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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: Final rule.

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 WTC Health Program regulations, which establish

procedures for adding a new condition to the list of covered health conditions, this final rule adds to the List of WTC-Related Health Conditions the types of cancer proposed for inclusion by the notice of proposed rulemaking.

DATES: This final rule is effective [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

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

VIII. Final Rule

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) to establish 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 regardless of whether the Administrator proposes to add a health condition based on the findings from periodic reviews of cancer,[1] a request from a petition, or 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

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

88.17 to add the types of cancer recommended by the STAC to the List in §88.1.

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
- 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 IV of this preamble) for determining which cancers to

propose for inclusion on the List of WTC-Related Health Conditions.

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 (see Section VII.A., below).

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, transfers, and benefits, 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

On June 13, 2012 HHS published a notice of proposed rulemaking (77 FR 35574) proposing to add certain cancers to the List of WTC-Related Health Conditions. HHS invited interested persons or organizations to submit written views, opinions, recommendations, and data on any topic related to the proposed rule. The Administrator specifically sought comments on the methodology proposed to evaluate evidence for the addition of types of cancer to the List of WTC-Related Health Conditions; the proposed cost estimates; information or published studies about the type of welding and/or metal cutting that occurred at any of the disaster sites and information about exposure to ultraviolet light; and information or published studies about the scheduling of work hours or shiftwork occurring at any of the disaster sites.

HHS received 27 substantive submissions to the docket for this rulemaking. Commenters included labor unions that represent WTC responders, including police department members and others who conducted rescue, recovery, and clean-up; private citizens, including WTC responders; the spouse of a responder; survivors; relatives of victims and survivors; physicians who have treated

WTC responders; health care professionals with no stated experience treating 9/11-exposed patients; health and research organizations; the WTC Health Program Survivors Steering Committee; a chemical supplier; and an elected official. Additionally, one private citizen submitted a comment that was outside the scope of this rulemaking. The substantive comments are described below, followed by the Administrator's response to each (see Section V., below).

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 PHS Act to add Title XXXIII[2] establishing the WTC Health Program within HHS. The WTC Health Program provides medical monitoring and treatment benefits to eligible firefighters and related personnel, law enforcement officers, and rescue, recovery, and cleanup workers who responded to the September 11, 2001, terrorist attacks in New York City, at the Pentagon, and in Shanksville, Pennsylvania, and to eligible survivors of the New York City attacks.

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

All references to the Administrator in this notice mean the NIOSH Director or his or her designee. Section 3312(a)(6) of the PHS Act requires the Administrator to conduct rulemaking to propose the addition of a health condition to the List of WTC-Related Health Conditions codified in 42 CFR 88.1.

B. Need for Rulemaking

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 codified in 42 CFR 88.1 regardless of whether the Administrator proposes to add a health condition based on the findings from periodic reviews of cancer,[3] a request from a petition, or a determination made at the Administrator's discretion that a proposed rule adding a condition should be initiated. On September 7, 2011, the Administrator received a written petition to add a health condition to the List of WTC-Related Health Conditions (Petition 001). Petition 001 requested that the Administrator "consider adding coverage for cancer" to the List in §88.1.[4]

On October 5, 2011, the Administrator formally exercised his option to request a recommendation from the STAC regarding the

[3] See PHS Act, sec, 3312(a)(5).
[4] Maloney CB, Nadler J, King PT, Schumer CE, Gillibrand KE, Rangel CB, Velazquez NM, Grimm MG, Clarke YD. [2011]. Letter from Congress to John Howard, MD, Director, National Institute for Occupational Safety and Health (NIOSH). WTC Health Program Petition 001. Petition 001 is included in the docket for this rulemaking. See http:www.regulations.gov and http://www.cdc.gov/niosh/docket/archive/docket257.html.

petition (PHS Act, sec. 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."[5] In response, the STAC submitted its recommendation on April 2, 2012, and the Administrator issued a notice of proposed rulemaking on June 13, 2012. The background to this rulemaking and a discussion of the STAC's recommendation are provided in the notice of proposed rulemaking published on June 13, 2012 (77 FR 35574).

C. Review of Scientific Evidence

As reviewed in detail in the June 13, 2012 notice of proposed rulemaking, the Administrator considered data from five information sources to decide whether to propose the addition of cancers to the List of WTC-Related Health Conditions: (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

[5] Howard J [2011]. October 5, 2011 Letter from John Howard, MD, Director, National Institute for Occupational Safety and Health (NIOSH) to the WTC Health Program Scientific/Technical Advisory Committee. This letter is included in the docket for this rulemaking. See http:www.regulations.gov and http://www.cdc.gov/niosh/docket/archive/docket257.html.

already on the List of WTC-Related Health Conditions;[6] (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,[7] as well as the World Health Organization's International Agency for Research on Cancer (IARC);[8] 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.

In September 2011, an epidemiologic study by Rachel Zeig-Owens and colleagues (hereafter, "Zeig-Owens"), "identified a

[6] The July 2011, First Periodic Review of the Scientific and Medical Evidence Related to Cancer for the World Trade Center Health Program (First Periodic Review), requested by the Administrator, was included among the information considered. NIOSH [2011]. First Periodic Review of Scientific and Medical Evidence Related to Cancer for the World Trade Center Health Program. NIOSH Publication No. 2011-197. http://www.cdc.gov/niosh/docs/2011-197/pdfs/2011-197.pdf/. Accessed April 18, 2012. As required by sec.3312(a)(5)(A) of the PHS Act, the review considered "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." At the time of publication, the First Periodic Review 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. Unlike the explicit standard prescribed for periodic reviews of cancer under sec. 3312(a)(5)(A), sec. 3312(a)(6) of the PHS Act does not specify the 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.

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

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

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."[9] This publication led to the submission of Petition 001. The Administrator requested that the STAC 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. 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 members of the public.

Following review of the STAC recommendation, the Administrator agreed with the STAC that individual exposure assessment information arising from the terrorist attacks is extremely limited and that its absence impairs definitive scientific analysis of the relationship between exposures arising from the attacks and the occurrence of any specific type of cancer. The Administrator also found that multiple

[9] 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.

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 are not currently available.

After considering various approaches to evaluate the available scientific evidence (see discussion in the June 13, 2012 notice of proposed rulemaking), the Administrator has adopted the methodology outlined in the proposed rule and set out in Section IV below. This methodology follows on criteria used by the STAC in its recommendation. Using the methodology, the Administrator adds the types of cancer, identified in Section V below, to the List of WTC-Related Health Conditions.

D. Physician Determination and Program Certification 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 type of cancer added to the List, a two-step process must be satisfied. First, a physician at a Clinical Center of Excellence (CCE) 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

on the List of WTC-Related Health Conditions and that 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.[10] Pursuant to 42 CFR 88.12(a), the physician's determination must be based on the following: (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. In addition, the statute requires that all physician determinations are reviewed by the Administrator and are certified for treatment coverage unless the Administrator determines that the condition is not a health condition on the List of WTC-Related Health Conditions or that the exposure resulting from the September 1, 2001, terrorist attacks is not substantially likely to be a significant factor in aggravating, contributing to, or causing the condition. Thus, the 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.

[10] See PHS Act, sec.3312(a)(1); 42 U.S.C. 300mm-22(a)(1).

Responders and survivors denied certification have a right to appeal the denial of certification.

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.[11] (See also Section VII.A., Effects on Other Agency Programs, below.)

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

[11] 28 CFR 104.21.

For the reasons discussed above and detailed in the notice of proposed rulemaking published in the Federal Register on June 13, 2012, 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 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:

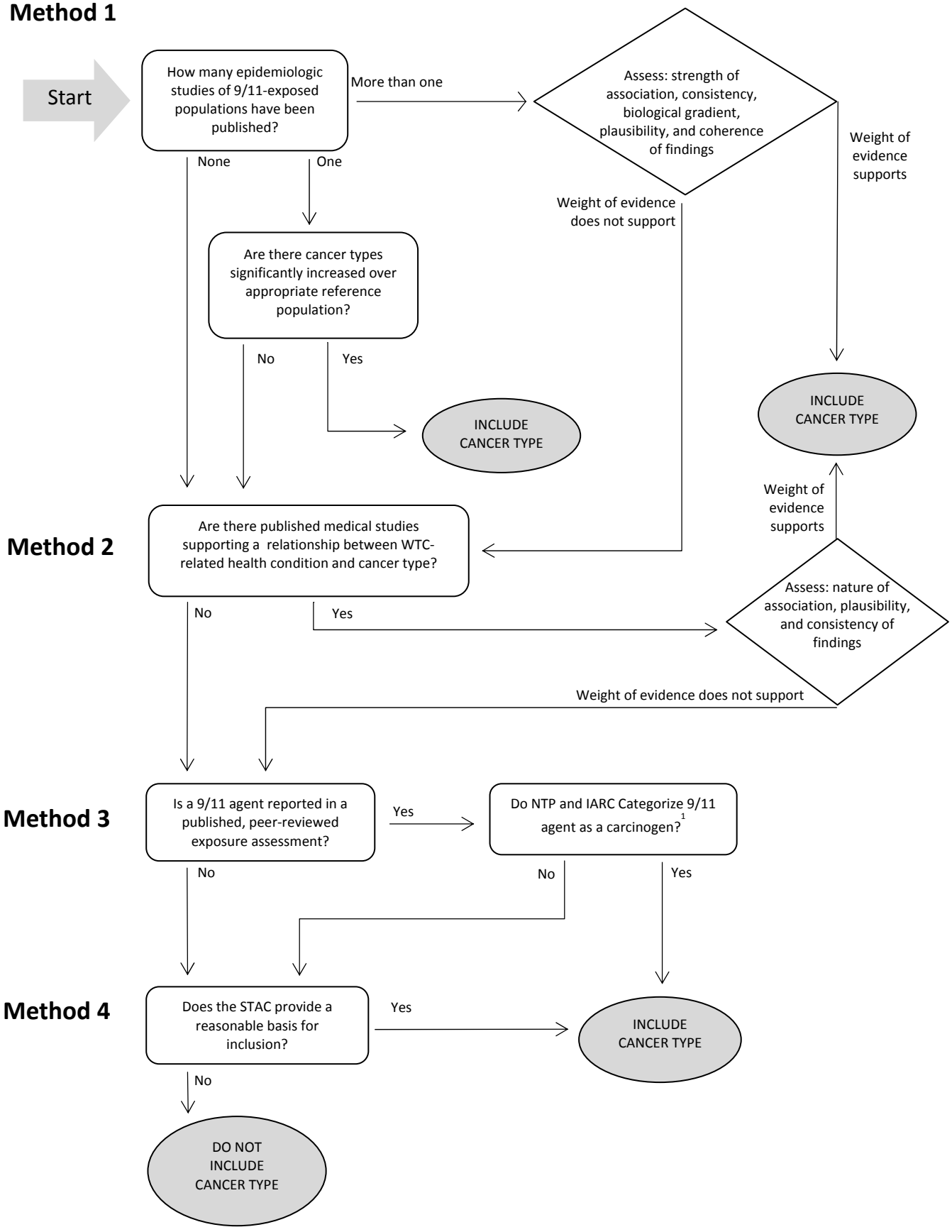
3A. Published Exposure Assessment Information. 9/11 agents were reported in a published, peer-reviewed exposure assessment study of responders or survivors who were present in either the New York City disaster area as

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 following schematic illustrates the methodology proposed in the notice of proposed rulemaking and established in this final rule.



[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.

V. Administrator's Determination Concerning Petition 001: Addition of Cancers to the List of WTC-Related Health Conditions, 42 CFR 88.1

Using the evidentiary standards established above for inclusion of a cancer on the List of WTC-Related Health Conditions in 42 CFR 88.1, and in accordance with the review of evidence discussed in the notice of proposed rulemaking published in the Federal Register on June 13, 2012, the Administrator adds the specific types of cancers in the list below to the List of WTC-Related Health Conditions in 42 CFR 88.1. In the list below, the name of the cancer is followed by its ICD-10 code[12] as well as the method used to include the cancer. A more detailed list, including sub-codes, is included in Table 1 in the regulatory text below.

- 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)
- Malignant neoplasm of the nasopharynx [C11] (Method 3)

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

- Malignant neoplasms of the nasal cavity [C30] and accessory sinuses [C31] (Method 3)
- Malignant neoplasm of the larynx [C32] (Method 3)
- Malignant neoplasms of the esophagus [C15] (Method 2)
- Malignant neoplasm of the stomach [C16] (Method 3)
- Malignant neoplasms of the colon (and rectum) [C18, C19, C20, C26.0] (Method 3)
- Malignant neoplasms of the liver and intrahepatic bile duct [C22] (Method 3)
- Malignant neoplasms of the retroperitoneum and peritoneum [C48] (Method 3)
- 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)
- Mesothelioma [C45] (Method 3)
- Malignant neoplasm of peripheral nerves and autonomic nervous system [C47) and malignant neoplasm of other connective and soft tissue [C49] (Method 3)
- Other malignant neoplasms of skin (non-melanoma) [C44] (Method 3), malignant melanoma of skin [C43] (Method 4), and malignant neoplasm of scrotum [C63.2] (Methods 3)
- Malignant neoplasm of the breast [C50] (Method 4)
- Malignant neoplasm of the ovary [C56] (Method 3)

- Malignant neoplasm of the urinary bladder [C67] (Method 3)
- Malignant neoplasm of the kidney [C64] (Method 3)
- Malignant neoplasm of the renal pelvis, ureter and other urinary organs [C65, C66 and C68] (Method 3)
- Malignant neoplasm of the eye and orbit [C69] (Method 4)
- Malignant neoplasm of thyroid gland [C73] (Method 3)
- 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)
- Childhood Cancers [any type of cancer occurring in a person less than 20 years of age] (Method 4)
- 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] (Method 4)

VI. Summary of Final Rule and Response to Public Comments

The final rule amends the definition of "List of WTC-Related Health Conditions" in 42 CFR 88.1, to include the types of cancer referenced above in Section V, which are the cancers proposed in the June 13, 2012, notice of proposed rulemaking (77 FR 35574). 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 in the regulatory text.

The effect of this amendment is 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. As discussed above, if the condition is certified by the Administrator, the individual may seek treatment and monitoring of this condition under the WTC Health Program.

As described in the Public Participation section, above, the Administrator received 27 substantive submissions from the

public on the methodology and the types of cancers proposed in the June 13, 2012 Federal Register notice (77 FR 35574). Upon consideration of the public comments, the Administrator has determined not to amend the methodology or the list of cancers in Table 1 of the regulatory text proposed in the June 13, 2012 notice of proposed rulemaking (77 FR 35574). The comments are summarized below, followed by the Administrator's response to each.

Comment: The Administrator received 12 comments in support of adding the proposed types of cancer to the List of WTC-Related Health Conditions. Some commenters expressed support for the specific methodologies proposed by the Administrator, including the use of the NTP and the IARC designations (Method 3). Commenters noted that requiring conclusive epidemiological evidence to add cancers to the List may not be fair to responders and survivors who are ill now, given the time required to collect sufficient data and publish studies in peer-reviewed journals. Some commenters correctly pointed out that an individual's diagnosis must be determined to be related to 9/11 exposure by a WTC Health Program physician and then certified by the Administrator in order for that individual to receive treatment through the Program. Some commenters wrote in support of specific types of cancer for inclusion.

Response: The Administrator agrees that establishing a broad continuum of decision-making methods is important to ensure that WTC responders and survivors receive care for health conditions associated with the September 11, 2001, terrorist attacks.

Comment: The Administrator received three comments opposing the addition of the proposed types of cancer to the List of WTC-Related Health Conditions using the methodology established in this final rule. One commenter concurred with the use of Methods 1 and 2, but stated that Methods 3 and 4 "leave the door open for speculation and anecdotal evidence to influence the decision process." Two commenters questioned the use of the Zeig-Owens[13] study by the STAC to recommend the addition of types of cancer to the List, e.g., thyroid and melanoma, mentioning the preliminary nature of the results and that the recommended types of cancer do not meet the traditional level of statistical significance. One commenter expressed opposition to Methods 3 and 4 as being overly broad, thus allowing into the Program those individuals who do not truly merit Program benefits.

Response: The Administrator appreciates the comments provided on the four methods proposed for listing types of cancer as WTC-related health conditions. The final rule adopts the methods outlined in the proposed rule. Under sec. 3312(a)(6)

[13] 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.

of the PHS Act, the Administrator is permitted to consider a wide range of approaches in adding conditions to the List.

The Administrator agrees with the commenter that Methods 1 and 2, which rely on epidemiologic evidence (Method 1) and established medical relationships between a WTC-related health condition and the development of a type of cancer (Method 2), provide traditional methods for associating exposure and health effects as a means of adding conditions to the List of WTC-Related Health Conditions. However, the Administrator also recognizes that there is a continuum of methods that can be used to establish relationships between exposure and disease: some methods are more definitive and provide a higher level of certainty when establishing an association between exposure and disease outcomes. Adding cancers to the List by Methods 1 and 2 fall in that portion of the continuum of methods that provide greater certainty.

However, Methods 1 and 2 are substantially limited in their ability to provide timely guidance on which types of cancer should be added to the List of WTC-Related Health Conditions to allow the WTC Health Program to provide services to the responders and survivors currently suffering from cancers following exposure to 9/11 agents. Due to the long latency period between exposure and cancer diagnosis for most types of cancer, many epidemiological studies of cancer associated with

particular exposures are produced years after a given exposure event. Waiting for definitive, scientifically-unassailable epidemiologic results before adding types of cancer to the List would prevent treatment of currently-enrolled WTC responders and survivors.

In addition, other factors make it difficult to establish definitive associations using traditional epidemiologic methods within any timeframe. The number of potentially exposed individuals is small, so the statistical power of any study will be substantially limited. Many of the cancers anticipated in the exposed population are uncommon. Thus, because of the anticipated small numbers of these cancers, detecting statistically significant increases will be difficult and may only be definitively established through a retrospective cohort study conducted decades from now. Upon thorough review of all available information, including peer-reviewed studies, expert opinion, the STAC recommendation, and comments from the public, the Administrator has determined that it is reasonable to acknowledge the limitations of traditional epidemiologic methods and to recognize other methods that incorporate additional sources of information.

Because of the limitations of using epidemiologic studies to establish relationships between exposure and health effects, and the WTC Health Program's responsibility to provide services to

affected individuals during their lifetime, the Administrator finds that this unique exposure situation merits the use of methods, in addition to Methods 1 and 2, that provide valuable information about the relationship between exposure and health effects. The Administrator acknowledges that Methods 3 and 4 provide less certainty about the relationship between exposure and cancer than do Methods 1 and 2.

Method 3 relies on identifying those agents categorized by the NTP as known or reasonably anticipated to be human carcinogens and by IARC as being known, probable, or possible human carcinogens and having sufficient or limited evidence for causing specific types of cancer in humans. IARC and NTP findings, including IARC's identification of agents associated with specific cancer types, have undergone substantial peer review and/or scientific scrutiny in their development.

Method 4 relies on findings from other sources of information relevant to 9/11 exposures and the potential occurrence of cancer, including the expert judgment and personal experiences of STAC members and comments from the public. The statute allows the Administrator to request a recommendation from the STAC. In this case, the Administrator requested a recommendation from the STAC as well as descriptions of the scientific and/or technical evidence members relied on, the quality of data supporting the evidence, and the methods used.

The Administrator found the STAC recommendations and their bases to be reasonable.

Two comments correctly pointed out that the Zeig-Owens study, which was cited as evidence by the STAC, was viewed by the Administrator as not meeting the statistical significance threshold for Method 1. However, the Administrator made the determination to include certain cancers (e.g. thyroid and melanoma) using Method 4 based on a reasonable recommendation from the STAC. The interpretation of statistical significance can vary between knowledgeable observers. The STAC interpreted the Zeig-Owens results as a sound basis for recommending the addition of some types of cancer to the List when the reported statistical significance of findings in the study was near the traditional 95 percent confidence level. The Administrator has determined that the STAC's interpretation is reasonable.

The evidence cited by the STAC for including thyroid cancer and melanoma in their recommendation was that the Standardized Incidence Ratios (SIR) were substantially greater than 1.0 and approached the 95 percent confidence level traditionally used for statistical significance. The STAC also considered other types of cancer that had an elevated SIR in the Zeig-Owens study, such as prostate cancer, and did not recommend them for addition after considering additional information on potential surveillance bias. Thus, the STAC made reasonable arguments for

the addition or exclusion of certain types of cancer. The STAC did not limit the basis of its recommendations to a level of statistical significance that would be recognized by all knowledgeable observers of epidemiologic studies.

Finally, the Administrator notes that listing a cancer as a WTC-related health condition does not necessarily mean that a cancer in an individual WTC responder or survivor will be determined to be WTC-related. Each WTC responder and survivor enrolled in the Program will go through a physician's determination and Program certification process to assess whether their individual cancer meets the statutory definition of a WTC-related health condition. When determining whether an individual's cancer has been contributed to, aggravated by, or caused by their exposures at the 9/11 sites, individual medical history and exposure assessment are used as part of the determination and certification process. Guidelines for physician determinations regarding WTC-related health conditions are jointly developed by the CCEs and the WTC Health Program for all conditions currently on the List. The CCEs and WTC Health Program will develop additional assessment information for use by physicians in making determinations regarding whether an individual's 9/11 exposure may have contributed to, aggravated, or caused their cancer.

Comment: One commenter stated that the STAC's recommendations do not merit the same decision-making weight as Methods 1 and 2 because most of the committee is not rigorously trained in epidemiology and biostatistics.

Response: The Administrator acknowledges the diverse background of the STAC members, but notes that the composition of the STAC was established in sec. 3302(a) of the PHS Act to provide a broad spectrum of backgrounds and expertise to the Administrator. The inclusion of non-scientists on the STAC adds value, knowledge, and perspective to the STAC that might not otherwise be available to the Administrator.

Comment: One commenter was concerned about the potential impact of adding the proposed types of cancer to the List of WTC-Related Health Conditions on the VCF administered by the Department of Justice, and believes that the use of Methods 3 and 4 will overextend the WTC Health Program and the VCF and leave them open to abuse.

Response: The Administrator notes that individuals who are not currently enrolled in the WTC Health Program must first be found to be eligible and qualified to enroll. As discussed above, physician determination and Program certification are two additional steps that must be completed before an individual can receive treatment and monitoring benefits from the Program. Similarly, the VCF employs rigorous standards used to determine

individual compensation awards. The Administrator acknowledges the issue of resource limits on the VCF, which is a capped-benefit program. This issue is discussed in Section VII.A below. Further consideration of the potential impact on the VCF is outside the scope of this rulemaking.

Comment: One comment stated that asbestos-related cancers generally have latencies far beyond the 10 years that have passed since September 11, 2001, and that there is great uncertainty in designating asbestos as a cause of stomach or colorectal cancers.

Response: The methodology established in this final rule for adding types of cancer to the List includes identifying those agents categorized by IARC as being known, probable, or possible human carcinogens and having sufficient or limited evidence for causing specific types of cancer in humans, and by the NTP as being known or reasonably anticipated to be human carcinogens. IARC and NTP findings have undergone substantial peer review and/or other scientific scrutiny in their development. These authoritative bodies have categorized all forms of asbestos as known human carcinogens, and IARC has determined there is limited evidence that they cause cancer of the stomach and colon.

When determining whether an individual's cancer has been contributed to, aggravated by, or caused by their exposures at

the 9/11 sites, an individual medical history and exposure assessment is used as part of the physician determination and Program certification process. Guidelines for physician determinations regarding WTC-related health conditions are jointly developed by the CCEs and the WTC Health Program for conditions on the List. The CCEs and WTC Health Program will develop additional assessment information for use by physicians in making determinations regarding whether an individual's 9/11 exposure may have contributed to, aggravated, or caused their cancer.

Comment: One comment stated that beryllium and beryllium compounds should be removed as an identified exposure agent for all respiratory cancers listed in Table A. Among other reasons, the commenter indicated that the collapse of the World Trade Center was unlikely to have resulted in emissions of beryllium metal and beryllium compounds above levels found in the natural environment.

Response: The quantitative exposures of individuals at the WTC, particularly during the collapse of the towers and for several days afterward, will likely never be fully known. While the concentrations of beryllium dust in settled dust samples collected from around the WTC sites approximate the concentrations in "background" samples, the exposure conditions that have been described (including thick dust clouds,

individuals being coated with dust, and large deposits of dust in homes) result in very different exposures than would be expected to be found in industrial settings or in windblown dirt. The Administrator finds that such conditions are likely to result in large, short-term exposures.

The methodology established in this final rule for adding types of cancer to the List includes identifying those agents categorized by IARC as being known, probable, or possible human carcinogens and having sufficient or limited evidence of carcinogenicity in humans, and by NTP as being known or reasonably anticipated to be human carcinogens. IARC and NTP findings have undergone substantial peer review and/or other scientific scrutiny in their development. These authoritative bodies have categorized beryllium and beryllium compounds as known human carcinogens, and IARC has determined there is sufficient evidence that they cause cancer of the lung.

Comment: Several commenters recognized the important distinction between a cancer being included on the List of WTC-Related Health Conditions and the physician determination and Program certification of a specific cancer in an individual responder or survivor. One comment noted that physicians will need guidance to make a determination that a type of cancer is related to the September 11, 2001, terrorist attacks.

Response: The Administrator recognizes the difficulty inherent in determining whether an individual's cancer can be considered WTC-related. Guidelines for physician determinations regarding WTC-related health conditions are jointly developed by the CCEs and the WTC Health Program for all conditions on the List. The CCEs and WTC Health Program will develop additional assessment information for use by physicians in making determinations regarding whether an individual's 9/11 exposure may have contributed to, aggravated, or caused their cancer.

Comment: One commenter asked that the Administrator exercise authority under the PHS Act to "cover a specific type of cancer in individual cases, notwithstanding the review and determination of when to generally add a type of cancer to the list of covered WTC conditions."

Response: The Administrator will use his authority under sec. 3312 of the Act and as detailed in 42 CFR 88.13 to cover a condition medically-associated with a condition on the List of WTC-Related Health conditions, as appropriate.

Comment: The Administrator received a number of comments requesting the addition of one or more types of cancer. Six commenters asked that cancer of the prostate be added to the List. One commenter asked that cancers of the brain and pancreas also be added to the List. Another commenter asked for the addition of melanoma, thyroid, and non-Hodgkin lymphoma to the

List. One of the commenters stated that the Administrator did not address a STAC recommendation to add pre-malignant and myelodysplastic diseases.

Response: The issue of whether to recommend the addition of cancers of the prostate, brain, and pancreas to the List of WTC-Related Health Conditions was considered and discussed by the STAC in the open meeting on March 28, 2012. In those discussions, the STAC considered the available evidence for recommending the addition of cancers of the prostate, brain, and pancreas, including the epidemiologic evidence and the NTP and IARC reviews. Following its deliberation on the matter, the STAC voted not to include prostate, brain, or pancreatic cancer in its recommendation.[14] The Administrator concurs with the decision of the STAC and is not adding these cancers to the List of WTC-Related Health Conditions at this time. The addition of these cancers may be reconsidered if additional information on the association of 9/11 exposures and those cancer outcomes becomes available. Regarding the request to add melanoma, thyroid cancer, and non-Hodgkin lymphoma, this final rule specifically includes the addition of melanoma, thyroid cancer, and non-Hodgkin lymphoma to the List of WTC-Related Health Conditions. Finally, the Administrator acknowledges that the STAC's

[14] See STAC (World Trade Center Health Program Scientific/Technical Advisory Committee) Letter from Elizabeth Ward, Chair, to John Howard, MD, Administrator [2012]. This letter is included in the docket for this rulemaking. See http://www.regulations.gov and http://www.cdc.gov/niosh/docket/archive/docket257.html.

recommendation to add pre-malignant and myelodysplastic diseases was not adopted. This final rule only addresses adding types of cancer to the List. The inclusion of pre-malignant or non-malignant conditions, such as myelodysplastic diseases, may be considered at a later time.

Comment: The Administrator received three comments expressing concern that gaps in data preclude the Administrator from considering cancers and other possible WTC-related health conditions that may affect WTC responders and survivors. Two of the comments expressed concern that the study of female responders and survivors has been lacking. Another commenter also expressed concern for those whose cancer has not been adequately studied or studied at all.

Response: The Administrator is aware of the limitations on the availability of data on cancers and other possible WTC-related health conditions, including the limited information on female responders and survivors. The inclusion of additional types of cancer will be considered at an appropriate time if additional information on the association of 9/11 exposures and cancer outcomes becomes available. The limitations on the availability of data on female responders and survivors will be addressed to the extent possible through analysis of clinical data from medical monitoring examination of responders and survivors, as well as through research studies. The issue of

gaps in data regarding non-cancer WTC-related health conditions is outside the scope of this rulemaking.

Comment: Two commenters offered general thoughts about the uncertainty associated with attributing 9/11 exposures to types of cancer, stating that it is not possible to determine which WTC responders and survivors would have been diagnosed with cancer in the absence of 9/11 exposures. These commenters asserted that NYC responders are overcompensated.

Response: For the reasons discussed above, the Administrator has determined that it is appropriate to add the types of cancer in this final rule to the List of WTC-Related Health Conditions in 42 CFR 88.1. While Congress did not include cancers in the statute, the PHS Act directs the Administrator to review all available scientific and medical evidence to determine if cancer or types of cancer should be added to the List and creates various mechanisms for the addition of cancers.[15] The Administrator recognizes the inherent difficulty in determining whether an individual's cancer can be considered WTC-related. Guidelines for physician determinations regarding WTC-related health conditions are jointly developed by the CCEs and the WTC Health Program for all conditions on the List. The CCEs and WTC Health Program will develop additional assessment information for use by physicians in making determinations regarding whether

[15] See PHS Act, sec. 3312(a)(5) and (6).

an individual's 9/11 exposure may have contributed to, aggravated, or caused their cancer.

VII. 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 sec. 3(f) of E.O. 12866. Accordingly, this rule has been reviewed by the Office of Management and Budget. The addition of specific types of cancer 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 I) for the first year (2013). Because a portion of responders and survivors are also covered by private health

[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.

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 (ACA)(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. The final rule does 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 +

[18] PHS Act, sec. 3311(a)(4)(A) and sec. 3321(a)(3)(A).
[19] See 42 CFR 88.8(b) for explanation of a certified-eligible survivor.

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.[21] Given the challenges associated with interpreting the Zeig-Owens findings,[22] we simply characterize 21 percent as a possible outcome rather than asserting the probability that 21 percent is a "likely" outcome.

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. However, for the purpose of this analysis, HHS has estimated that all diagnosed cancers 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

[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] 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.
[22] 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.

of individuals who were responders or survivors in the New York City disaster area.

Costs of Cancer Treatment

HHS estimated the treatment costs associated with covering the types of cancer 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 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 the following: 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 A. The costs of treatment are divided into three phases: the costs for the first year following diagnosis, the costs of intervening years or continuing treatment after the first year, and the costs of treatment for the last year of life. The first year costs of cancer treatment are higher due to the initial need for aggressive medical (e.g., radiation, chemotherapy) and surgical care. The costs during last year of life are often dominated by

increased hospitalization costs.[23] 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 A--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 the Surveillance, Epidemiology, and End Results (SEER) program maintained by the National Cancer Institute using Medicare files.[24] The average costs of treatment described above

[23] 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.
[24] 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.

are given in 2011 prices adjusted using the Medical Consumer Price Index for all urban consumers.[25]

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 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 B.

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

Group	Age percentile (years)								
	Min	1	10	30	50	70	90	99	Max

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

Male responders	28	32	39	44	49	54	62	74	92
Female responders	28	30	38	44	49	54	62	76	92
Male survivors	12	23	35	46	52	58	67	81	99
Female survivors	12	21	38	49	54	60	68	84	95

HHS assumed race and ethnic origin distributions for responders and survivors according to distributions in the WTC Health Registry cohort:[26] 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).[27] A life-table analysis program, LTAS.NET, was used

[26] 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. Note: percentages may not sum to 100 percent due to rounding.

[27] Centers for Disease Control and Prevention, National Center for Health Statistics. Compressed Mortality File 1999-2008. CDC WONDER Online Database, compiled from Compressed Mortality File 1999-2008 Series 20 No. 2N, 2011. http://wonder.cdc.gov/cmf-icd10.html. Accessed February 15, 2012.

to estimate the expected number of incident cancers for cancer types added.[28] HHS calculated cancer incidence rates using data through 2006 from the Surveillance Epidemiology and End Results (SEER) Program, and estimated rates for 2007-2016.[29] The Program applied the resulting gender, race, age, and year-specific cancer incidence rates to the estimated person-years at risk to estimate the expected number of cancer cases for each cancer type starting from year 2002, the first full year following the September 11, 2001, terrorist attacks, to 2016, the last year for which this Program is currently funded.

Prevalence of Cancer

To determine the potential number of 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.[30]

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

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

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).[31] 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.[32] Therefore the number of deceased persons in 2002 would be 18.78 x (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 x 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 C as an example.

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

[31] The 15-year survival limit is imposed based on the analytic time horizon.
[32] National Cancer Institute, Surveillance Epidemiology and End Results (SEER). http://seer.cancer.gov/. Accessed May 27, 2012.

Table C--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
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 A, year adjusted) were applied to the predicted newly incident (Year 1) cases for each year. Likewise, the costs of treatment for the last year of life were applied in each year to the number of people predicted to die from their cancer in

that year. The costs of continuing treatment from Table 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 D 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 A by the number of persons dying in that year from that type of cancer.

Table D--Cost per 80,000 Responders for Lung Cancer, 2011$

	Years covered by the WTC Health Program			
Year	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 D are based on an assumed responder population size of 80,000.

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

The estimated treatment costs for responders and survivors were re-computed under the following two assumptions: (1) the rate of cancer in the WTC Health Program is equal to the rate of cancer observed in the general population; and (2) the rate of cancer exceeds the general population rate by 21 percent due to their exposures in the New York City disaster area.[33] HHS is not aware of any other estimates of excess cancer rates in the 9/11-exposed population in the peer-reviewed literature.

[33] 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 E. A summary of the estimated treatment costs to the WTC Health Program is provided in Table F.

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

Table E – Estimated prevalence by year and cancer type based on 55,000 and 5,000 responder and survivor population, respectively and assuming cancer rates at U.S. population average

Based on 55,000 responder population	Prevalence (incident + live cases)			
Cancer type	2013	2014	2015	2016
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	1038.88	1136.78
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 F – 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
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 G – Estimated prevalence by year and cancer type based on 80,000 and 30,000 responder and survivor population, respectively and assuming incidence of cancer is 21% higher than the U.S. population due to 9/11 exposure

	Prevalence (incident +live cases)			
Based on 80,000 responder population				
Cancer type	2013	2014	2015	2016
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	1504.09	1663.77	1828.43	2000.74
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
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 H – Estimated treatment costs by year and cancer type based on 80,000 and 30,000 responder and survivor population, respectively and assuming incidence of cancer is 21% higher than the U.S. population due to 9/11 exposure (2011 $)

Based on 80,000 responder population					
Cancer type	2013	2014	2015	2016	2013-2016
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
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 both a low rate of cancer (U.S. population average rate) and an increased rate (21 percent greater than the U.S. population average) on the number of cases and the resulting estimated treatment costs to the WTC Health Program. This analysis does not include administrative costs associated with certifying additional 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 indicated 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.[34] 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[35] 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.[36]

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.

[34] United States Preventive Services Task Force (USPSTF) [2008]. Screening for Colorectal Cancer. http://www.uspreventiveservicestaskforce.org/uspstf/uspscolo.htm. Accessed May 28, 2012.
[35] Mandel JS, et. al, Reducing Mortality From Colorectal Cancer by Screening for Fecal Occult Blood, NEJM 328(19): 1365-1371 (1993).
[36] 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.

The cost of a mammogram was estimated at $139.32 based on FECA rates for mammography.[37]

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.[38] Ward et al.[39] found that access to health care services, quality of care received,

[37] FECA rates for Mammography for New York; FECA code 77057.
[38] U.S. Census Bureau [2011]. Current Population Survey. http://www.census.gov/cps/data/. Accessed May 26, 2012.
[39] 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.

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

Table I – 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		$417,521		$1,271,478

Breast Screening				
110,000 Total		**$5,019,182**		**$33,308,060**

Examination of Benefits (Health Impact)

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

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 ACA 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.

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

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 epidemiologic 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[40] 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

[40] 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.

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

G. Executive Order 13132 (Federalism)

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

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

In accordance with Executive Order 13045, HHS has evaluated the environmental health and safety effects of this final 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 final rule on energy supply, distribution or use, and has determined that the rule will not have a significant adverse effect.

J. Plain Writing Act of 2010

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

VIII. Final 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 amends 42 CFR Part 88 as follows:

PART 88--WORLD TRADE CENTER HEALTH PROGRAM

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

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

2. 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).

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	• C49.4	• 171.5

	abdomen		
	• 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	• C84.5	• 202.0

	lymphomas		
	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 type	• 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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Dated: September 5, 2012

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[FR Doc. 2012-22304 Filed 09/10/2012 at 4:15 pm; Publication Date: 09/12/2012]