancer of the lung and intrathoracic organs. [IARC 2012a] IARC has determined that results of epidemiologic studies of exposure by inhalation provide *sufficient* epidemiologic evidence that cadmium and cadmium compounds cause cancer of the lung and intrathoracic organs in humans. [Cogliano, *et al.* 2011; IARC 2012a] IARC has determined that results of epidemiologic studies of exposure by inhalation provide *sufficient* epidemiologic evidence that nickel compounds and nickel metal cause cancer of the lung and intrathoracic organs in humans. [Cogliano, *et al.* 2011; IARC 2012a] IARC has determined that results of epidemiologic studies of exposure by inhalation provide *sufficient* epidemiologic evidence that crystalline silica in the form of quartz causes cancer of the lung and intrathoracic organs in humans. IARC has also determined that there is *sufficient* evidence in humans that soot causes cancer of the lung. [IARC 2012c] In addition, IARC has determined that strong inorganic acids, welding fumes, diesel exhaust and 2,3,7,8-tetrachlorodibenzo-para-dioxin have *limited* evidence for causing cancer of the respiratory system.

Cancer of the Mesothelium. For the reasons discussed below, the Administrator proposes the inclusion of cancer found in the mesothelium.

- *Mesothelioma [C45]:* (Method 3) The review of published exposure assessment studies identified asbestos as present in the New York City disaster area. [Lioy, *et al.* 2002; COPC 2003; Lorber, *et al.* 2007] IARC has determined that results of epidemiologic studies of exposure by inhalation provide *sufficient* epidemiologic evidence that all forms of asbestos (chrysotile, crocidolite, amosite, tremolite, actinolite, and anthophyllite) cause mesothelioma in humans. [IARC 2012a]

Cancer of the Soft Tissues. For the reasons discussed below, the Administrator proposes the inclusion of cancer found in the soft tissues.

- *Malignant neoplasm of peripheral nerves and autonomic nervous system [C47) and malignant neoplasm of other connective and soft tissue [C49]:* (Method 3) The review of published exposure assessment studies identified 2,3,7,8-tetrachlorodibenzo-para-dioxin as present in the New York City disaster area. [COPC 2003] IARC has found *limited* evidence for increased risk of soft tissue sarcoma associated with exposure to 2,3,7,8-tetrachlorodibenzo-para-dioxin.

Cancer of the Skin (non-melanoma and melanoma), including scrotum. For the reasons discussed below, the Administrator proposes the inclusion of cancer found in the skin.

- *Other malignant neoplasms of skin (non-melanoma) [C44], malignant melanoma of skin [C43], and malignant neoplasm of scrotum [C63.2]:* (Method 3 and 4) The review of published exposure assessment studies identified arsenic and soot as present in the New York City disaster area [COPC 2033). Both NTP and IARC determined that arsenic [IARC 2012c] and occupational exposure to soot [IARC 2012c] are *known human carcinogens* and that there is *sufficient* evidence that they cause non-melanoma skin cancer.

The STAC recommended including melanoma based on its interpretation of the Zeig-Owens study. The STAC stated:

> the Zeig-Owens study found a statistically significant increase in melanoma among exposed firefighters compared to the general population; the Standardized Incidence Ratio (SIR) was slightly larger but not significant when compared to non-exposed firefighters. No adjustment for surveillance bias was reported for malignant melanoma, although early detection through medical surveillance is likely.

Because the Zeig-Owens finding for melanoma was not statistically significant (when compared to non-exposed firefighters), the Administrator cannot propose to add melanoma to the List of WTC-Related Health Conditions based on Method 1. Melanoma is proposed for inclusion based on Method 4. The Administrator will continue to monitor cohort studies that address site-specific cancers such as melanoma in 9/11-exposed populations.

Cancer of the Breast. For the reasons discussed below, the Administrator proposes the inclusion of cancer found in the breast.

- *Malignant neoplasm of the breast [C50]:* (Method 4) The STAC recommended inclusion of breast cancer based on the professional judgment and personal experience of STAC members and on public comments. The STAC stated

> There is evidence of PCB exposures to WTC responders and survivors based on air samples, window film samples and one biomonitoring study. Studies have linked total and congener-specific PCB levels in serum and adipose tissue with breast cancer, although evidence has been conflicting. PCBs and some other substances at the WTC site are endocrine disruptors. Breast cancer risks are highly related to hormonal factors, including endogenous and exogenous estrogens, and could plausibly be affected by endocrine disruptors. A recent study found that PCBs enhanced the metastatic properties of breast cancer cells by activating rho-associated kinase. Shiftwork involving circadian rhythm disruption has been classified by IARC as probably carcinogenic to humans, based in part on epidemiologic studies associating shiftwork with increased risks of breast cancer. Both shiftwork and long shifts were common for workers involved in rescue, recovery, clean up, restoration and other activities at the WTC site. [STAC 2012, references omitted]

The STAC further noted the lack of opportunity to find evidence for breast cancer among exposed occupations because so few women work in the occupations mainly involved with response work in the New York City disaster area, at the Pentagon, and in Shanksville, Pennsylvania.

Shiftwork has been classified by IARC as *probably* carcinogenic based in part on *limited* evidence in humans demonstrating an increased risk of breast cancer among shift workers. IARC notes that mechanistic studies suggest that exposure to light at night may increase the risk of breast cancer by suppressing the normal nocturnal production of melatonin, which in turn, may alter gene expression in cancer-related pathways. [Straif, *et al.* 2007] NTP has not yet examined the evidence for an association of shiftwork and breast cancer, however, NTP recently requested comment from the public whether shiftwork involving light at night should be nominated for possible review for future editions of the RoC. [NTP 2012] The Administrator is not aware of any published exposure assessment study of shiftwork and 9/11, although the Administrator is aware that extended work hours for many responders occurred at all three 9/11 sites over several months. The Administrator proposes to add breast cancer to the List of WTC-Related Health Conditions based on Method 4, and continues to seek information about

any exposures in the New York City disaster area, at the Pentagon, or in Shanksville, Pennsylvania that would further support adding breast cancer to the List of WTC-Related Health Conditions.

Cancer of the Female Reproductive Organs. For the reasons discussed below, the Administrator proposes the inclusion of cancer found in the ovary.

▪ *Malignant neoplasm of the ovary [C56]:* (Method 3) The review of published exposure assessment studies identified asbestos as present in the New York City disaster area. [Lioy, *et al.* 2002; COPC 2003; Lorber, *et al.* 2007] IARC has determined that results of epidemiologic studies of exposure by inhalation provide *sufficient* epidemiological evidence that all forms of asbestos (chrysotile, crocidolite, amosite, tremolite, actinolite, and anthophyllite) cause cancer of the ovary in humans, based on five strongly positive cohort mortality studies of women with heavy occupational exposure to asbestos. [IARC 2012a]

Cancers of the Urinary System. For the reasons discussed below, the Administrator proposes the inclusion of cancer found in the urinary bladder, kidney, renal pelvis, ureter and other urinary organs.

▪ *Malignant neoplasm of the urinary bladder [C67]:* (Method 3) The review of published exposure assessment studies identified arsenic, inorganic arsenic, diesel exhaust and soot as present in the New York City disaster area. Both NTP and IARC determined that arsenic is *known to be a human carcinogen* [IARC 2012a], and IARC has determined there is *limited* evidence that diesel engine exhaust and soot cause cancer of the urinary bladder.

▪ *Malignant neoplasm of the kidney [C64]:* (Method 3) The review of published exposure assessment studies identified arsenic, inorganic arsenic compounds, and cadmium and cadmium compounds as present in the New York City disaster area. [COPC 2003] The evidence for carcinogenicity of inorganic arsenic compounds and cadmium are categorized as *limited* by IARC and NTP, which meets the requirements for inclusion based on Method 3.

▪ *Malignant neoplasm of the renal pelvis, ureter and other urinary organs [C65, C66 and C68]:* (Method 3) The Administrator has determined that the types of cancer proposed to be added in the urinary system under Method 3 share an anatomic continuum and can be included together with other added urinary system types of cancer.

Cancer of the Eye and Orbit. For the reasons discussed below, the Administrator proposes the inclusion of cancer found in the eye and orbit.

▪ *Malignant neoplasm of the eye and orbit [C69]:* (Method 4) Cancers of the eye and eye orbit are not addressed in the only published epidemiologic study of September 11, 2001 exposed populations to date (Method 1). The STAC noted that eye irritation from dust was ubiquitous in the New York City disaster area and postulated an association between irritation from dust and cancers of the eye and eye orbit. However, irritation has not been associated with cancers of the eye and eye orbit in the published literature (Method 2). The STAC also noted that IARC determined the evidence is *sufficient* for welding to cause ocular melanoma by occupational exposure to ultraviolet radiation. The review of published exposure assessment studies identified metal cutting as occurring in the New York City disaster area, but the exposure assessment literature is silent about welding involving ultraviolet light exposure. The Administrator proposes to add cancer of the eye and orbit based on Method 4, but seeks information on welding activities in the New York City disaster area, at the Pentagon, or in Shanksville, Pennsylvania, including information on the types of welding, frequency, and locations to better understand the nature of the exposures that occurred that could further support adding cancer of the eye and orbit to the List of WTC-Related Health Conditions.

Cancer of the Thyroid. For the reasons discussed below, the Administrator proposes the inclusion of cancer found in the thyroid.

▪ *Malignant neoplasm of thyroid gland [C73]:* (Method 3) The STAC recommended thyroid cancer for inclusion, noting that it has not been associated with any of the agents known to be present in the New York City disaster area. The primary evidence that the STAC based its recommendation for inclusion on was ''an excess in risk [for thyroid cancer] from the Zeig-Owens study.'' [STAC 2012] Even though the Administrator views the significance of the Zeig-Owens finding relating to thyroid cancer differently than does the STAC, the Administrator proposes to add thyroid cancer to the List of WTC-Related Health Conditions based on Method 4. The Administrator will continue to monitor cohort studies that address site-specific cancer in 9/11-exposed populations.

Cancers of the Blood and Lymphoid Tissue. For the reasons discussed below for each type, the Administrator proposes adding malignant neoplasms of the blood and lymphoid tissues, including, but not limited to, lymphoma, leukemia, and myeloma.

▪ *Hodgkin's disease [C81]; follicular [nodular] non-Hodgkin lymphoma [C82]; diffuse non-Hodgkin lymphoma [C83]; peripheral and cutaneous T-cell lymphomas [C84]; other and unspecified types of non-Hodgkin lymphoma [C85]; malignant immunoproliferative diseases [C88]; multiple myeloma and malignant plasma cell neoplasms [C90]; lymphoid leukemia [C91]; myeloid leukemia [C92]; monocytic leukemia [C93]; other leukemias of specified cell type [C94]; leukemia of unspecified cell type [C95]; other and unspecified malignant neoplasms of lymphoid, hematopoietic and related tissue [C96]:* (Method 3) The review of published exposure assessment studies identified benzene [Lorber, *et al.* 2007; Wallingford and Snyder 2001], 1,3-butadiene [Lorber, *et al.* 2007; Wallingford and Snyder 2001], and formaldehyde [COPC 2003] as present in the New York City disaster area. IARC determined that there is *sufficient* evidence that exposure to 1,3-butadiene causes cancer of the hematolymphatic organs. IARC considers hematolymphatic cancers attributable both to leukemia and malignant lymphoma. The IARC working group recognized that the epidemiological evidence for an association with specific subtypes of hematolymphatic cancers is weaker, but when malignant lymphomas and leukemias are distinguished, the evidence is strongest for leukemia. [IARC, 2012c] IARC also determined that there is *sufficient* evidence that exposure to benzene causes acute myeloid leukemia and acute non-lymphocytic leukemia. [Cogliano, *et al.* 2011; IARC 2012c] IARC has determined that results of epidemiological studies of exposure by inhalation provide *sufficient* epidemiological evidence that formaldehyde causes leukemia in humans. [Cogliano, *et al.* 2011; IARC 2012c] In addition, IARC has determined that there is *limited* evidence in humans that styrene, tetrachloroethylene, trichloroethylene, and 2,3,7,8-tetrachlorodibenzo-para-dioxin cause leukemia. For the reasons discussed above, the Administrator intends to include all hematolymphatic cancers.

Childhood Cancers. (Method 4) The STAC recommended that childhood cancers be included on the List of WTC-Related Health Conditions based on the ''unique vulnerability of children to synthetic chemicals'' and that ''childhood cancers are rare and excess risks are not likely to be detectable in the small number of children being

followed in epidemiologic studies.'' [STAC 2012] The STAC defines childhood cancers as all cancers diagnosed in persons less than 20 years old. The most common types of childhood cancers are hematopoietic, bone, kidney, sarcomas, eye, and brain cancers. Childhood cancers involving the blood and lymphoid tissues, kidney, sarcomas, and eye cancers have already been added to the List and are described elsewhere in Section III.D.5. The Administrator proposes to add childhood cancers—any type of cancer occurring in a person less than 20 years of age—to the List of WTC-Related Health Conditions based on Method 4. The Administrator will continue to monitor cohort studies that address site-specific cancer in 9/11-exposed populations of children less than 20 years of age.

Rare Cancers. (Method 4) The STAC recommended that rare cancers be included in the List of WTC-Related Health Conditions but noted that there is no uniform definition a rare cancer. The STAC also recommended that ''definitions be based on age-specific incidence rates by gender, decade of age, site and histology. Site/histology combinations to be considered as unique cancers should be determined a priori in consultation with appropriate experts.'' The Rare Diseases Act of 2002 defines a rare disease as one affecting ''small patient populations, typically populations smaller than 200,000 individuals in the United States.'' [12] The National Cancer Institute notes that ''there are some anatomic sites in which cancer rarely occurs.'' [Young, *et al.* 2007] For a limited population like that of the WTC Health Program, cancers that are considered rare based on occurrence rates in the U.S. population will be rare cancers for the 9/11-exposed populations. The Administrator proposes to add rare cancers—any type of cancer affecting 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—to the List of WTC-Related Health Conditions based on Method 4 and will consult with appropriate experts as recommended by the STAC. The Administrator also seeks information about rare cancers from the public.

The Administrator will continue to review and evaluate the scientific evidence available to determine whether these types and any other types of cancer should be included in the List. These reviews will be published in the periodic reviews of cancer. Petitions to add types of cancer may also be filed with the Administrator. In the event additional studies are published prior to the issuance of a final rule regarding the subject of this notice of proposed rulemaking, the Administrator will consider those studies as appropriate in the process of developing a final rule.

6. Certification and Treatment of WTC-Related Health Conditions Including Types of Cancer

In order for an individual enrolled as a WTC responder or survivor to obtain coverage for treatment of any health condition on the List of WTC-Related Health Conditions, including any of type of cancer added to the List, a two-step process must be satisfied. First, a physician at a Clinical Center of Excellence or in the nationwide provider network must make a determination that the particular type of cancer for which the responder or survivor seeks treatment coverage is both: (1) On the List of WTC-Related Health Conditions; and that (2) exposure to airborne toxins, other hazards, or adverse conditions resulting from the September 11, 2001, terrorist attacks is substantially likely to be a significant factor in aggravating, contributing to, or causing the type of cancer for which the responder or survivor seeks treatment coverage.[13] Pursuant to 42 CFR 88.12(a), the physician's determination must be based on: (1) An assessment of the individual's exposure to airborne toxins, any other hazard, or any other adverse condition resulting from the September 11, 2001, attacks; and (2) the type of symptoms reported and the temporal sequence of those symptoms. As a second statutory requirement, all physician determinations are reviewed by the Administrator and, if found to satisfactorily meet the exposure assessment and symptom requirements, are certified for treatment coverage. Thus, inclusion of a condition on the List of WTC-Related Health Conditions, in and of itself, does *not* guarantee that a particular individual's condition will be certified as eligible for treatment. Responders and survivors denied certification have a right to appeal the denial of certification.

Early detection of cancer in 9/11-exposed populations—either as part of medical monitoring of enrolled WTC responders and survivors or part of ongoing research—is an important adjunct to the WTC Health Program. Screening for the cancers proposed by this rulemaking follow U.S. Preventive Services Task Force (USPSTF) Guidelines. There are two types of cancer proposed to be added to the List of WTC-Related Health Conditions for which the USPSTF has a current recommendation for screening. The USPSTF recommends screening for colorectal cancer (cancer of the colon and rectum) using fecal occult blood testing, sigmoidoscopy, or colonoscopy, in adults, beginning at age 50 years and continuing until age 75 years. [USPSTF 2008] The Task Force also recommends breast cancer screening using biennial mammography for women beginning at age 40.[14]

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E. 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 11, 2001 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.[15]

IV. Summary of Proposed Rule

The proposed rule would amend the definition of ''List of WTC-Related Health Conditions'' in 42 CFR 88.1, to include the types of cancer discussed above in section II.D. Table 1 in the regulatory text describes types of cancers included in 42 CFR 88.1 and identifies each by ICD–10 code. Because the ICD–10 modification will not be used by the U.S. healthcare system until October 1, 2014, the corresponding ICD–9 codes for the included cancer types are also provided in Table 1.

The effect of this amendment would be that, for the types of cancers added, an enrolled WTC responder, certified-eligible survivor, or screening-eligible survivor may seek certification of a physician's determination that the September 11, 2001, terrorist attacks were substantially likely to be a significant factor in aggravating, contributing to, or causing the individual's cancer. If the condition is certified by the Administrator, the individual may seek treatment and monitoring of this condition under the WTC Health Program.

[15] 28 CFR 104.21.

V. 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 rule has been determined to be a ''significant regulatory action,'' under § 3(f) of E.O. 12866. The addition of specific types of cancer proposed to be added to the List of WTC-Related Health Conditions by this rule is estimated to cost the WTC Health Program between $2,124,624 [16] and $5,019,182 [17] (see Table 9) for the first year (2013). Because a portion of responders and survivors are also covered by private health insurance, employer-provided insurance (such as FDNY), or Medicare or Medicaid, only a portion of the costs, those costs representing the uninsured, are societal costs. All other costs to the WTC Health Program are transfers. After the implementation of provisions of the Patient Protection and Affordable Care Act (Pub. L. 111–148) on January 1, 2014, all of the costs to the WTC Health Program will be transfers. Transfers from FY 2013 through FY 2016 are expected to be between $12,458,535 and $33,308,060 per annum. Accordingly, this rule has been reviewed by the Office of Management and Budget. The proposed rule would not interfere with State, local, and Tribal governments in the exercise of their governmental functions.

Cost Estimates

The WTC Health Program has, to date, enrolled approximately 55,000 New York City responders and approximately 5,000 survivors, or approximately 60,000 individuals in total. Of that total population, approximately 59,000 individuals were participants in previous WTC medical programs and were 'grandfathered' into the WTC Health Program established by Title XXXIII. 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.'' In addition to those currently identified WTC responders and survivors already enrolled, the PHS Act [18] sets a numerical 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 certified-eligible WTC survivors [19] (*i.e.,* the statute restricts new enrollment). Since July 1, 2011, a total of approximately 1,000 new WTC responders and new WTC survivors have enrolled in the WTC Health Program, resulting in only a minor impact on the statutory enrollment limits for new members. For the purpose of calculating a baseline estimate of cancer prevalence only, HHS assumed that this gradual rate of enrollment would continue, and that the currently enrolled population numbers would remain around 55,000 WTC responders and 5,000 WTC survivors. The estimate is further based on the average U.S. cancer prevalence rate, and 7 percent discount rate.

As it is not possible to identify an upper bound estimate, HHS 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 currently identified + 25,000 new) and 30,000 survivors (5,000 currently identified + 25,000 new). The upper cost estimate also assumes an overall increase in population cancer rates of 21 percent due to 9/11 exposure,[20] 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 un-exposed population is based on findings presented in the only published epidemiologic study of September 11, 2001 exposed populations to date. [Zeig-Owens, *et al.* 2011] Given the challenges associated with interpreting the Zeig-Owens findings,[21] we simply characterize 21 percent as a possible outcome rather than asserting the probability that 21 percent is a ''likely'' outcome. HHS invites public comment on alternative approaches to estimating the costs and benefits described in this rulemaking, considering for example cancer latency.

HHS acknowledges that some cancer cases are not likely to have been caused by exposure to 9/11 agents. The certification of individual cancer diagnoses will be conducted on a case-by-case basis, after consideration of the individual responder's or survivor's exposure to 9/11 agents and the temporal sequence of symptoms. However, for the purpose of this analysis, HHS has estimated that all diagnosed cancers proposed to be added to the List will be certified for treatment by the WTC Health Program. Finally, because there are no existing data on cancer rates related to exposure to 9/11 agents at either the Pentagon or in Shanksville, Pennsylvania, HHS has used only data from studies of individuals who were responders or survivors in the New York City disaster area. HHS invites comment on this approach.

Costs of Cancer Treatment

HHS estimated the treatment costs associated with covering the select types of cancer proposed in this rulemaking using the methods described below. In the following discussion, the category of ''Head and Neck'' includes all cancer cases from nasal cavity, nasopharynx, accessory sinuses, and larynx. The survival rates for all cancers in the ''Head and Neck'' category were approximated using survival rates for cancer of the larynx. The category described as ''Lung'' in this discussion includes cancer of the trachea, bronchus and lung, heart, mediastinum and pleura, and other sites in the respiratory system and intrathoracic organs. Treatment costs for all respiratory system cancers including ''mesothelioma'' were approximated by treatment costs for lung cancer. Costs of treatment for the ''digestive system'' were approximated using the costs of gastric cancer; costs for cancer of the ''skin'' were approximated using costs for melanoma of the skin; ''female reproductive organs'' were

[16] Based on a population of 60,000 at the U.S. cancer rate and discounted at 7 percent.

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

[18] PHS Act, Title XXXIII § 3311(a)(4)(A) and § 3321(a)(3)(A).

[19] *See* 42 CFR 88.8(b) for explanation of a certified-eligible survivor.

[20] 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. Lancet. 378(9794):898–905.

[21] 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 WTC-exposure and cancer means that the outcomes remain speculative.

approximated using costs for cancer of the ovary; ''urinary system'' cancer was approximated by costs of urinary bladder cancer; and ''blood and lymphoid tissue'' cancers were approximated using leukemia and lymphoma. The costs for cancer identified with the ''endocrine system,'' the ''soft tissue sarcomas,'' and ''eye/orbit'' were approximated using costs for treatment of ''other'' tumors. The ''other'' category includes treatments costs from: salivary gland, nasopharynx, tonsil, small intestine, anus, intrahepatic bile duct, gallbladder, other biliary, retroperitoneum, peritoneum, other digestive organs, nose, nasal cavity, middle ear, larynx, pleura, trachea, mediastinum and other respiratory organs, bones and joints, soft tissue, other nonepithelial skin, vagina, vulva, other female genital organs, penis, other male genital organs, ureter, other urinary organs, eye and orbit, thyroid, other endocrine multiple myeloma, and miscellaneous.

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 1. 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.[22] Therefore, we used 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.

TABLE 1—AVERAGE COSTS OF TREATMENT, MALE AND FEMALE

[2011 $]

Category	Initial (12 month)	Continuing (annual)	Last year of life (12 mos.)
Head and Neck	$28,265	$3,136	$47,730
Digestive System	59,551	2,544	68,242
Respiratory System	45,493	5,026	65,592
Mesothelium	45,493	5,026	65,592
Skin	3,938	1,040	25,351
Female Reproductive Organs	66,527	5,023	64,728
Urinary System	16,926	3,630	40,905
Blood & Lymphoid Tissue	33,312	5,782	69,070
Endocrine System	30,859	3,791	58,623
Soft Tissue Sarcomas	30,859	3,791	58,623
Melanoma	3,938	1,040	25,351
Breast	15,136	1,550	37,684
Eye/Orbit	30,859	3,791	58,623

Source: 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.

These cost figures were based on a study of elderly cancer patients from Surveillance, Epidemiology, and End Results (SEER) program maintained by the National Cancer Institute, using Medicare files.[23] The average costs of treatment described above are given in 2011 prices adjusted using the Medical Consumer Price Index for all urban consumers.[24]

Incident Cases of Cancer

HHS 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 cancer types proposed to be added to the List of WTC-Related Health Conditions under this rulemaking. Demographic characteristics of the cohort were assigned since the actual data are not available for individuals in the responder and survivor populations who have not yet enrolled in the WTC Health Program. 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. The age distribution for current enrollees by gender and responder/survivor status is presented in Table 2.

TABLE 2—PERCENTILES OF CURRENT AGE (ON APRIL 11, 2012) FOR CURRENT ENROLLEES IN THE WTC HEALTH PROGRAM BY GENDER AND RESPONDER/SURVIVOR STATUS

Age percentile (years)	Group								
	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

[22] 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.

[23] 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.

[24] Bureau of Labor Statistics. Consumer Price Index *https://research.stlouisfed.org/fred2/series/CPIMEDSL/downloaddata?cid=32419.* Accessed April, 23, 2012.

TABLE 2—PERCENTILES OF CURRENT AGE (ON APRIL 11, 2012) FOR CURRENT ENROLLEES IN THE WTC HEALTH PROGRAM BY GENDER AND RESPONDER/SURVIVOR STATUS—Continued

Age percentile (years)	Group								
	Min	1	10	30	50	70	90	99	Max
Male survivors	12	23	35	46	52	58	67	81	99
Female survivors	12	21	38	49	54	60	68	84	95

HHS assumed race and ethnic origin distributions for responders and survivors according to distributions in the WTC Health Registry cohort:[25] 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 persons less than 15 years of age. Follow-up ended on December 31, 2016 or the estimated last year of life, whichever was earlier. The estimated last year of life was used since not all persons would be expected to remain alive at the end of 2016. The estimated last year of life was based on U.S. gender, race, age, and year-specific death rates from CDC Wonder (since rates are currently available through 2008, the rate from 2008 was applied to 2009 and later).[26] A life-table analysis program, LTAS.NET, was used to estimate the expected number of incident cancers for cancer types proposed to be added.[27] HHS calculated cancer incidence rates using data through 2006 from the Surveillance Epidemiology and End Results (SEER) Program, and estimated rates for 2007–2016.[28] 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 authorized.

Prevalence of Cancer

To determine the potential number of persons in the responder and survivor populations with cancer, HHS 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.[29]

Using the incident cases and survival rate statistics for each cancer type, HHS has estimated the prevalence (number of persons 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 persons surviving up to 15 years beyond their first diagnosis with one table for each type of cancer (prevalence).[30] For example, in 2002 there are 23.47 projected new lung cancer cases, which would be listed as incident cases for that year. The survival rate for lung cancer in the first year of diagnosis is 40.6 percent.[31] Therefore the number of deceased persons in 2002 would be $18.78 \times (1–0.406) = 11.15$. For the lung cancer prevalence table, in year 2003, the number of incident cases would be 20.88 cases. In addition to 20.88 newly diagnosed cases in 2003, there would be the one-year survivors from 2002 which would be 18.78—11.15 (or $18.78 \times 0.406) = 7.62$ cases. This computation process can be repeated for each year through year 2016. A portion of the lung cancer prevalence table is provided in Table 3 as an example.

Prevalence tables were created for each type of covered cancer and the results are summarized in Tables 5, and 7. This analysis considers cancers diagnosed in 2002 through 2016.

TABLE 3—EXAMPLE FROM PREVALENCE TABLE FOR LUNG CANCER

[Based on 80,000 responders]

Year	Years since exposure to 9/11 agents			Years covered by WTC Health Program			
	2002	2003	2012	2013	2014	2015	2016
1 (incidence)	18.78	20.88	46.53	51.22	56.10	60.69	66.03
2	.....	7.62	17.00	18.89	20.79	22.78	24.64
3	.....	.....	9.25	10.18	11.30	12.45	13.63
4	.....	.....	6.42	7.08	7.79	8.66	9.53
5	.....	.....	4.95	5.46	6.02	6.62	7.35
6	.....	.....	4.01	4.45	4.90	5.40	5.94
7	.....	.....	3.28	3.67	4.07	4.49	4.94
8	.....	.....	2.71	3.03	3.38	3.76	4.14
9	.....	.....	2.55	2.49	2.78	3.10	3.45

[25] Jordan HT, Brackbill RM, Cone JE, Debchoudhury I, Farfel MR, Greene CM, Hadler JL, Kennedy J, Li J, Liff J, Stayner L, Stellman SD. Mortality Among Survivors of the Sept 11, 2001, Word Trade Center Disaster: Results from the World Trade Center Health Registry Cohort. Lancet 2011;378:879–887.

[26] 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. Accessed at *http://wonder.cdc.gov/cmf-icd10.html* 15 February 2012.

[27] 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.

[28] National Cancer Institute, Surveillance Epidemiology and End Results (SEER). *http://seer.cancer.gov/*. Accessed May 27, 2012.

[29] National Cancer Institute, Surveillance Epidemiology and End Results (SEER). *http://seer.cancer.gov/*. Accessed May 27, 2012.

[30] The 15-year survival limit is imposed based on the analytic time horizon.

[31] National Cancer Institute, Surveillance Epidemiology and End Results (SEER). *http://seer.cancer.gov/*. Accessed May 27, 2012.

TABLE 3—EXAMPLE FROM PREVALENCE TABLE FOR LUNG CANCER—Continued

[Based on 80,000 responders]

Year	Years since exposure to 9/11 agents			Years covered by WTC Health Program			
	2002	2003	2012	2013	2014	2015	2016
10			2.15	2.38	2.33	2.60	2.90
11			1.78	1.98	2.20	2.14	2.40
12				1.66	1.84	2.04	1.99
13					1.52	1.69	1.88
14						1.42	1.58
15							1.35
Live cases from previous years			54.11	61.26	68.94	77.16	85.74
Prevalence	18.78	28.50	100.64	112.48	125.03	137.85	151.78
Last year of life	11.15	15.46	39.38	43.54	47.87	52.10	56.79

Cost Computation

To compute the costs for each type of cancer, HHS assumes that all of the individuals who are diagnosed with a cancer type will be certified by the WTC Health Program for treatment and monitoring services. The treatment costs for the first year of treatment (Table 1, 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 1 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 is constructed for each year covered by the WTC Health Program. Table 4 provides an illustrative example for lung cancer. The row for Year 1 is the cost of incident cases for that year. Rows 2–15 show the cost from continuing care for persons 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 from Table 1 by the number of persons dying in that year from that type of cancer.

TABLE 4—COST PER 80,000 RESPONDERS FOR LUNG CANCER, 2011$

Year	Years covered by the WTC Health Program			
	2013	2014	2015	2016
1	$914,986	$1,002,168	$1,084,205	$1,179,677
2	91,825	101,077	110,708	119,770
3	49,469	54,959	60,497	66,261
4	34,408	37,865	42,068	46,306
5	26,537	29,228	32,165	35,735
6	21,624	23,850	26,268	28,908
7	17,840	19,797	21,834	24,048
8	14,727	16,468	18,274	20,155
9	12,080	13,500	15,096	16,751
10	11,608	11,311	12,641	14,135
11	9,642	10,706	10,433	11,659
12	8,032	8,932	9,917	9,664
13		7,393	8,221	9,128
14			6,936	7,714
15				6,571
Prevalent care	1,212,778	1,337,254	1,459,263	1,589,911
Last year of life care	2,762,609	3,037,261	3,305,416	3,603,198
Total	3,975,387	4,374,515	4,764,679	5,193,109

The sum of the annual costs for the years 2013 through 2016 represents the estimated treatment costs to the WTC Health Program for coverage of lung cancer for 80,000 responders. The cost projections in Table 4 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 two assumptions: (1) Assuming the rate of cancer in the WTC Health Program is equal to the rate of cancer observed in the general population; and (2) assuming the rate of cancer exceeds the general population rate by 21 percent due to their exposures in the New York City disaster area.[32] HHS is not aware of any other estimates of excess cancer rates in the 9/11-exposed population in the peer-reviewed literature.

[32] 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. 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 WTC-exposure and cancer outcomes; and potential unmeasured confounders.

A summary of the estimated prevalence at the U.S. population average for the assumed population of 55,000 responders and 5,000 survivors is provided in Table 5. A summary of the estimated treatment costs to the WTC Health Program is provided in Table 6.

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 7. A summary of the estimated treatment costs to the WTC Health Program is provided in Table 8.

TABLE 5—ESTIMATED PREVALENCE BY YEAR AND CANCER TYPE BASED ON 55,000 AND 5,000 RESPONDER AND SURVIVOR POPULATION, RESPECTIVELY AND ASSUMING CANCER RATES AT U.S. POPULATION AVERAGE

Cancer type	Prevalence (incident + live cases)			
	2013	2014	2015	2016
Based on 55,000 responder population				
Head & Neck	89.41	99.20	109.35	119.83
Digestive System	136.54	150.69	165.19	180.38
Respiratory System	77.91	86.61	95.50	105.16
Mesothelioma	1.02	1.12	1.23	1.35
Skin	11.04	12.22	13.43	14.71
Female Reproductive Organs	5.14	5.64	6.14	6.65
Urinary System	108.78	121.39	134.69	148.90
Blood & Lymphoid Tissue	119.72	130.72	141.97	153.71
Endocrine System	53.50	58.75	64.05	69.40
Soft Tissue Sarcomas	11.02	11.86	12.67	13.47
Melanoma	134.33	149.37	165.05	181.42
Breast	102.30	113.46	124.91	136.66
Eye/Orbit	3.89	4.29	4.71	5.14
Total	854.59	945.32	1,038.88	1,136.78
Based on 5,000 survivor population				
Head & Neck	7.78	7.78	7.78	7.78
Digestive System	15.48	15.48	15.48	15.48
Respiratory System	10.28	10.28	10.28	10.28
Mesothelioma	0.10	0.10	0.10	0.10
Skin	1.13	1.13	1.13	1.13
Female Reproductive Organs	2.58	2.58	2.58	2.58
Urinary System	10.47	10.47	10.47	10.47
Blood & Lymphoid Tissue	12.48	12.48	12.48	12.48
Endocrine System	4.29	4.29	4.29	4.29
Soft Tissue Sarcomas	0.96	0.96	0.96	0.96
Melanoma	12.21	13.58	15.00	16.49
Breast	9.30	10.31	11.36	12.42
Eye/Orbit	0.35	0.39	0.43	0.47
Total	87.41	89.83	92.33	94.93

TABLE 6—ESTIMATED TREATMENT COSTS BY YEAR AND CANCER TYPE BASED ON 55,000 AND 5,000 RESPONDER AND SURVIVOR POPULATION, RESPECTIVELY AND ASSUMING CANCER RATES AT U.S. POPULATION AVERAGE

[2011 $]

Cancer type	2013	2014	2015	2016	2013–2016
Based on 55,000 responder population					
Head & Neck	$925,673	$1,007,744	$1,089,966	$1,164,226	$4,187,609
Digestive System	4,181,699	4,525,672	4,856,402	5,191,940	18,755,713
Respiratory System	2,832,704	3,117,317	3,395,504	3,701,062	13,046,587
Mesothelioma	49,088	54,012	58,869	64,417	226,387
Skin	18,078	20,075	21,834	23,072	83,059
Female Reproductive Organs	121,957	130,292	137,643	144,194	534,086
Urinary System	1,278,299	1,398,867	1,521,993	1,642,997	5,842,157
Blood & Lymphoid Tissue	2,224,916	2,391,015	2,551,304	2,697,317	9,864,552
Endocrine System	362,248	385,533	408,544	419,353	1,575,678
Soft Tissue Sarcomas	148,358	158,024	167,208	175,680	649,270
Melanoma	229,538	249,805	270,744	284,528	1,034,615
Breast	420,290	453,613	485,454	510,289	1,869,646
Eye/Orbit	36,018	39,242	42,470	45,255	162,985
Total	12,828,867	13,931,212	15,007,935	16,064,330	57,832,344

TABLE 6—ESTIMATED TREATMENT COSTS BY YEAR AND CANCER TYPE BASED ON 55,000 AND 5,000 RESPONDER AND SURVIVOR POPULATION, RESPECTIVELY AND ASSUMING CANCER RATES AT U.S. POPULATION AVERAGE—Continued

[2011 $]

Cancer type	2013	2014	2015	2016	2013–2016
Based on 5,000 survivor population					
Head & Neck	77,325	82,580	87,736	92,044	339,685
Digestive System	471,917	502,369	531,352	559,893	2,065,532
Respiratory System	362,274	389,675	416,326	444,551	1,612,827
Mesothelioma	4,625	4,974	5,291	5,659	20,549
Skin	1,843	2,034	2,196	2,300	8,372
Female Reproductive Organs	58,454	61,173	63,740	65,729	249,097
Urinary System	119,698	128,808	137,954	146,467	532,927
Blood & Lymphoid Tissue	229,578	245,051	259,869	272,842	1,007,340
Endocrine System	60,893	62,633	63,909	64,476	251,910
Soft Tissue Sarcomas	14,017	14,748	15,415	15,960	60,140
Melanoma	30,943	32,541	33,962	35,142	132,588
Breast	230,196	241,382	251,227	258,804	981,609
Eye/Orbit	3,434	3,642	3,832	3,994	14,903
Total	1,665,197	1,771,611	1,872,809	1,967,862	7,277,478
Total					
Head & Neck	1,002,998	1,090,324	1,177,702	1,256,270	4,527,294
Digestive System	4,653,616	5,028,041	5,387,754	5,751,833	20,821,244
Respiratory System	3,194,979	3,506,992	3,811,830	4,145,613	14,659,414
Mesothelioma	53,713	58,987	64,160	70,076	246,936
Skin	19,921	22,109	24,030	25,371	91,431
Female Reproductive Organs	180,411	191,466	201,383	209,923	783,183
Urinary System	1,397,997	1,527,675	1,659,948	1,789,465	6,375,084
Blood & Lymphoid Tissue	2,454,494	2,636,067	2,811,173	2,970,159	10,871,892
Endocrine System	423,141	448,166	472,452	483,829	1,827,588
Soft Tissue Sarcomas	162,376	172,772	182,622	191,640	709,410
Melanoma	260,481	282,346	304,706	319,670	1,167,203
Breast	650,486	694,995	736,681	769,093	2,851,255
Eye/Orbit	39,452	42,885	46,302	49,250	177,888
Total	14,494,064	15,702,823	16,880,744	18,032,192	65,109,823

TABLE 7—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)			
	2013	2014	2015	2016
Based on 80,000 responder population				
Head & Neck	157.36	174.59	192.45	210.91
Digestive System	240.31	265.21	290.74	317.47
Respiratory System	137.12	152.43	168.07	185.08
Mesothelioma	1.79	1.98	2.16	2.38
Skin	19.43	21.50	23.64	25.89
Female Reproductive Organs	9.05	9.92	10.81	11.71
Urinary System	191.45	213.66	237.05	262.06
Blood & Lymphoid Tissue	210.70	230.07	249.86	270.52
Endocrine System	94.16	103.40	112.73	122.15
Soft Tissue Sarcomas	19.40	20.87	22.29	23.70
Melanoma	236.42	262.90	290.50	319.30
Breast	180.05	199.69	219.84	240.52
Eye/Orbit	6.85	7.56	8.29	9.05
Total	1,504.09	1,663.77	1,828.43	2,000.74
Based on 30,000 survivor population				
Head & Neck	56.51	56.51	56.51	56.51
Digestive System	112.39	112.39	112.39	112.39
Respiratory System	74.61	74.61	74.61	74.61
Mesothelioma	0.70	0.70	0.70	0.70
Skin	8.21	8.21	8.21	8.21

TABLE 7—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—Continued

Cancer type	Prevalence (incident + live cases)			
	2013	2014	2015	2016
Female Reproductive Organs	18.73	18.73	18.73	18.73
Urinary System	76.04	76.04	76.04	76.04
Blood & Lymphoid Tissue	90.61	90.61	90.61	90.61
Endocrine System	31.11	31.11	31.11	31.11
Soft Tissue Sarcomas	6.94	6.94	6.94	6.94
Melanoma	88.66	98.59	108.94	119.74
Breast	67.52	74.88	82.44	90.20
Eye/Orbit	2.57	2.83	3.11	3.39
Total	634.60	652.16	670.34	689.18

TABLE 8—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	2013	2014	2015	2016	2013–2016
Based on 80,000 responder population					
Head & Neck	$1,656,113	$1,802,945	$1,950,049	$2,082,906	$7,492,013
Digestive System	7,481,440	8,096,839	8,688,544	9,288,852	33,555,675
Respiratory System	5,067,965	5,577,164	6,074,865	6,621,536	23,341,531
Mesothelioma	87,823	96,633	105,323	115,248	405,027
Skin	32,344	35,916	39,063	41,278	148,600
Female Reproductive Organs	218,192	233,104	246,256	257,976	955,528
Urinary System	2,286,993	2,502,701	2,722,984	2,939,472	10,452,150
Blood & Lymphoid Tissue	3,980,577	4,277,744	4,564,514	4,825,745	17,648,581
Endocrine System	648,095	689,754	730,922	750,261	2,819,031
Soft Tissue Sarcomas	265,426	282,719	299,150	314,308	1,161,603
Melanoma	410,664	446,924	484,385	509,047	1,851,021
Breast	751,937	811,554	868,522	912,953	3,344,966
Eye/Orbit	64,439	70,208	75,983	80,965	291,595
Total	22,952,009	24,924,205	26,850,560	28,740,547	44,654,652
Based on 30,000 survivor population					
Head & Neck	467,817	499,610	530,802	556,869	2,055,097
Digestive System	2,855,098	3,039,331	3,214,682	3,387,354	12,496,466
Respiratory System	2,191,761	2,357,535	2,518,774	2,689,533	9,757,602
Mesothelioma	27,979	30,096	32,010	34,239	124,324
Skin	11,149	12,304	13,285	13,912	50,650
Female Reproductive Organs	353,646	370,100	385,629	397,662	1,507,036
Urinary System	724,172	779,285	834,625	886,127	3,224,209
Blood & Lymphoid Tissue	1,388,944	1,482,561	1,572,207	1,650,695	6,094,408
Endocrine System	368,403	378,927	386,647	390,079	1,524,055
Soft Tissue Sarcomas	84,805	89,226	93,258	96,557	363,846
Melanoma	187,204	196,873	205,471	212,608	802,156
Breast	1,392,687	1,460,361	1,519,924	1,565,763	5,938,735
Eye/Orbit	20,776	22,037	23,182	24,166	90,160
Total	4,912,377	5,256,038	5,588,087	5,914,152	21,670,654
Total					
Head & Neck	2,123,930	2,302,555	2,480,851	2,639,775	9,547,110
Digestive System	10,336,538	11,136,171	11,903,227	12,676,206	46,052,141
Respiratory System	7,259,726	7,934,699	8,593,639	9,311,069	33,099,133
Mesothelioma	115,803	126,729	137,333	149,487	529,350
Skin	43,493	48,220	52,348	55,190	199,251
Female Reproductive Organs	571,838	603,204	631,884	655,638	2,462,564
Urinary System	3,011,165	3,281,986	3,557,609	3,825,599	13,676,358
Blood & Lymphoid Tissue	5,369,522	5,760,305	6,136,721	6,476,440	23,742,988
Endocrine System	1,016,497	1,068,681	1,117,568	1,140,340	4,343,086
Soft Tissue Sarcomas	350,231	371,945	392,408	410,864	1,525,449
Melanoma	597,868	643,798	689,857	721,654	2,653,177

TABLE 8—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—Continued

[2011 $]

Cancer type	2013	2014	2015	2016	2013–2016
Breast	2,144,624	2,271,916	2,388,445	2,478,716	9,283,702
Eye/Orbit	85,215	92,244	99,165	105,132	381,756
Total	33,026,449	35,642,452	38,181,054	40,646,111	147,496,066

Summary of Costs and Transfers

Because HHS lacks data to account for either recoupment by health insurance or workers' compensation insurance or reduction by 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 a low rate of cancer (U.S. population average rate), and an increased rate (21 percent greater than the U.S. population average) on the number of cases and the resulting estimated treatment costs to the WTC Health Program. This analysis does not include administrative costs associated with certifying additional 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).

Costs and transfers of screening have been added to the summary estimates. The screening proposed by this rulemaking follows U.S. Preventive Services Task Force (USPSTF) guidelines.

The USPSTF recommends screening for colorectal cancer (cancer of the colon and rectum) using fecal occult blood testing (FOBT), sigmoidoscopy, or colonoscopy, in adults, beginning at age 50 years and continuing until age 75 years.[33] The costs and transfers include the costs of one FOBT for all Program enrollees who are over the age of 50 in 2013, and for those who will reach 50 years of age in 2014 through 2016. In the general population, HHS expects there to be 9 percent positive tests. In a previous study[34] of those with positive tests who were outside the study university system, 44 percent had a colonoscopy, 42 percent had flexible sigmoidoscopy, 11 percent had repeat FOBT, and 3 percent were told by their physician that no further examination was necessary. HHS applied these rates to the population and assigned costs for each test assuming FOBT cost was $7.60, sigmoidoscopy was $238, and a colonoscopy was $674.[35]

The USPSTF recommends breast cancer screening using biennial mammography for women beginning at age 40. HHS assumed that the population of responders was 12 percent female and the population of survivors was 50 percent female. Based on age distribution information available, HHS estimated the number of women eligible for screening between 2013 and 2016. For those screened in 2013 HHS predicted repeat screening in 2015 and for those screened in 2014 HHS predicted repeat screening in 2016. The cost of a mammogram was estimated at $139.32 based on FECA rates for mammography.[36]

Some responders and survivors enrolled or expected to enroll in the WTC Health Program already have or have access to medical insurance coverage by private health insurance, employer-provided insurance, Medicare, or Medicaid. Therefore, costs to the WTC Health Program can be divided between societal costs and transfer payments.

To describe these societal costs and transfers, the following assumptions were used. For the period of coverage between January 1, 2013 and December 31, 2013, HHS has assumed that 16.3 percent of the survivor population will be uninsured, or based on grandfathered enrollment of responders, 16,925 are covered by the FDNY health plan, while 39,482 are listed as general responders and include construction workers, contractors, and others. For this analysis, HHS assumed that the non-FDNY general responders and all future responder-enrollees are uninsured at the same 16.3 percent rate that HHS applied to the survivor population, based on those without insurance coverage in the general U.S. population.[37] Ward et al.[38] found that access to health care services, quality of care received, stage of disease at diagnosis, and survival outcomes for cancer patients varied according to socioeconomic status and demographic characteristics.

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

Table 9 describes the allocation of WTC Health Program costs between societal costs and transfer payments based on 55,000 responders and 5,000 survivors. Table 10 describes the allocation of WTC Health Program costs between societal costs and transfer payments based on 80,000 responders and 30,000 survivors.

[33] United States Preventive Services Task Force (USPSTF) [2008]. Screening for Colorectal Cancer. Available at *http://www.uspreventiveservicestaskforce.org/uspstf/uspscolo.htm*. Accessed May 28, 2012.

[34] Mandel JS, et. al, Reducing Mortality From Colorectal Cancer by Screening for Fecal Occult Blood, NEJM 328(19): 1365–1371 (1993).

[35] Subramanian S, et. al. When Budgets Are Tight, There Are Better Options Than Colonoscopies For Colorectal Cancer Screening. Health Affairs, September 2010, 29:9, 1734–1740.

FECA Rates for FOBT, sigmoidoscopy and colonoscopy at non-facility rates: codes 82270, 45330, and 45378 respectively.

[36] FECA rates for Mammography for New York; FECA code 77057.

[37] U.S. Census Bureau [2011]. Current Population Survey. *http://www.census.gov/cps/data/*. Accessed May 26, 2012.

[38] 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.

TABLE 9—BREAKDOWN OF ESTIMATED ANNUAL WTC HEALTH PROGRAM COSTS AND TRANSFERS, 80,000 & 55,000 RESPONDERS AND 30,000 AND 5,000 SURVIVORS, 2013–2016, 2011$

	Societal costs for 2013, 2011$		Annualized transfers for 2013–2016, 2011$	
	Based on the 16.3 percent of general responders and survivors who are expected to be uninsured		Discounted at 7 percent	Discounted at 3 percent
	Cancer rate		Cancer rate	
	U.S. Average	U.S. + 21%	U.S. Average	U.S. + 21%
55,000 Responders	$1,648,706	.....	$10,172,308	.....
5,000 Survivors	271,427	.....	1,572,907	.....
Colorectal and Breast Screening	204,491	.....	713,321	.....
60,000 Total	2,124,624	.....	12,458,535	.....
80,000 Responders	.....	$2,631,100	.....	$19,912,464
30,000 Survivors	.....	1,970,560	.....	12,124,118
Colorectal and Breast Screening	.....	417,521	.....	1,271,478
110,000 Total	.....	5,019,182	.....	33,308,060

Examination of Benefits (Health Impact)

This section describes qualitatively the potential benefits of the proposed 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.

HHS does not have information on the health of the population that may have been exposed to 9/11 agents and is not currently enrolled in the WTC Health Program. In addition, HHS has only limited information about health insurance and health care services for cancers caused by exposure to 9/11 agents 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, HHS 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 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, HHS 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 overwhelmingly covered by employer-based health insurance.

Although HHS cannot quantify the benefits associated with the WTC Health Program, enrollees with cancer are expected to experience a higher quality of care than they would in the absence of the Program. Mortality and morbidity improvements for cancer patients expected to enroll in the WTC Health Program are anticipated because barriers may exist to access and delivery of quality health care services for cancer patients in the absence of the services provided by the WTC Health Program. HHS anticipates benefits to cancer patients treated through the WTC Health Program, who may otherwise not have access to health care services (16.3 percent of general responders and survivors who are expected to be uninsured), to accrue in 2013. Starting in 2014, continued implementation of the Affordable Care Act will result in increased access to health insurance and health care services will improve for the general responder and survivor population that currently is uninsured. HHS is requesting public comment on issues relating to access to care, quality of care, and the potential benefits associated with the WTC Health Program.

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, HHS was not able to estimate benefits in terms of averted healthcare costs. Nor was HHS 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.

Regulatory Alternatives

As discussed in section III.D.2., above, the Administrator considered alternative approaches to the methods set forth in this rulemaking.

One alternative would involve a presumption that 9/11 exposures could have resulted in the development of *any* and *all* types of cancer in the exposed populations. A presumption that any and all types of cancer could occur after exposure to 9/11 agents does not require any scientific evidence of a positive association between exposure and a type of cancer. The Administrator declined to determine inclusion of types of cancer based on a presumption approach. The STAC affirmatively rejected a recommendation to include any and all types of cancer to the List of WTC-Related Health Conditions. The Administrator made the policy decision to include only those types of cancer when a positive relationship has been established between exposure to the 9/11 agent and human cancer.

Another alternative would be to rely on epidemiologic studies of the association of 9/11 exposures and the development of cancer or a type of cancer in 9/11-exposed populations *exclusively*. There are several limitations to using an exclusive 9/11 populations study approach. The Administrator finds that vast uncertainties exist in conducting epidemiologic studies of cancer in 9/11-exposed populations. For example, there exists only very limited, individual exposure data in 9/11-exposed populations. This lack of

personal, quantitative exposure data impedes the definitive epidemiologic evidence that exposure to 9/11 agents causes certain types of cancer in responder and survivor populations. In addition, cancer is generally a long latency set of diseases which in some cases may take many years or even decades to manifest clinically. Requiring evidence of positive associations from studies of 9/11-exposed populations exclusively does not serve the best interests of WTC Health Program members.

By expanding the scope of scientific information reviewed to include three complementary methods (including studies in 9/11 exposed populations and generally available epidemiologic criteria), the Administrator has developed a hierarchy of methods to guide consideration of whether to include types of cancers on the List of WTC-Related Health Conditions.

Effects on Other Agency Programs

HHS finds that this rulemaking also has an effect on the VCF [39] administered by DOJ. DOJ administers the VCF under rules promulgated at 28 CFR part 104. The DOJ regulations define, in 28 CFR 104.2 (f), the term ''WTC-related health condition'' to mean ''those health conditions identified as WTC-related by Title I of Public Law 111–347 and by regulations implementing that Title.'' The preamble to the VCF final rule (76 FR 54115) states, ''If the WTC Health Program determines that certain forms of cancer should be added to the list of WTC-related conditions, the final rule requires the Special Master to add such conditions to the list of presumptively covered conditions for the Fund.''

Under the VCF program, compensation awards are generally calculated using three components: Economic loss *plus* non-economic loss *minus* collateral source payments. To determine economic loss, the Special Master considers any prior loss of earnings or other benefits related to employment, medical expense loss, replacement services loss, and loss of business or employment opportunity. The regulations provide presumed non-economic awards for deceased individuals. Because every physical injury is unique, the Special Master may determine presumed non-economic losses on a case-by-case basis for physically injured claimants. The Special Master then subtracts any collateral offsets received or eligible to be received. The computation of individual compensation due under the fund is based on factors pertinent to each individual claimant.

The statute caps the total amount of funds allocated to the VCF. The VCF regulation at 28 CFR 104.51 provides that, ''the total amount of Federal funds paid for expenditures including compensation with respect to claims filed on or after October 3, 2011, will not exceed $2,775,000,000. Furthermore, the total amount of Federal funds expended during the period from October 3, 2011, through October 3, 2016, may not exceed $875,000,000.''

To meet these requirements, the Special Master is authorized to reduce the amount of compensation due to each claimant by prorating the total amount of the compensation award determined for each individual claimant. The VCF intends to establish the fraction for proration such that all claimants receive some payment related to their claim within the overall funding limitation of the program. The Special Master may adjust the percentage of the total award that is to be paid to eligible claims based on experiential information as well as estimates related to potential future claims and availability of funds.

The amount of compensation that would be awarded to each of the living claimants who develop, or the heirs of those who died from, a covered type of cancer during the years 2002 through 2016, would be determined by individual factors considered under the VCF. Depending on the total number of new claims and compensation eligibility, the overall impact on the VCF of increasing the number of eligible VCF claimants as a result of adding eligible health condition under the WTC Health Program may be to reduce the proration fraction that is applied to all VCF claimants such that the total cost to the government remains unchanged. The additional costs to the VCF due to processing and computing the entitlement for the extra claimants eligible as a result of having a covered type of cancer, plus the costs of paying newly covered claimants their prorated share of the compensation award, would result in amounts that will not be available to pay increased shares for the claimants with non-cancer conditions.

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. HHS believes 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.*).

The WTC Health Program has contracted with the following healthcare providers and provider network managers to offer treatment and monitoring to enrolled responders and survivors: Seven Clinical Centers of Excellence (CCE), which serve responders and survivors in the New York City metropolitan area (City of New York Fire Department; Mount Sinai School of Medicine; Research Foundation of State University of New York; New York University, Bellevue Hospital Center; University of Medicine and Dentistry of New Jersey; Long Island Jewish Medical Center; and New York City Health and Hospitals Corporation); Logistics Health Incorporated, which manages the nationwide provider network for populations geographically distant from New York City; three Data Centers, which analyze CCE data and coordinate activities (City of New York Fire Department; Mount Sinai School of Medicine; and New York City Health and Hospitals Corporation); and Emdeon, which manages pharmacy benefits.

Of these entities, six of the seven CCEs and two of the three Data Centers are hospitals (NAICS 622110—General Medical and Surgical Hospitals). The Small Business Administration (SBA) identifies as a small business those hospitals with average annual receipts below $34.5 million; none of the six fall below the SBA threshold for small businesses. The City of New York Fire Department's Bureau of Health Services, which provides medical monitoring and treatment for FDNY members as a CCE, and provides data analysis and other services for the FDNY CCE as a Data Center, is considered a local government agency (NAICS 922160—Fire Protection), and as such cannot be considered a small entity by SBA. Finally, neither Logistics Health Incorporated, which manages the national provider network, nor Emdeon, which manages pharmacy benefits, (NAICS 551112—Management of Companies and Enterprises) falls below

[39] The September 11th Victim Compensation Fund of 2001 (VCF) was initially established in 2001 pursuant to Title IV of Public Law 107–42, 115 Stat. 230 (Air Transportation Safety and System Stabilization Act) and was open for claims from December 21, 2001, through December 22, 2003. Title II of the Zadroga Act amends and reactivates the September 11th Victim Compensation Fund of 2001. Public Law 111–347. Administered through DOJ by a Special Master, the VCF provides compensation to any individual (or a personal representative of a deceased individual) who suffered physical harm or was killed as a result of the terrorist-related aircraft crashes of September 11, 2001, or the debris removal efforts that took place in the immediate aftermath of those crashes.

SBA's $7 million threshold for small businesses in that sector.

Because no small businesses are impacted by this rulemaking, HHS certifies that this rule will not have a significant economic impact on a substantial number of small entities within the meaning of the RFA. Therefore, a regulatory flexibility analysis as provided for under RFA is not required.

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). HHS 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 proposed rule does not include any Federal mandate that may result in increased annual expenditures in excess of $100 million by State, local or Tribal governments in the aggregate, or by the private sector. However, the rule may result in an increase in the contribution made by New York City for treatment and monitoring, as required by Title XXXIII, § 3331(d)(2). For 2012, the inflation adjusted threshold is $139 million.

F. Executive Order 12988 (Civil Justice)

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

G. Executive Order 13132 (Federalism)

HHS has reviewed this proposed rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have ''federalism implications.'' The rule does not ''have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

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

In accordance with Executive Order 13045, HHS has evaluated the environmental health and safety effects of this proposed rule on children. HHS has determined that the rule would have no environmental health and safety effect on children, although an eligible child who has been diagnosed with a cancer type specified in this rulemaking 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, HHS has evaluated the effects of this proposed rule on energy supply, distribution or use, and has determined that the rule will not have a significant adverse effect.

J. Plain Writing Act of 2010

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

VI. Proposed Rule

List of Subjects in 42 CFR Part 88

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

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

§ 88.1 [Amended]

2. Amend § 88.1 by adding paragraph (4) to the definition of ''List of WTC-related health conditions'' to read as follows:

§ 88.1 Definitions.

* * * * *

List of WTC-related health conditions

* * *

* * * * *

(4) Cancers: This list includes those individual cancer types specified in Table 1, below, according to the International Classification of Diseases, 10th Edition (ICD–10) and International Classification of Diseases, 9th Edition (ICD–9).

BILLING CODE P

Table 1 -- List of types of cancer included in the List of WTC-Related Health Conditions

Region	Type of Cancer	ICD-10[1]	ICD-9[2]
Head & Neck	**Malignant neoplasm of lip**	**C00**	**140**
	• External upper lip	• C00.0	• 140.0
	• External lower lip	• C00.1	• 140.1
	• External lip, unspecified	• C00.2	• 140.9
	• Upper lip, inner aspect	• C00.3	• 140.3
	• Lower lip, inner aspect	• C00.4	• 140.4
	• Lip, unspecified, inner aspect	• C00.5	• 140.5
	• Commissure of lip	• C00.6	• 140.6
	• Overlapping lesion of lip	• C00.8	• 140.8
	• Lip, unspecified	• C00.9	• 140.9
	Malignant neoplasm of base of tongue	**C01**	**141.0**
	Malignant neoplasm of other and unspecified parts of tongue	**C02**	**141.1-141.9**
	• Dorsal surface of tongue	• C02.0	• 141.1
	• Border of tongue	• C02.1	• 141.2
	• Ventral surface of tongue	• C02.2	• 141.3
	• Anterior two-thirds of tongue, part unspecified	• C02.3	• 141.4
	• Lingual tonsil	• C02.4	• 141.6
	• Overlapping lesion of tongue	• C02.8	• 141.5, 141.8
	• Tongue, unspecified	• C02.9	• 141.9
	Malignant neoplasm of parotid gland	**C07**	**142.0**
	Malignant neoplasm of other and unspecified major salivary glands	**C08**	**142.1-142.9**
	• Submandibular gland	• C08.0	• 142.1
	• Sublingual gland	• C08.1	• 142.2
	• Overlapping lesion of major salivary glands	• C08.8	• 142.8
	• Major salivary gland, unspecified	• C08.9	• 142.9
	Malignant neoplasm of floor of mouth	**C04**	**144**
	• Anterior floor of mouth	• C04.0	• 144.0
	• Lateral floor of mouth	• C04.1	• 144.1

	• Overlapping lesion of floor of mouth	• C04.8	• 144.8
	• Floor of mouth, unspecified	• C04.9	• 144.9
	Malignant neoplasm of gum	**C03**	**143**
	• Upper gum	• C03.0	• 143.0
	• Lower gum	• C03.1	• 143.1
	• Gum, unspecified	• C03.9	• 143.8-143.9
	Malignant neoplasm of palate	**C05**	**145.2-145.5, 149.9**
	• Hard palate	• C05.0	• 145.2
	• Soft palate	• C05.1	• 145.3
	• Uvula	• C05.2	• 145.4
	• Overlapping lesion of palate	• C05.8	• 145.5
	• Palate, unspecified	• C05.9	• 145.9
	Malignant neoplasm of other and unspecified parts of mouth	**C06**	**145.0-145.1 145.6, 145.8-145.9**
	• Cheek mucosa	• C06.0	• 145.0
	• Vestibule of mouth	• C06.1	• 145.1
	• Retromolar area	• C06.2	• 145.6
	• Overlapping lesion of other and unspecified parts of mouth	• C06.8	• 145.8
	• Mouth, unspecified	• C06.9	• 149.9
	Malignant neoplasm of tonsil	**C09**	**146.0-146.2, 146.5**
	• Tonsillar fossa	• C09.0	• 146.1
	• Tonsillar pillar (anterior) (posterior)	• C09.1	• 146.2
	• Overlapping lesion of tonsil	• C09.8	• 146.5
	• Tonsil, unspecified	• C09.9	• 146.0
	Malignant neoplasm of oropharynx	**C10**	**146.3-146.4, 146.6-146.9**
	• Vallecula	• C10.0	• 146.3
	• Anterior surface of epiglottis	• C10.1	• 146.4
	• Lateral wall of oropharynx	• C10.2	• 146.6
	• Posterior wall of oropharynx	• C10.3	• 146.7
	• Branchial cleft	• C10.4	• 146.9
	• Overlapping lesion of oropharynx	• C10.8	• 146.8

	• Oropharynx, unspecified	• C10.9	• 146.9
	Malignant neoplasm of nasopharynx	**C11**	**147**
	• Superior wall of nasopharynx	• C11.0	• 147.0
	• Posterior wall of nasopharynx	• C11.1	• 147.1
	• Lateral wall of nasopharynx	• C11.2	• 147.2
	• Anterior wall of nasopharynx	• C11.3	• 147.3
	• Overlapping lesion of nasopharynx	• C11.8	• 147.8
	• Nasopharynx, unspecified	• C11.9	• 147.9
	Malignant neoplasm of piriform sinus	**C12**	**148.1**
	Malignant neoplasm of hypopharynx	**C13**	**148.0-148.9**
	• Postcricoid region	• C13.0	• 148.0
	• Aryepiglottic fold, hypopharyngeal aspect	• C13.1	• 148.2
	• Posterior wall of hypopharynx	• C13.2	• 148.3
	• Overlapping lesion of hypopharynx	• C13.8	• 148.8
	• Hypopharynx, unspecified	• C13.9	• 148.9
	Malignant neoplasms of other and ill-defined conditions in the lip, oral cavity and pharynx	**C14**	**149**
	• Pharynx, unspecified	• C14.0	• 149.0
	• Waldeyer's ring	• C14.2	• 149.1
	• Overlapping lesion of lip, oral cavity and pharynx	• C14.8	• 149.8
	Malignant neoplasm of nasal cavity	**C30**	**160.0**
	• Nasal cavity	• C30.0	• 160.0
	Malignant neoplasm of accessory sinuses	**C31**	**160.2-160.9**
	• Maxillary sinus	• C31.0	• 160.2
	• Ethmoidal sinus	• C31.1	• 160.3
	• Frontal sinus	• C31.2	• 160.4
	• Sphenoidal sinus	• C31.3	• 160.5
	• Overlapping lesion of accessory sinuses	• C31.8	• 160.8
	• Accessory sinus, unspecified	• C31.9	• 160.9
	Malignant neoplasm of larynx	**C32**	**161**
	• Glottis	• C32.0	• 161.0
	• Supraglottis	• C32.1	• 161.1
	• Subglottis	• C32.2	• 161.2
	• Laryngeal cartilage	• C32.3	• 161.3
	• Overlapping lesion of larynx	• C32.8	• 161.8

	• Larynx, unspecified	• C32.9	• 161.9
Digestive System	**Malignant neoplasm of the esophagus**	**C15**	**150**
	• Cervical part of esophagus	• C15.0	• 150.0
	• Thoracic part of esophagus	• C15.1	• 150.1
	• Abdominal part of esophagus	• C15.2	• 150.2
	• Upper third of esophagus	• C15.3	• 150.3
	• Middle third of esophagus	• C15.4	• 150.4
	• Lower third of esophagus	• C15.5	• 150.5
	• Overlapping lesion of esophagus	• C15.8	• 150.8
	• Esophagus, unspecified	• C15.9	• 150.9
	Malignant neoplasm of the stomach	**C16**	**151**
	• Cardia	• C16.0	• 151.0
	• Fundus of stomach	• C16.1	• 151.3
	• Body of stomach	• C16.2	• 151.4
	• Pyloric antrum	• C16.3	• 151.2
	• Pylorus	• C16.4	• 151.1
	• Lesser curvature of stomach, unspecified	• C16.5	• 151.5
	• Greater curvature of stomach, unspecified	• C16.6	• 151.6
	• Overlapping lesion of stomach	• C16.8	• 151.8
	• Stomach, unspecified	• C16.9	• 151.9
	Malignant neoplasm of colon	**C18**	**153**
	• Caecum	• C18.0	• 153.4
	• Appendix	• C18.1	• 153.5
	• Ascending colon	• C18.2	• 153.6
	• Hepatic flexure	• C18.3	• 153.0
	• Transverse colon	• C18.4	• 153.1
	• Splenic flexure	• C18.5	• 153.7
	• Descending colon	• C18.6	• 153.2
	• Sigmoid colon	• C18.7	• 153.3
	• Overlapping lesion of colon	• C18.8	• 153.8
	• Colon, unspecified	• C18.9	• 153.9
	Malignant neoplasm of rectosigmoid junction	**C19**	**154.0**
	Malignant neoplasm of rectum	**C20**	**154.1**
	Malignant neoplasm of other and ill-defined digestive organs	**C26.0, C26.8-C26.9**	**154.8**
	• Intestinal tract, part unspecified	• C26.0	• 154.8
	• Overlapping lesion of digestive system	• C26.8	• 154.8
	• Ill-defined sites within the digestive system	• C26.9	• 154.8
	Malignant neoplasm of liver and intrahepatic bile ducts	**C22**	**155**
	• Liver cell carcinoma	• C22.0	• 155.0

	• Intrahepatic bile duct carcinoma	• C22.1	• 155.1
	• Hepatoblastoma	• C22.2	• 155.0
	• Angiosarcoma of liver	• C22.3	• 155.0
	• Other sarcomas of liver	• C22.4	• 155.0
	• Other specified carcinomas of liver	• C22.7	• 155.0
	• Liver, unspecified	• C22.9	• 155.2
	Malignant neoplasm of retroperitoneum and peritoneum	**C48**	**158**
	• Retroperitoneum	• C48.0	• 158.0
	• Specified parts of peritoneum	• C48.1	• 158.8
	• Peritoneum, unspecified	• C48.2	• 158.9
	• Overlapping lesion of retroperitoneum and peritoneum	• C48.8	• 158.8
Respiratory System	**Malignant neoplasm of trachea**	**C33**	**162.0**
	Malignant neoplasm of bronchus and lung	**C34**	**162.2-162.9**
	• Main bronchus	• C34.0	• 162.2
	• Upper lobe, bronchus or lung	• C34.1	• 162.3
	• Middle lobe, bronchus or lung	• C34.2	• 162.4
	• Lower lobe, bronchus or lung	• C34.3	• 162.5
	• Overlapping lesion of bronchus and lung	• C34.8	• 162.8
	• Bronchus or lung, unspecified	• C34.9	• 162.9
	Malignant neoplasm of heart, mediastinum and pleura	**C38**	**164.1-164.9, 163.9**
	• Heart	• C38.0	• 164.1
	• Anterior mediastinum	• C38.1	• 164.2
	• Posterior mediastinum	• C38.2	• 164.3
	• Mediastinum, part unspecified	• C38.3	• 164.9
	• Pleura	• C38.4	• 163.9
	• Overlapping lesion of heart, mediastinum and pleura	• C38.8	• 164.8
	Malignant neoplasm of other and ill-defined sites in the respiratory system and intrathoracic organs	**C39**	**165**
	• Upper respiratory tract, part unspecified	• C39.0	• 165.0
	• Overlapping lesion of respiratory and intrathoracic organs	• C39.8	• 165.8

	• III-defined sites within the respiratory system	• C39.9	• 165.9
Mesothelium	**Mesothelioma**	**C45**	**158.8, 163.9, 164.1**
	• Mesothelioma of pleura	• C45.0	• 163.9
	• Mesothelioma of peritoneum	• C45.1	• 158.8
	• Mesothelioma of pericardium	• C45.2	• 164.1
	• Mesothelioma of other sites	• C45.7	No Code
	• Mesothelioma, unspecified	• C45.9	No Code
Soft Tissue	**Malignant neoplasm of peripheral nerves and autonomic nervous system**	**C47**	**171**
	• Peripheral nerves of head, face and neck	• C47.0	• 171.0
	• Peripheral nerves of upper limb, including shoulder	• C47.1	• 171.2
	• Peripheral nerves of lower limb, including hip	• C47.2	• 171.3
	• Peripheral nerves of thorax	• C47.3	• 171.4
	• Peripheral nerves of abdomen	• C47.4	• 171.5
	• Peripheral nerves of pelvis	• C47.5	• 171.6
	• Peripheral nerves of trunk, unspecified	• C47.6	• 171.7
	• Overlapping lesion of peripheral nerves and autonomic nervous system	• C47.8	• 171.8
	• Peripheral nerves and autonomic nervous system, unspecified	• C47.9	• 171.9
	Malignant neoplasm of other connective and soft tissue	**C49**	**171**
	• Connective and soft tissue of head, face and neck	• C49.0	• 171.0
	• Connective and soft tissue of upper limb, including shoulder	• C49.1	• 171.2
	• Connective and soft tissue of lower limb, including hip	• C49.2	• 171.3
	• Connective and soft tissue of thorax	• C49.3	• 171.4
	• Connective and soft tissue of abdomen	• C49.4	• 171.5
	• Connective and soft tissue of pelvis	• C49.5	• 171.6
	• Connective and soft tissue of trunk, unspecified	• C49.6	• 171.7
	• Overlapping lesion of connective and soft tissue	• C49.8	• 171.8
	• Connective and soft tissue, unspecified	• C49.9	• 171.9
Skin (Non-Melanoma)	**Other malignant neoplasms of skin**	**C44**	**172, 187.7**
	• Skin of lip	• C44.0	• 172.0
	• Skin of eyelid, including canthus'	• C44.1	• 172.1

	• Skin of ear and external auricular canal	• C44.2	• 172.2
	• Skin of other and unspecified parts of face	• C44.3	• 172.3
	• Skin of scalp and neck	• C44.4	• 172.4
	• Skin of trunk	• C44.5	• 172.5
	• Skin of upper limb, including shoulder	• C44.6	• 172.6
	• Skin of lower limb, including hip	• C44.7	• 172.7
	• Overlapping lesion of skin	• C44.8	• 172.8
	• Malignant neoplasm of skin, unspecified	• C44.9	• 172.9
	Scrotum	**C63.2**	**187.7**
Melanoma	**Malignant melanoma of skin**	**C43**	**172**
	• Malignant melanoma of lip	• C43.0	• 172.0
	• Malignant melanoma of eyelid, including canthus	• C43.1	• 172.1
	• Malignant melanoma of ear and external auricular canal	• C43.2	• 172.2
	• Malignant melanoma of other and unspecified parts of face	• C43.3	• 172.3
	• Malignant melanoma of scalp and neck	• C43.4	• 172.4
	• Malignant melanoma of trunk	• C43.5	• 172.5
	• Malignant melanoma of upper limb, including shoulder	• C43.6	• 172.6
	• Malignant melanoma of lower limb, including hip	• C43.7	• 173.7
	• Overlapping malignant melanoma of skin	• C43.8	• 173.8
	• Malignant melanoma of skin, unspecified	• C43.9	• 173.9
Breast	**Malignant neoplasm of breast**	**C50**	**174**
	• Nipple and areola	• C50.0	• 174.0
	• Central portion of breast	• C50.1	• 174.1
	• Upper-inner quadrant of breast	• C50.2	• 174.2
	• Lower-inner quadrant of breast	• C50.3	• 174.3
	• Upper-outer quadrant of breast	• C50.4	• 174.4
	• Lower-outer quadrant of breast	• C50.5	• 174.5
	• Axillary tail of breast	• C50.6	• 174.6
	• Overlapping lesion of breast	• C50.8	• 174.8
	• Breast, unspecified	• C50.9	• 174.9

Female Reproductive Organs	**Malignant neoplasm of ovary**	**C56**	**183.0**
Urinary System	**Malignant neoplasm of bladder**	**C67**	**183.0**
	• Trigone of bladder	• C67.0	• 188.0
	• Dome of bladder	• C67.1	• 188.1
	• Lateral wall of bladder	• C67.2	• 188.2
	• Anterior wall of bladder	• C67.3	• 188.3
	• Posterior wall of bladder	• C67.4	• 188.4
	• Bladder neck	• C67.5	• 188.5
	• Ureteric orifice	• C67.6	• 188.6
	• Urachus	• C67.7	• 188.7
	• Overlapping lesion of bladder	• C67.8	• 188.8
	• Bladder, unspecified	• C67.9	• 188.9
	Malignant neoplasms of kidney except renal pelvis	**C64**	**189.0**
	Malignant neoplasm of renal pelvis	**C65**	**189.1**
	Malignant neoplasm of ureter	**C66**	**189.2**
	Malignant neoplasm of other and unspecified urinary organs	**C68**	**189.3-189.9**
	• Urethra	• C68.0	• 189.3
	• Paraurethral gland	• C68.1	• 189.4
	• Overlapping lesion of urinary organs	• C68.8	• 189.8
	• Urinary organ, unspecified	• C68.9	• 189.9
Eye & Orbit	**Malignant neoplasm of eye and adnexa**	**C69**	**190**
	• Conjunctiva	• C69.0	• 190.3
	• Cornea	• C69.1	• 190.4
	• Retina	• C69.2	• 190.5
	• Choroid	• C69.3	• 190.6
	• Ciliary body	• C69.4	• 190.0
	• Lacrimal gland and duct	• C69.5	• 190.2
	• Orbit	• C69.6	• 190.1
	• Overlapping lesion of eye and adnexa	• C69.8	• 190.8
	• Eye, unspecified	• C69.9	• 190.0
Thyroid	**Malignant neoplasm of thyroid gland**	**C73**	**193**

Blood & Lymphoid Tissue	**Hodgkin's disease**	**C81**	*
	• Lymphocytic predominance	• C81.0	• 201.4
	• Nodular sclerosis	• C81.1	• 201.5
	• Mixed cellularity	• C81.2	• 201.6
	• Lymphocytic depletion	• C81.3	• 201.7
	• Other Hodgkin's disease	• C81.7	• 201.0-201.2
	• Hodgkin's disease, unspecified	• C81.9	• 201.9
	Follicular [nodular] non-Hodgkin lymphoma	**C82**	*
	• Small cleaved cell, follicular	• C82.0	• 202.0
	• Mixed small cleaved and large cell, follicular	• C82.1	• 202.0
	• Large cell, follicular	• C82.2	• 202.0
	• Other types of follicular non-Hodgkin lymphoma	• C82.7	• 202.0
	• Follicular non-Hodgkin lymphoma, unspecified	• C82.9	• 202.0
	Diffuse non-Hodgkin lymphoma	**C83**	*
	• Small cell (diffuse)	• C83.0	• 200.8
	• Small cleaved cell (diffuse)	• C83.1	• 202.4
	• Mixed small and large cell (diffuse)	• C83.2	• 200.8
	• Large cell (diffuse)	• C83.3	• 200.0
	• Immunoblastic (diffuse)	• C83.4	• 200.8
	• Lymphoblastic (diffuse)	• C83.5	• 200.1
	• Undifferentiated (diffuse)	• C83.6	• 202.8
	• Burkitt's tumor	• C83.7	• 200.2
	• Other types of diffuse non-Hodgkin lymphoma	• C83.8	• 200.8
	• Diffuse non-Hodgkin lymphoma, unspecified	• C83.9	• 202.0
	Peripheral and cutaneous T-cell lymphomas	**C84**	*
	• Mycosis fungoides	• C84.0	• 202.1
	• Sezary's disease	• C84.1	• 202.2
	• T-zone lymphoma	• C84.2	• 202.8
	• Lymphoepithelioid lymphoma	• C84.3	• 202.8
	• Peripheral T-cell lymphoma	• C84.4	• 202.0
	• Other and unspecified T-cell lymphomas	• C84.5	• 202.0
	Other and unspecified types of non-Hodgkin lymphoma	**C85**	*
	• Lymphosarcoma	• C85.0	• 200.1
	• B-cell lymphoma, unspecified	• C85.1	• 202.8

	• Other specified types of non-Hodgkin lymphoma	• C85.7	• 202.3
	• Non-Hodgkin lymphoma, unspecified	• C85.9	• 200.8
	Malignant immunoproliferative diseases	**C88**	*
	• Waldenstrom's macroglobulinemia	• C88.0	• 273.3
	• Alpha heavy chain disease	• C88.1	• 203.8
	• Gamma heavy chain disease	• C88.2	• 203.8
	• Immunoproliferative small intestinal disease	• C88.3	• 203.8
	• Other malignant immunoproliferative diseases	• C88.7	• 203.8
	• Malignant immunoproliferative disease, unspecified	• C88.9	• 203.8
	Multiple myeloma and malignant plasma cell neoplasms	**C90**	*
	• Multiple myeloma	• C90.0	• 203.0
	• Plasma cell leukemia	• C90.1	• 203.1
	• Plasmacytoma, extramedullary	• C90.2	• 203.8
	Lymphoid leukemia	**C91**	*
	• Acute lymphoblastic leukemia	• C91.0	• 204.0
	• Chronic lymphocytic leukemia	• C91.1	• 204.1
	• Subacute lymphocytic leukemia	• C91.2	• 204.2
	• Prolymphocytic leukemia	• C91.3	• 204.9
	• Hairy-cell leukemia	• C91.4	• 202.4
	• Adult T-cell leukemia	• C91.5	• 204.8
	• Other lymphoid leukemia	• C91.7	• 204.8
	• Lymphoid leukemia, unspecified	• C91.9	• 204.9
	Myeloid leukemia	**C92**	*
	• Acute myeloid leukemia	• C92.0	• 205.0
	• Chronic myeloid leukemia	• C92.1	• 205.1
	• Subacute myeloid leukemia	• C92.2	• 205.2
	• Myeloid sarcoma	• C92.3	• 205.3
	• Acute promyelocytic leukemia	• C92.4	• 205.0
	• Acute myelomonocytic leukemia	• C92.5	• 205.0
	• Other myeloid leukemia	• C92.7	• 205.8
	• Myeloid leukemia, unspecified	• C92.9	• 205.9
	Monocytic leukemia	**C93**	*
	• Acute monocytic leukemia	• C93.0	• 206.0
	• Chronic monocytic leukemia	• C93.1	• 206.1
	• Subacute monocytic leukemia	• C93.2	• 206.2
	• Other monocytic leukemia	• C93.7	• 206.8
	• Monocytic leukemia, unspecified	• C93.9	• 206.9

	Other leukemias of specified cell type	**C94**	*
	• Acute erythremia and erythroleukemia	• C94.0	• 207.0
	• Chronic erythremia	• C94.1	• 207.1
	• Acute megakaryoblastic leukemia	• C94.2	• 207.2
	• Mast cell leukemia	• C94.3	• 207.8
	• Acute pan myelosis	• C94.4	• 238.7
	• Acute myelofibrosis	• C94.5	• 238.7
	• Other specified leukemias	• C94.7	• 207.8
	Leukemia of unspecified cell type	**C95**	*
	• Acute leukemia of unspecified cell type	• C95.0	• 208.0
	• Chronic leukemia of unspecified cell type	• C95.1	• 208.1
	• Subacute leukemia of unspecified cell type	• C95.2	• 208.2
	• Other leukemia of unspecified cell type	• C95.7	• 208.8
	• Leukemia, unspecified	• C95.9	• 208.9
	Other and unspecified malignant neoplasms of lymphoid, hematopoietic and related tissue	**C96**	*
	• Letterer-Siwe disease	• C96.0	• 202.5
	• Malignant histiocytosis	• C96.1	• 202.3
	• Malignant mast cell tumor	• C96.2	• 202.6
	• True histiocytic lymphoma	• C96.3	• 202.3
	• Other specified malignant neoplasms of lymphoid, hematopoietic and related tissue	• C96.7	• 202.8
	• Malignant neoplasm of lymphoid, hematopoietic and related tissue, unspecified	• C96.9	• 202.9
Childhood cancers	Any type of cancer occurring in a person less than 20 years of age.		
Rare cancers	Any type of cancer affecting 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.		

*For ICD-10 C81-C96 the following ICD 9 codes correlate: 200-208, 238.7, 273.3, 289.8

1. WHO (World Health Organization) [1978]. International Classification of Diseases, Ninth Revision. Geneva: World Health Organization.
2. WHO (World Health Organization) [1997]. International Classification of Diseases. Tenth Revision. Geneva: World Health Organization.

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