DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. CDC-2013-0012]

42 CFR Part 88

RIN 0920-AA54

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

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: On May 2, 2013, the Administrator of the World Trade Center (WTC) Health Program received a petition (Petition 002) requesting the addition of prostate cancer to the List of WTC-Related Health Conditions (List) covered in the WTC Health Program. The Administrator has determined to publish a proposed rule adding malignant neoplasm of the prostate (prostate cancer) to the List in the WTC Health Program regulations.

DATES: Comments must be received by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: WRITTEN COMMENTS: You may submit comments by any of the following methods:

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

INSTRUCTIONS: All submissions received must include the agency name (Centers for Disease Control and Prevention, HHS) and docket number (CDC-2013-0012) or Regulation Identifier Number (0920-AA54) for this rulemaking. All relevant comments, including any personal information provided, will be posted without change to http://www.regulations.gov. For detailed instructions on submitting public comments, see the "Public Participation" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

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

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

SUPPLEMENTARY INFORMATION:

This notice is organized as follows:

I. Executive Summary

A. Purpose of Regulatory Action

This rulemaking is being conducted in response to a petition to the Administrator of the WTC Health Program by the Patrolmen's Benevolent Association, a union representing New York City police

officers (Petition 002). The petition asks that the Administrator add prostate cancer to the List of WTC-Related Health Conditions.

B. Summary of Major Provisions

The rule proposes the addition of prostate cancer to the cancers identified in 42 CFR 88.1, Table 1 as covered by the WTC Health Program for treatment and monitoring.

C. Costs and Benefits

The proposed addition of prostate cancer by this rulemaking is estimated to cost the WTC Health Program between $3,462,675 and $6,995,817 per annum. All of the costs to the WTC Health Program will be transfers after the implementation of provisions of the Patient Protection and Affordable Care Act (Pub. L. 111-148) on January 1, 2014.

II. Public Participation

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

Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or

supporting materials that you consider confidential or inappropriate for public disclosure.

Comments submitted electronically or by mail should be titled "Docket No. CDC-2013-0012" and should identify the author(s) and contact information in case clarification is needed. Electronic and written comments can be submitted to the addresses provided in the **ADDRESSES** section, above. All communications received on or before the closing date for comments will be fully considered by the Administrator of the WTC Health Program.

III. Background

A. WTC Health Program Statutory Authority

Title I of the James Zadroga 9/11 Health and Compensation Act of 2010 (Pub. L. 111-347), amended the Public Health Service Act (PHS Act) to add Title XXXIII[1] establishing the WTC Health Program within the Department of Health and Human Services (HHS). The WTC Health Program provides medical monitoring and treatment benefits to eligible firefighters and related personnel, law enforcement officers, and rescue, recovery, and cleanup workers (responders) who responded to the September 11, 2001, terrorist attacks in New York City, at the Pentagon, and in Shanksville, Pennsylvania, and to eligible persons (survivors) who were present in the dust or dust

[1] 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.

cloud on September 11, 2001 or who worked, resided, or attended school, childcare, or adult daycare in the New York City disaster area.

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

B. Rulemaking History

On September 7, 2011, the Administrator received a written petition to add a health condition to the List in §88.1 (Petition 001). Petition 001 requested that the Administrator "conduct an immediate review of new medical evidence showing increased cancer rates among firefighters who served at ground zero and that [the Administrator] consider adding coverage for cancer under the Zadroga Act."[2]

Pursuant to sec. 3312(a)(6)(B) of the PHS Act, interested parties may petition to add a health condition to the List. Within 60 calendar days after receipt of a petition to add a condition to the List, the Administrator must take one of the following four actions

[2] Letter dated September 7, 2011 from U.S. Senators Charles E. Schumer and Kirsten E. Gillibrand, and U.S. Representatives Carolyn B. Maloney, Jerrold Nadler, Peter T. King, Charles B. Rangel, Nydia M. Velázquez, Michael C. Grimm and Yvette D. Clarke to John Howard, M.D.

described in 42 CFR 88.17: (i) request a recommendation of the WTC Health Program Scientific/Technical Advisory Committee (STAC); (ii) publish a proposed rule in the **Federal Register** to add such health condition; (iii) publish in the **Federal Register** the Administrator's determination not to publish such a proposed rule and the basis for such determination; or (iv) publish in the **Federal Register** a determination that insufficient evidence exists to take action under (i) through (iii) above.

On October 5, 2011, the Administrator formally exercised his option to request a recommendation from the STAC regarding Petition 001.[3] In a letter to the STAC 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."[4]

In response to the Administrator's request, the STAC submitted its recommendation on April 2, 2012. After considering the STAC's recommendation, the Administrator issued a notice of proposed rulemaking on June 13, 2012 (77 FR 35574). On September 12, 2012, the Administrator published a final rule in the **Federal Register** adding over 50 types of cancer to the List of WTC-Related Health Conditions in 42 CFR 88.1 (77 FR 56138).[5]

[3] See PHS Act, sec. 3312(a)(6)(B)(i); 42 CFR 88.17(a)(2)(i).
[4] Letter dated October 5, 2011 from John Howard, M.D. to Elizabeth Ward, Ph.D., STAC Chair available at http://www.cdc.gov/niosh/docket/archive/pdfs/NIOSH-248/0248-100511-letter.pdf. Accessed June 1, 2013.
[5] On October 12, 2012, HHS published a **Federal Register** notice to correct errors in Table 1 of the final rule (the list of cancers covered by the Program) (77 FR 62167).

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

In the final rule published September 12, 2012, the Administrator established a four-part hierarchical methodology to apply in evaluating whether to propose adding certain types of cancer to the List of WTC-Related Health Conditions included in 42 CFR 88.1.[6] Method 1 is the preferred method for adding types of cancer to the List. When the analysis of epidemiologic studies in Method 1 does not support a causal association between 9/11 exposures and a type of cancer, the Administrator applies the criteria of Method 2.[7] If no causal association between a currently listed condition and the type of cancer is identified using Method 2, the Administrator applies the criteria of Method 3. If Method 3 does not indicate that a recognized 9/11 exposure is categorized by the National Toxicology Program (NTP) as a known or reasonably anticipated human carcinogen[8] or the International Agency for Research on Cancer (IARC) has not determined there is sufficient or limited evidence in humans that a 9/11 exposure is causally associated with a type of cancer,[9] then the criteria of Method 4 are applied. Under Method 4, the Administrator determines whether the STAC has provided a reasonable basis for

[6] 77 FR 56138, 56142.
[7] The results of epidemiologic studies are the primary and best evidence for making a determination of a causal association between an exposure and a health outcome, such as cancer. An analysis of the results of any epidemiologic study has three possible outcomes: (1) the analysis supports an association between exposures and a health outcome (yes); (2) the analysis supports that there is no association between exposures and a health outcome (no); or (3) the analysis is inconclusive about whether an association exists between exposures and a health outcome (inconclusive).
[8] National Toxicology Program (NTP), U.S. Department of Health and Human Services. Report on Carcinogens (RoC). http://ntp.niehs.nih.gov/?objectid=72016262-BDB7-CEBA-FA60E922B18C2540. Accessed May 15, 2013.
[9] World Health Organization International Agency for Research on Cancer (IARC). http://monographs.iarc.fr/. Accessed May 15, 2013.

adding the type of cancer, aside from Methods 1, 2, or 3. Only where the Administrator is satisfied that one of the four methods provides a reasonable basis to add the cancer will he propose that a type of cancer be added to the List. The four methods are presented in detail below:

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 a type of cancer. 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 (or exposure)-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 exposures 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 any of the 9/11 exposures are 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 exposure 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 Methods 1, 2, or 3.

D. Consideration of Prostate Cancer, 2011-2012

Since 2011, the Administrator has twice evaluated whether to add health conditions to the List. In both instances, the Administrator considered adding certain types of cancer to the List, including prostate cancer.

1. First Periodic Review of the Scientific and Medical Evidence Related to Cancer, July 2011

The Administrator's first evaluation was published in the July 2011 First Periodic Review of the Scientific and Medical Evidence Related to Cancer (First Periodic Review) for the WTC Health Program. As required by Title XXXIII, sec. 3312(a)(5)(A) of the PHS Act, the Administrator reviewed "all available scientific and medical evidence, including findings and recommendations of Clinical Centers of Excellence, published in peer-reviewed journals to determine if, based on such evidence, cancer or a certain type of cancer should be

added to the applicable list of WTC-related health conditions." The Administrator used a "weight of the evidence" approach to evaluate the available data. At that time, there were no significant epidemiologic studies available which evaluated the association of 9/11 exposures and health outcomes involving types of cancer. As a result, the Administrator determined that insufficient evidence existed at that time to propose the addition of cancer, or certain types of cancer, to the List, but cautioned that,

> the current absence of published scientific and medical findings demonstrating a causal association between exposures resulting from the September 11, 2001, terrorist attacks and the occurrence of cancer in responders and survivors does not indicate evidence of the absence of a causal association.[10]

2. Rulemaking in Response to Petition 001

The Administrator's second evaluation of whether to add cancer or certain types of cancer to the List followed receipt of Petition 001 and the subsequent recommendation on the Petition from the STAC. During meetings held November 9-10, 2011, February 15-16, 2012, and March 28, 2012, the STAC reviewed the available scientific evidence for adding cancer or certain types of cancer to the List and made its recommendation to the Administrator regarding Petition 001 on April 2, 2012.

In reviewing Petition 001, the STAC compiled and reviewed the available evidence for adding all types of cancer, including prostate

[10] First Periodic Review of Scientific and Medical Evidence Related to Cancer for the World Trade Center Health Program, VI.C, p. 40.

cancer, to the List. Specifically, with regard to the analysis of prostate cancer, this evidence included (1) the results of a study by Zeig-Owens et al., published in The Lancet in September 2011;[11] and (2) a determination by NTP that arsenic and cadmium, 9/11 exposures, are known to be human carcinogens[12] and a determination by IARC that limited evidence supports a causal association between prostate cancer and arsenic or cadmium exposure.[13]

At the March 28, 2012 meeting, STAC members noted that prostate cancer would qualify for inclusion in its recommendation of types of cancer that should be added to the List based on evidence from NTP and IARC.[14] However, other STAC members expressed concern that the increased rate of prostate cancer in both exposed and unexposed firefighters in the Zeig-Owens study was a result of surveillance bias associated with widespread screening for prostate cancer. The Zeig-Owens study involved a small population that was subject to substantial medical screening. STAC members expressed concern that the observed excess risk for prostate cancer seen in the Zeig-Owens study was the result of screening for prostate cancer by means of the prostate-specific antigen (PSA) test.[15]

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[11] 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.

[12] NTP (National Toxicology Program)[2011]. 12th Report on Carcinogens. National Toxicology Program, Public Health Service, U.S. Department of Health and Human Services, Research Triangle Park, NC. http://ntp.niehs.nih.gov/?objectid=03C9AF75-E1BF-FF40-DBA9EC0928DF8B15. Accessed May 24, 2013.

[13] IARC (International Agency for Research on Cancer) [2012]. IARC Monographs on the Evaluation of the Carcinogenic Risks to Humans: Vol. 100C--Arsenic, Metals, Fibres, and Dusts. IARC, Lyon, France. http://monographs.iarc.fr/ENG/Monographs/vol100C/index.php. Accessed May 24, 2013.

[14] STAC (WTC Health Program Scientific/Technical Advisory Committee) [2012]. Transcript of the STAC meeting, March 28, 2012:97-105. http://www.cdc.gov/niosh/docket/archive/pdfs/NIOSH-248/0248-032812-transcript3.pdf. Accessed June 1, 2013.

[15] The PSA test was approved by the Food and Drug Administration in 1986 for the purpose of monitoring disease status in prostate cancer, and in 1994 for the detection of prostate cancer in men 50 years and older. The routine use of the PSA test for screening increased dramatically beginning in 1998, along with the prostate cancer incidence, but the incidence has since fallen. See Etzioni R, Penson DF, Legler

During the meeting, the STAC considered a motion to "recommend adding prostate cancer to the list of covered conditions."[16] The motion failed in an 8 to 7 vote. In the April 2, 2012 recommendation, the STAC noted that "the WTC-exposed FDNY [Fire Department of New York] group did not show an increased risk over the unexposed, with estimated SIR [standardized incidence ratio] ratio [of] 0.90 (after correction for possible surveillance bias)," and concluded "therefore, despite the statistically significant SIR for prostate cancer in WTC-exposed firefighters compared to the general population, the overall results do not support an increased risk of prostate cancer associated with WTC exposures."[17] The STAC's discussion and subsequent vote indicated that the members found that the epidemiologic evidence of 9/11-exposed populations outweighed the NTP and IARC evidence of carcinogenicity of arsenic and cadmium.

In evaluating whether to add prostate cancer based on Method 1, the Administrator considered the STAC's concerns about the findings of the one epidemiologic study that was available to review at the time, the Zeig-Owens study, which involved a small, heavily medically screened population. The Administrator agreed that surveillance bias could have explained the excess prostate cancer risk found in the

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JM, di Tommaso D, Boer R, Gann PH, Feuer EJ. (2002) Overdiagnosis due to prostate-specific antigen screening: lessons from U.S. prostate cancer incidence. JNCI 94(13):981-990; Potosky AL, Miller BA, Albertsen PC, Kramer BS. (1995) The role of increasing detection in the rising incidence of prostate cancer. JAMA 273:548-552; and Altekruse SF, Kosary C, Krapcho M et al. (2010) SEER cancer statistics review 1975-2007. Bethesda, MD: National Cancer Institute. http://seer.cancer.gov/csr/1975_2007/. Accessed June 2, 2013.

[16] See STAC (WTC Health Program Scientific/Technical Advisory Committee) [2012]. Transcript of the STAC meeting, March 28, 2012:98, lines 23-31. http://www.cdc.gov/niosh/docket/archive/pdfs/NIOSH-248/0248-032812-transcript3.pdf. Accessed June 1, 2013.

[17] STAC (WTC Health Program Scientific/Technical Advisory Committee)[2012]. Letter from Elizabeth Ward, Chair to John Howard, MD, Administrator at 24. This letter is included in the docket for this rulemaking.

study. In addition, as the STAC noted -- and the Administrator agreed -- the SIR for prostate cancer fell to 0.90 after correction for surveillance bias. The Administrator determined that, based on the information then available, the prostate cancer risk was not significantly increased over an appropriate reference population (Method 1). Additionally, no evidence existed for a causal association between prostate cancer and a condition already on the List (Method 2).

As described above, the basis for adding a cancer according to the criteria in Method 3 is a determination by NTP that 9/11 exposures are known or reasonably anticipated to be human carcinogens, and a determination by IARC that sufficient or limited evidence in humans supports a causal association between a cancer and a 9/11 exposure. The STAC considered the determinations by NTP and IARC regarding the carcinogenicity of arsenic and cadmium and still voted not to recommend adding prostate cancer to the List. The Administrator was aware that two additional epidemiologic studies in 9/11-exposed populations were then in progress and might provide additional information about the association of prostate cancer and 9/11 exposures in the future. Given the STAC's decision not to recommend the addition of prostate cancer, which relied on the epidemiologic evidence available at that time, the Administrator determined that there was not a reasonable basis for adding prostate cancer to the List.

E. Petition 002

On May 2, 2013, the Administrator received Petition 002 from the Patrolmen's Benevolent Association, a union representing New York City police officers. Petition 002 references, and relies upon, a study of over 25,000 WTC responders enrolled in the WTC Health Program, authored by Solan et al. and published in the scientific journal Environmental Health Perspectives.[18] Petition 002 asserts that the Solan study:

> [A]ffirms what was reported in prior published studies, that those exposed to the Ground Zero toxins are at higher risk of developing cancer than the general population. Notably, the Study found a statistically significant incidence rate for prostate cancer, including a 17% greater than expected rate of prostate cancer among responders. According to the Study, these findings were "concordant" with the findings of the New York City Fire Department [FDNY] and the New York City Department of Health and Mental Hygiene World Trade Center Health City Registry.[19]

The "prior published studies" referenced in Petition 002 were authored by Zeig-Owens et al., and by Li et al., published in the Journal of the American Medical Association (JAMA) in December 2012.[20] The Zeig-Owens, Li, and Solan studies are reviewed and analyzed by

[18] Solan S, Wallenstein S, Shapiro M, Teitelbaum SL, Stevenson L, Kochman A, Kaplan J, Dellenbaugh C, Kahn A, Biro FN, Crane M, Crowley L, Gabrilove J, Gonsalves L, Harrison D, Herbert R, Luft B, Markowitz SB, Moline J, Niu X, Sacks H, Shukla G, Udasin I, Lucchini RG, Boffetta P, Landrigan PJ. [2013] Cancer incidence in World Trade Center rescue and recovery workers, 2001-2008. Environ Health Perspect 121(6):699-704.

[19] The Petitioner incorrectly states that the Solan study reported a 17 percent increase in prostate cancer. Solan et al. report a 21 percent increase in prostate cancer when the timeframe for diagnosis is unrestricted, and 23 percent when the timeframe for diagnosis is restricted.

[20] Li J, Cone JE, Kahn AR, Brackbill RM, Farfel MR, Greene CM, Hadler JL, Stayner LT, Stellman SD [2012]. Association Between World Trade Center Exposure and Excess Cancer Risk. JAMA 308(23):2479-2488.

the Administrator below. In reviewing Petition 002, the Administrator is mindful of what the STAC stated in its April 2, 2012 recommendation to the Administrator:

> The Committee recognizes that additional epidemiologic studies will soon become available, and recommends that as they do become available, their findings be reviewed and modifications made to the list as appropriate.

Accordingly, the Administrator reviewed the two new epidemiologic studies in 9/11 exposed populations published subsequent to the 2011 Zeig-Owens study. The Administrator's review focused on the information that the three epidemiologic studies, taken as a whole, provided on the question of the risk of prostate cancer in association with 9/11 exposures and the role of surveillance bias in explaining any observed excess risk. The Administrator's findings regarding the three studies are described below, under Method 1.

IV. Administrator's Determination on Petition 002 Requesting the Addition of Prostate Cancer to the List

In response to Petition 002, the Administrator has reviewed the available evidence pertinent to the four-part hierarchical methodology detailed above. The Administrator's review of the relevant evidence is below.

Method 1

Method 1 requires that the Administrator evaluate the available information in published, peer-reviewed epidemiologic studies for evidence of an adequate strength of the association between 9/11 exposure and a health effect (including the magnitude of the effect and its statistical significance), consistency of the findings across multiple studies, biological gradient, or dose (or exposure)-response relationships between 9/11 exposures and the cancer type, and plausibility and coherence with known facts about the biology of the cancer type.

The Zeig-Owens study. The first published study of cancer outcomes associated with the 9/11 attacks was authored by Zeig-Owens et al. and published in September 2011. The study involved examination of the potential association between exposure and cancer outcomes among 9,853 male Fire Department of the City of New York (FDNY) firefighters within 7 years of September 11, 2001.[21] The study evaluated cancer cases identified by self-reporting and through five state cancer registries. SIRs were used to determine if the number of observed cancer cases in the studied firefighters was greater or less than the number of cases expected to occur if the same disease rate in a large reference population occurred in the studied group.[22] The reference cancer incidence data was obtained from the U.S. National

[21] Zeig-Owens et al. 2011.

[22] If the observed number of cancer cases equals the expected number of cases, the SIR equals 1 (one). If more cases are observed in the studied population than expected, the SIR is greater than 1 (one). If fewer cases are observed in the studied population than expected, the SIR is less than 1.

Cancer Institute Surveillance Epidemiology and End Results (SEER) database.

In the Zeig-Owens study, the SIRs for various types of cancer, including prostate cancer, were reported in two ways: (1) by comparing the exposed FDNY firefighters to the general population; and (2) by comparing the SIR for 9/11 exposed FDNY firefighters to the SIR for non-9/11 exposed FDNY firefighters (the ratio of standardized incidence ratios is referred to as the "SIR ratio"). When compared to the general population, the SIR for prostate cancer was increased, and that increase was statistically significant (SIR=1.49, 95% confidence interval (CI) 1.20-1.85). When compared to non-9/11 exposed FDNY firefighters, the SIR ratio was slightly greater than 1 (one),[23] but the increase was not statistically significant (SIR ratio=1.11, 95% CI 0.77-1.59). Zeig-Owens noted the potential for surveillance bias, that is, FDNY firefighters may be medically followed more closely or have more diagnostic tests performed than the general population, which could lead to finding more disease among this population.

A standard method to adjust for surveillance bias is not available, and the adequacy of any adjustment method is uncertain. In an attempt to correct for surveillance bias, Zeig-Owens adjusted the SIRs and SIR ratios by delaying the recorded date of diagnosis by 2 years for 25 cases of prostate and other cancers that potentially

[23] If the SIR in the studied population equals the SIR in the reference population, the SIR ratio equals 1 (one). If the SIR in the studied population is greater than the SIR in the reference population, the SIR ratio is greater than 1 (one). If the SIR ratio in the studied population is less than the SIR in the reference population, the SIR ratio is less than 1 (one).

could be detected early by FDNY surveillance (i.e., medical screening). When the estimates were adjusted in this way, the comparison to the general population produced a SIR for prostate cancer that was increased, but not statistically significant (SIR=1.21, 95% CI 0.96-1.52). When compared to non-exposed firefighters, the SIR ratio was not increased (SIR ratio=0.90, 95% CI 0.62-1.30). The authors noted that they had gone to "great lengths" to assess and correct for potential biases and provided arguments against the existence of considerable bias. However, the authors further noted that delaying the date of diagnosis may have over-corrected or under-corrected for surveillance bias, and the authors could not rule out the potential for surveillance bias in several types of cancer, including prostate cancer.

The Li study. Li et al. authored the second published epidemiologic study of cancer outcomes associated with the 9/11 attacks, published in December 2012. It involved examination of cancer health outcomes of 55,778 members of the WTC Health Registry, including rescue and recovery workers as well as people not involved in rescue and recovery (e.g., area residents, workers, and passersby).[24] In comparison to the Zeig-Owens study, the Li study involves a much larger and more heterogeneous population that is likely subjected to much less medical screening and surveillance bias.

[24] Li et al., 2012.

In the Li study, cancer cases were identified through 11 state cancer registries; New York State cancer rates were used as the reference. The authors accounted for cancer latency by assuming that any exposure-related cancers would be more likely to occur at least 5 years after the 9/11 exposures. The study population was divided into two groups: early period (WTC Health Registry participants who were diagnosed with cancer between enrollment and 2006) and later period (WTC Health Registry participants who were diagnosed with cancer between 2007 and 2008). Among rescue and recovery workers, a statistically significant increase in the incidence of prostate cancer was reported for the later period (SIR=1.43, 95% CI 1.11-1.82). In the early period, the SIR was slightly, but not statistically significantly, increased (SIR=1.12, 95% CI 0.83-1.40).

The potential for surveillance bias in the Li study was assessed by: (1) comparing the number of Stage 1 cancers for selected cancer sites as a proportion of total cancer diagnoses in the study population to the corresponding proportion in the New York State reference population during the same period; and (2) comparing the proportion of participants who reported a routine physical checkup within the preceding 12 months to the number of follow-up participants with and without subsequent cancers. Importantly, the Li study noted that the proportions were similar in both cases and stated:

> These observations suggest that cancer cases in this study may not have received more thorough cancer screening than the NYS

> [New York State] population in general, although they do not eliminate the possible role of surveillance altogether. Also, our findings might be prone to type 1 error[25] given the large number of comparisons.[26]

The Solan study. The third epidemiologic study of cancer outcomes in 9/11 exposed populations was authored by Solan et al. First published online in April 2013 and then in print in June of 2013, this study addressed cancer health outcomes associated with the 9/11 attacks involving 20,984 WTC responders (including rescue and recovery workers) enrolled in the WTC Health Program.[27] Cancer cases diagnosed between 2001 and 2008 were identified through the New York, New Jersey, Connecticut, and Pennsylvania cancer registries, and SIRs were calculated using the general population of the state of residence as the reference population. No adjustments were made for potential surveillance bias. When all prostate cancers diagnosed after September 11, 2001 were included, a small statistically significant increase in the SIR for prostate cancer among WTC responders was observed (SIR=1.21, 95% CI 1.01-1.44). The authors note that, "[e]vidence for occupational risk factors of prostate cancer is very weak, and heightened diagnosis due to increased medical surveillance is a possible explanation for greater than expected numbers of prostate cancer diagnoses."[28] The SIR was also calculated for those WTC responders who were diagnosed with prostate

[25] A type 1 error is a "false positive." In this case, the authors are noting that they made a large number of comparisons in the study and, when making a large number of comparisons, it is likely that some statistically significant findings will occur by chance.
[26] Li et al., at 2486.
[27] Solan et al., 2013.
[28] Solan et al., at 702.

cancer 6 months after enrollment in the WTC Health Program. This adjustment reduces the potential for selection bias[29] in the results. After this adjustment, the SIR for prostate cancer remained increased, but was not statistically significant (SIR= 1.23, 95% CI 0.98-1.53).

When more than one epidemiologic study in 9/11 exposed populations has been published, Method 1 directs the Administrator to evaluate findings from the studies using the following criteria: (1) strength of any association between a 9/11 exposure and a health effect (including the magnitude of the effect and statistical significance); (2) consistency of the findings across multiple studies; (3) biological gradient or dose-response relationships between 9/11 exposures and the cancer type; and (4) the plausibility and coherence with known facts about the biology of the cancer type. After review, the Administrator finds that the strength of the association between 9/11 exposures and prostate cancer across all three studies is weak (criteria 1), but that excess risk is consistently reported in each of the three studies (criteria 2). A dose (exposure)-response relationship between 9/11 exposures and prostate cancer is difficult to establish because of the substantial limitations of 9/11 exposure information (criteria 3). Finally, there is limited evidence of the potential plausibility of the development of prostate cancer with two of the documented 9/11 exposures—arsenic

[29] Selection bias might have occurred when individuals decided to enroll in the WTC Health Program after being diagnosed with prostate cancer. If this occurred, the number of prostate cancers among the exposed population would be increased and result in a higher SIR.

and cadmium (criteria 4). The Li study provides evidence that surveillance bias does not fully explain the observed excess risk for prostate cancer.

Because surveillance bias may not explain all of the observed excess risk in studies of 9/11-exposed populations and because the strength of the association between 9/11 exposures and prostate cancer across all three studies is weak, the Administrator has determined that the evidence to add prostate cancer based on Method 1 is inconclusive.

Method 2

Method 2 requires that the Administrator find that multiple epidemiologic studies show a causal association between a type of cancer and a health condition already on the List of WTC-Related Health Conditions. After review of the scientific literature, the Administrator finds that there is no evidence that any of the conditions on the List of WTC-Related Health Conditions increase the risk of prostate cancer and Method 3 should be reviewed.

Method 3

Method 1 provides insufficient evidence to add prostate cancer to the List and Method 2 provides no evidence to add prostate cancer. The Administrator next reviewed 9/11 exposures in relation to NTP and IARC information pertinent to prostate cancer (Method 3).

Arsenic and cadmium are 9/11 exposures that have been reported in several exposure assessment studies of responders or survivors of the September 11, 2001, terrorist attacks in New York City (Method 3A);[30] and NTP identified arsenic and cadmium as known to be human carcinogens[31] **and** IARC found limited[32] evidence in humans that arsenic and cadmium cause prostate cancer (Method 3B). Based on the evidence provided in Methods 3A and 3B, the Administrator has determined that prostate cancer should be added to the List.

Method 4

Because Method 3 supports the addition of prostate cancer, Method 4 is not analyzed.

Administrator's Determination

Following review of all relevant evidence, the Administrator has determined that the decision to not add prostate cancer in the 2012 rulemaking is superseded by his new evaluation incorporating the Li and Solan study findings. The 2012 evaluation relied on the only epidemiologic study available at that time, Zeig-Owens, and the STAC's assessment of that study and vote to not include prostate

[30] Butt CM, Diamond ML, Truong J, Ikonomou MG, Helm PA, Stern GA [2004]. Semivolatile organic compounds in window films from lower Manhattan after the September 11th World Trade Center attacks. Environmental Science & Technology. 38(13):3514-3524.
Lorber M, Gibb H, Grant L, Pinto J, Pleil J, Cleverly D [2007] Assessment of inhalation exposures and potential health risks to the general population that resulted from the collapse of the World Trade Center towers. Risk Anal 27(5):1203–21.
Lioy PJ, Gochfeld M [2002]. Lessons learned on environmental, occupational, and residential exposures from the attack on the World Trade Center. Am J Ind Med 42(6):560–565.

[31] NTP (National Toxicology Program)[2011]. 12th Report on Carcinogens. National Toxicology Program, Public Health Service, U.S. Department of Health and Human Services, Research Triangle Park, NC. http://ntp.niehs.nih.gov/?objectid=03C9AF75-E1BF-FF40-DBA9EC0928DF8B15. Accessed May 24, 2013.

[32] IARC (International Agency for Research on Cancer) [2012]. IARC Monographs on the Evaluation of the Carcinogenic Risks to Humans: Vol. 100C--Arsenic, Metals, Fibres, and Dusts. IARC, Lyon, France. http://monographs.iarc.fr/ENG/Monographs/vol100C/index.php. Accessed May 24, 2013.

cancer in their recommendation. The Li and Solan studies present epidemiologic findings from larger, more heterogeneous populations and present evidence that surveillance bias may not be occurring in the studied populations. Review of the two new studies leads the Administrator to believe that surveillance bias may not fully explain the increased incidence of prostate cancer and, accordingly, the Administrator can no longer attribute increased incidence of prostate cancer to surveillance bias with certainty. After comprehensive review of all three epidemiology studies of 9/11-exposed populations, the Administrator has determined that the epidemiologic evidence evaluated under Method 1 is inconclusive and therefore turns to evaluating the evidence of carcinogenicity provided by NTP and IARC under Method 3. The Administrator now finds that, based on the evidence provided in Methods 3A and 3B, prostate cancer may be added to the named cancer types in 42 CFR 88.1, Table 1.

V. Early Detection of Prostate Cancer

Early detection of cancer in 9/11-exposed populations—either as part of medical monitoring of enrolled WTC responders and survivors or part of ongoing research—is an important adjunct to the WTC Health Program. The WTC Health Program adheres to the recommendations of the U.S. Preventive Services Task Force (USPSTF) with regard to coverage for preventive measures, including screening tests, counseling, immunizations, and preventive medications. The USPSTF recommends

against PSA-based screening for prostate cancer.[33] Therefore, PSA-based screening for prostate cancer will not be covered by the WTC Health Program.

VI. Effects of Rulemaking on Federal Agencies

Title II of the James Zadroga 9/11 Health and Compensation Act of 2010 (Pub. L. 111-347) reactivated the September 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.

VII. Summary of Proposed Rule

For the reasons discussed above, the Administrator proposes to amend 42 CFR 88.1, paragraph (4), Table 1, to add malignant neoplasm

[33] U.S. Preventive Services Task Force. Recommendation: Screening for Prostate Cancer (2012). http://www.uspreventiveservicestaskforce.org/prostatecancerscreening.htm. Accessed June 2, 2013.

of the prostate (prostate cancer) and to add the corresponding medical diagnostic codes.[34]

VIII. Regulatory Assessment Requirements

A. Executive Order 12866 and Executive Order 13563

Executive Orders (E.O.) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

This notice of proposed rulemaking has been determined not to be a "significant regulatory action" under sec. 3(f) of E.O. 12866. The proposed addition of prostate cancer by this rulemaking is estimated to cost the WTC Health Program between **$3,462,675**[35] and **$6,995,817**[36] per annum. All of the costs to the WTC Health Program will be transfers after the implementation of provisions of the Patient Protection and Affordable Care Act (Pub. L. 111-148) on January 1, 2014. This notice of proposed rulemaking has been reviewed by the Office of Management and Budget (OMB). The rule would not interfere

[34] ICD-9 code 185 and ICD-10 code C61. See, respectively, WHO (World Health Organization) [1978]. International Classification of Diseases, Ninth Edition, and WHO [1997] International Classification of Diseases, Tenth Edition.
[35] Based on a population of 60,000 at the U.S. cancer rate and discounted at 7 percent.
[36] Based on a population of 110,000 at 21 percent above the U.S. cancer rate and discounted at 3 percent.

with State, local, and Tribal governments in the exercise of their governmental functions.

Cost Estimates

The WTC Health Program has, to date, enrolled approximately 58,500 WTC responders and approximately 6,500 survivors, or approximately 65,000 individuals in total. Of that total population, approximately 60,000 individuals were participants in previous WTC medical programs and were 'grandfathered' into the WTC Health Program established by Title XXXIII.[37] In addition to those grandfathered WTC responders and survivors already enrolled, the PHS Act 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 WTC survivors (i.e., the statute restricts new enrollment).[38] Since July 1, 2011, a total of approximately 3,000 new WTC responders and new WTC survivors (over 1,700 responders and 1,200 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, the Administrator assumed that this gradual rate of enrollment would continue, and that the currently enrolled population numbers would remain around 58,500 WTC responders and 6,500 WTC survivors. The estimate is further based on the average U.S. cancer

[37] 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."
[38] PHS Act, secs. 3311(a)(4)(A) and 3321(a)(3)(A).

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 grandfathered + 25,000 new) and 30,000 survivors (5,000 grandfathered + 25,000 new). The upper cost estimate also assumes an overall increase in population cancer rates (for malignant neoplasm of the prostate [prostate cancer] of 21 percent due to 9/11 exposure),[39] 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 first published epidemiologic study of September 11, 2001 exposed populations.[40] Given the challenges associated with interpreting the Zeig-Owens findings,[41] we simply characterize 21 percent as a possible outcome rather than asserting the probability that 21 percent is a "likely" outcome.

The Administrator acknowledges that some prostate cancer cases are not likely to have been caused by 9/11 exposures. The

[39] 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.
[40] 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.
[41] 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.

certification of individual cancer diagnoses will be conducted on a case-by-case basis. However, for the purpose of this analysis, the Administrator has estimated that all diagnosed cancers added to the List will be certified for treatment by the WTC Health Program. Finally, because there are no existing data on cancer rates related to 9/11 exposures at either the Pentagon or in Shanksville, Pennsylvania, the Administrator has used only data from studies of individuals who were responders or survivors in the New York City disaster area.

Costs of Cancer Treatment

The Administrator estimated the treatment costs associated with covering prostate cancer in this rulemaking using the methods described below. The WTC Health Program obtained data for the cost of providing medical treatment for prostate cancer.[42] The costs of treatment 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.[43] Therefore, we used

[42] 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.
[43] 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.

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 rates for prostate cancer.

Table A--Average Costs of Treatment for Prostate Cancer (2011$)		
Initial (12 month)	Continuing (annual)	Last year of life (12 mos.)
$13,696	$2,754	$43,481

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.[44] The average costs of treatment described above are given in 2011 prices adjusted using the Medical Consumer Price Index for all urban consumers.[45]

Incident Cases of Cancer

The Administrator estimated the expected number of cases of cancer that would be observed in a cohort of responders and survivors followed for cancer incidence after September 11, 2001 using U.S. population cancer rates for prostate cancer. 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

[44] 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.
[45] Bureau of Labor Statistics. Consumer Price Index. Available at https://research.stlouisfed.org/fred2/series/CPIMEDSL/downloaddata?cid=32419. Accessed April 23, 2012.

and survivors were assumed to be the same as current members in the WTC Health Program. According to WTC Health Program data, males comprise 88 percent of the current responder members and 50 percent of survivor members. Because prostate cancer occurs only in males, all calculations only take into account male WTC Health Program members. The age distribution for current members by gender and responder/survivor status is presented in Table B.

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

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

The Administrator assumed race and ethnic origin distributions for responders and survivors according to distributions in the WTC Health Registry cohort:[46] 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

[46] 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.

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).[47] A life-table analysis program, LTAS.NET, was used to estimate the expected number of incident cancers for prostate cancer.[48] The Administrator calculated cancer incidence rates using data through 2006 from the Surveillance Epidemiology and End Results (SEER) Program and estimated rates for 2007-2016.[49] 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 prostate cancer 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, the Administrator used the number of incident cases described above for each year starting with

[47] 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.
[48] 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.
[49] National Cancer Institute, Surveillance Epidemiology and End Results (SEER). http://seer.cancer.gov/. Accessed May 27, 2012.

2002 and estimated the prevalence of cancer using survival rate statistics for each incident cancer group through 2016.[50] Using the incident cases and survival rate statistics, HHS has estimated the prevalence (number of persons living with cancer) of cases during the 15 year period (2002-2016) since September 11, 2001. The resulting table provides for each year from 2002 through 2016, the number of new cases occurring in that year (incidence), the number of individuals who died from their cancer in that year, and the number of persons surviving up to 15 years beyond their first diagnosis (prevalence).[51] For example, in 2002 there are 34.22 projected new cases of prostate cancer, which would be listed as incident cases for that year. The survival rate for prostate cancer in the first year of diagnosis is 99.44 percent.[52] Therefore the number of deceased persons in 2002 would be 34.22 x (1 - 0.9944) = 0.19. For the prostate cancer prevalence table, in year 2003, the number of incident cases would be 38.55 cases. In addition to 38.55 newly diagnosed cases in 2003, there would be the one-year survivors from 2002 which would be 34.22-0.19 = 34.03 cases. This computation process can be repeated for each year through year 2016. A portion of the prostate cancer prevalence tables are provided in Table C. Prevalence is summarized in Tables E and G. This analysis considers cancers diagnosed in 2002 through 2016.

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

Table C-- Prevalence Table for Prostate Cancer [Based on 80,000 responders]						
Year	Years since 9/11 exposure			Years covered by WTC Health Program		
New/Surv.	2002	2003	2013	2014	2015	2016
1	34.22	38.55	112.54	123.98	134.46	146.33
2		34.03	100.76	111.92	123.29	133.72
3			88.67	99.55	110.57	121.81
4			79.02	87.58	98.33	109.22
5			71.15	78.61	87.13	97.82
6			63.27	70.41	77.80	86.23
7			55.71	62.74	69.83	77.15
8			48.22	55.06	62.01	69.01
9			42.10	47.91	54.71	61.61
10			39.77	41.51	47.24	53.95
11			35.02	39.38	41.11	46.77
12			30.91	34.83	39.17	40.88
13				30.43	34.29	38.56
14					30.26	34.10
15						30.06
Live cases from previous years	0.00	34.03	654.61	759.95	875.74	1000.89
Prevalence	34.22	72.58	767.15	883.93	1010.20	1147.22
Last year of life	0.19	0.62	7.20	8.19	9.31	10.65

Cost Computation

To compute the costs for prostate cancer, the Administrator assumes that all of the individuals who are diagnosed with prostate cancer will be certified by the WTC Health Program for treatment and monitoring services. The treatment costs for the first year of treatment (Table A, year adjusted) were applied to the predicted newly incident (Year 1) cases for each year. Likewise, the costs of treatment for the last year of life were applied in each year to the number of people predicted to die from their cancer in that year. The

costs of continuing treatment from Table A were applied to the number of prevalent cases who had survived their cancers beyond their year of diagnosis, for each year of survival (Year 2-15).

Using this procedure, a cost table was constructed for each year covered by the WTC Health Program and the results are presented in Table D. The row for Year 1 in each table is the cost of incident cases for that year. Rows for years 2-15 show the cost from continuing care for 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 prostate cancer from Table C.

Table D--Cost per 80,000 Responders for Prostate Cancer, 2011$			
	Years covered by the WTC Health Program		
Year	2014	2015	2016
1	$1,688,586	$1,831,435	$1,993,026
2	$308,251	$339,563	$368,289
3	$274,159	$304,530	$335,464
4	$241,216	$270,809	$300,809
5	$216,509	$239,972	$269,413
6	$193,930	$214,266	$237,486
7	$172,786	$192,305	$212,470
8	$151,653	$170,779	$190,071
9	$131,942	$150,680	$169,685
10	$114,331	$130,098	$148,574
11	$108,466	$113,209	$128,822
12	$95,925	$107,868	$112,586
13	$83,816	$94,438	$106,196
14		$83,345	$93,906
15			$82,779
Prevalent care	$3,781,570	$4,243,298	$4,666,796
Last year of life care	$356,227	$404,804	$463,183
Total	$4,137,798	$4,648,102	$5,129,979

The sum of the annual costs in the table for the years 2014 through 2016 represents the estimated treatment costs to the WTC Health Program for coverage of prostate cancer for 80,000 responders. 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. 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 WTC exposures.[53]

A summary of the estimated prevalence at the U.S. population average for the assumed population of 58,500 responders and 6,500 survivors is provided in Table E. A summary of the estimated treatment costs to the WTC Health Program is provided in Table F. A summary of the estimated prevalence using cancer rates 21 percent over the U.S. population average for the increased rate of 80,000 responders and 30,000 survivors is given in Table G. A summary of the estimated treatment costs to the WTC Health Program is provided in Table H.

[53] 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.

Table E – Estimated prevalence of prostate cancer by year based on 58,500 and 6,500 responder and survivor population, respectively and assuming cancer rates at U.S. population average			
Population	Prevalence (incident + live cases)		
	2014	2015	2016
Based on 58,500 responders	646.37	738.71	838.90
Based on 6,500 survivors	65.95	73.93	82.41

Table F – Estimated treatment costs of prostate cancer by year based on 58,500 and 6,500 responder and survivor population, respectively and assuming cancer rates at U.S. population average (2011 $)				
Population	2014	2015	2016	2014-2016
Based on 58,500 responders	$3,025,765	$3,398,924	$3,751,298	$10,175,987
Based on 6,500 survivors	$296,297	$326,642	$352,170	$975,109

Table G – Estimated prevalence of prostate cancer by year 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			
Population	Prevalence (incident + live cases)		
	2014	2015	2016
Based on 80,000 responders	1069.55	1222.34	1388.13
Based on 30,000 survivors	368.31	412.86	460.19

Table H – Estimated treatment costs of prostate cancer by year 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 $)				
Population	2014	2015	2016	2014-2016
Based on 80,000 responders	$5,089,491	$5,717,165	$6,309,875	$17,116,531
Based on 30,000 survivors	$1,378,925	$1,520,138	$1,638,947	$4,538,010

Summary of Costs

Because HHS lacks data to account for recoupment by workers'

compensation insurance or reduction by either health insurance or Medicare/Medicaid payments, the estimates offered here are reflective of estimated WTC Health Program costs only. This analysis offers an assumption about the number of individuals who might enroll in the WTC Health Program and estimates the impact of both a low rate of cancer (U.S. population average rate) and an increased rate (21 percent greater than the U.S. population average) on the number of cases and the resulting estimated treatment costs to the WTC Health Program. This analysis does not include administrative costs associated with certifying additional diagnoses of cancers that are WTC-related health conditions that might result from this action. Those costs were addressed in the interim final rule that established regulations for the WTC Health Program (76 FR 38914, July 1, 2011).

After the implementation of provisions of the Affordable Care Act on January 1, 2014, all of the members and future members can be assumed to have or have access to medical insurance coverage other than through the WTC Health Program. Therefore, all treatment and screening costs to be paid by the WTC Health Program from 2014 through 2016 are considered transfers. Table I describes the allocation of WTC Health Program transfer payments based on 58,500 responders and 6,500 survivors and, alternatively, 80,000 responders and 30,000 survivors.

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

	Discounted at 7 percent	Discounted at 3 percent
	Cancer Rate	
	U.S. average	U.S. average + 21%
58,500 Responders	$3,159,619	
6,500 Survivors	$303,056	
65,000 Total	**$3,462,675**	
80,000 Responders		$5,529,266
30,000 Survivors		$1,466,551
110,000 Total		**$6,995,817**

Examination of Benefits (Health Impact)

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

The Administrator does not have information on the health of the population that may have experienced 9/11 exposures and is not currently enrolled in the WTC Health Program. In addition, the Administrator has only limited information about health insurance and health care services for prostate cancers potentially caused by 9/11 exposures and suffered by any population of responders and survivors, including responders and survivors currently enrolled in the WTC Health Program and responders and survivors not enrolled in the Program. For the purposes of this analysis, the Administrator assumes that broad trends on demographics and access to health insurance

reported by the U.S. Census Bureau and health care services for cancer similar to those reported by Ward et al.[54] would apply to the population of general responders (those individuals who are not members of the FDNY and who meet the eligibility criteria in 42 CFR Part 88 for WTC responders) and survivors both within and outside the Program. For the purposes of this analysis, the Administrator assumes that access to health insurance and health care services for FDNY responders within and outside the Program would be equivalent because this population is overwhelmingly covered by employer-based health insurance.

Although the Administrator cannot quantify the benefits associated with the WTC Health Program, members with prostate cancer would have improved access to care and thereby the Program should produce better treatment outcomes than in its absence. Under other insurance plans, patients would have deductibles and copays, which impact access to care and particularly its timeliness.[55] WTC Health Program members would have first-dollar coverage and hence are likely to seek care sooner when indicated, resulting in improved treatment outcomes.

Limitations

The analysis presented here was limited by the dearth of verifiable data on the prostate cancer status of responders and

[54] 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.
[55] Wharam JF, Galbraith AA, Kleinman KP, Soumerai SB, Ross-Degnan D, Landon BE. Cancer Screening before and after Switching to a High-Deductible Health Plan. Annals of Internal Medicine. 2008 May;148(9):647-655.

survivors who have yet to apply for enrollment in the WTC Health Program. Because of the limited data, the Administrator was not able to estimate benefits in terms of averted healthcare costs. Nor was the Administrator able to estimate administrative costs, or indirect costs, such as averted absenteeism, short and long-term disability, and productivity losses averted due to premature mortality.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601 et seq., requires each agency to consider the potential impact of its regulations on small entities including small businesses, small governmental units, and small not-for-profit organizations. The Administrator 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.).

C. Paperwork Reduction Act

The Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., requires an agency to invite public comment on, and to obtain OMB approval of, any regulation that requires 10 or more people to report information to the agency or to keep certain records. Data collection and recordkeeping requirements for the WTC Health Program are approved by OMB under "World Trade Center Health Program Enrollment, Appeals & Reimbursement" (OMB Control No. 0920-0891, exp. December

31, 2014). The Administrator has determined that no changes are needed to the information collection request already approved by OMB.

D. Small Business Regulatory Enforcement Fairness Act

As required by Congress under the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.), HHS will report the promulgation of this rule to Congress prior to its effective date.

E. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531 et seq.) directs agencies to assess the effects of Federal regulatory actions on State, local, and Tribal governments, and the private sector "other than to the extent that such regulations incorporate requirements specifically set forth in law." For purposes of the Unfunded Mandates Reform Act, this proposed rule does not include any Federal mandate that may result in increased annual expenditures in excess of $100 million in 1995 dollars by State, local or Tribal governments in the aggregate, or by the private sector. 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 2013, the inflation adjusted threshold is $150 million.

F. Executive Order 12988 (Civil Justice)

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

G. Executive Order 13132 (Federalism)

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

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

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

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

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

J. Plain Writing Act of 2010

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

Proposed Rule

List of Subjects in 42 CFR Part 88:
Aerodigestive disorders, Appeal procedures, Cancer, Health care, Mental health conditions, Musculoskeletal disorders, Respiratory and pulmonary diseases.

For the reasons discussed in the preamble, the Department of Health and Human Services proposes to amend 42 CFR Part 88 as follows:

PART 88--WORLD TRADE CENTER HEALTH PROGRAM

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

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

2. In §88.1, the under the definition "**List of WTC-related health conditions**", following paragraph (4), revise Table 1 to read as follows:

§ 88.1 Definitions.

*****

List of WTC-related health conditions ***

(4)***

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**
	• 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	• 145.5
	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	• 145.9
	Malignant neoplasm of tonsil	**C09**	**146.0-146.2**
	• Tonsillar fossa	• C09.0	• 146.1
	• Tonsillar pillar (anterior)(posterior)	• C09.1	• 146.2
	• Overlapping lesion of tonsil	• C09.8	• 146.0
	• Tonsil, unspecified	• C09.9	• 146.0
	Malignant neoplasm of oropharynx	**C10**	**146.3-146.9**
	• 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	• 146.8
	• Overlapping lesion of oropharynx	• C10.8	• 146.5, 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, 148.2-148.9**
	• 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, 149.9
	Malignant neoplasm of 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, 154.8**
	Malignant neoplasm of other and ill-defined digestive organs	**C26.0, C26.8-C26.9**	**159.0, 159.8, 159.9**
	• Intestinal tract, part unspecified	• C26.0	• 159.0
	• Overlapping lesion of digestive system	• C26.8	• 159.8
	• Ill-defined sites within the digestive system	• C26.9	• 159.9
	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**
	• 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	• 163.0-163.9
	• Overlapping lesion of heart, mediastinum and pleura	• C38.8	• 164.8
	Malignant neoplasm of other and ill-defined sites in the respiratory system and intrathoracic organs	**C39**	**165**
	• Upper respiratory tract, part unspecified	• C39.0	• 165.0
	• Overlapping lesion of respiratory and intrathoracic organs	• C39.8	• 165.8
	• III-defined sites within the respiratory system	• C39.9	• 165.9
Mesothelium	**Mesothelioma**	**C45**	**158.8, 163.9, 164.1**
	• Mesothelioma of pleura	• C45.0	• 163.9
	• Mesothelioma of peritoneum	• C45.1	• 158.8
	• Mesothelioma of pericardium	• C45.2	• 164.1
	• Mesothelioma of other sites	• C45.7	No Code
	• Mesothelioma, unspecified	• C45.9	No Code
Soft Tissue	**Malignant neoplasm of peripheral nerves and autonomic nervous system**	**C47**	**171**
	• Peripheral nerves of head, face and neck	• C47.0	• 171.0
	• Peripheral nerves of upper limb, including shoulder	• C47.1	• 171.2
	• Peripheral nerves of lower limb, including hip	• C47.2	• 171.3
	• Peripheral nerves of thorax	• C47.3	• 171.4
	• Peripheral nerves of abdomen	• C47.4	• 171.5
	• Peripheral nerves of pelvis	• C47.5	• 171.6
	• Peripheral nerves of trunk, unspecified	• C47.6	• 171.7
	• Overlapping lesion of peripheral nerves and autonomic nervous system	• C47.8	• 171.8
	• Peripheral nerves and autonomic nervous system, unspecified	• C47.9	• 171.9
	Malignant neoplasm of other connective and soft tissue	**C49**	**171**
	• Connective and soft tissue of head, face and neck	• C49.0	• 171.0
	• Connective and soft tissue of upper limb, including shoulder	• C49.1	• 171.2
	• Connective and soft tissue of lower limb, including hip	• C49.2	• 171.3
	• Connective and soft tissue of thorax	• C49.3	• 171.4
	• Connective and soft tissue of abdomen	• C49.4	• 171.5
	• Connective and soft tissue of pelvis	• C49.5	• 171.6
	• Connective and soft tissue of trunk, unspecified	• C49.6	• 171.7
	• Overlapping lesion of connective and soft tissue	• C49.8	• 171.8
	• Connective and soft tissue, unspecified	• C49.9	• 171.9
Skin (Non-Melanoma)	**Other malignant neoplasms of skin**	**C44**	**173**
	• Skin of lip	• C44.0	• 173.0
	• Skin of eyelid, including canthus	• C44.1	• 173.1
	• Skin of ear and external auricular canal	• C44.2	• 173.2
	• Skin of other and unspecified parts of face	• C44.3	• 173.3
	• Skin of scalp and neck	• C44.4	• 173.4
	• Skin of trunk	• C44.5	• 173.5

	• Skin of upper limb, including shoulder	• C44.6	• 173.6
	• Skin of lower limb, including hip	• C44.7	• 173.7
	• Overlapping lesion of skin	• C44.8	• 173.8
	• Malignant neoplasm of skin, unspecified	• C44.9	• 173.9
	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	• 172.7
	• Overlapping malignant melanoma of skin	• C43.8	• 172.8
	• Malignant melanoma of skin, unspecified	• C43.9	• 172.9
Female 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
	• Auxillary 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 prostate**	**C61**	**185**
	Malignant neoplasm of bladder	**C67**	**188**
	• 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	• C67.4d	• 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, 190.7
	• Orbit	• C69.6	• 190.1
	• Overlapping lesion of eye and adnexa	• C69.8	• 190.8
	• Eye, unspecified	• C69.9	• 190.9
Thyroid	**Malignant neoplasm of thyroid gland**	**C73**	**193**
Blood & Lymphoid Tissue	**Hodgkin's disease**	**C81**	*
	• Lymphocytic predominance	• C81.0	• 201.4
	• Nodular sclerosis	• C81.1	• 201.5
	• Mixed cellularity	• C81.2	• 201.6
	• Lymphocytic depletion	• C81.3	• 201.7
	• Other Hodgkin's disease	• C81.7	• 201.0-201.2
	• Hodgkin's disease, unspecified	• C81.9	• 201.9
	Follicular [nodular] non-Hodgkin lymphoma	**C82**	*
	• Small cleaved cell, follicular	• C82.0	• 202.0
	• Mixed small cleaved and large cell, follicular	• C82.1	• 202.0
	• Large cell, follicular	• C82.2	• 202.0
	• Other types of follicular non-Hodgkin lymphoma	• C82.7	• 202.0
	• Follicular non-Hodgkin lymphoma, unspecified	• C82.9	• 202.0
	Diffuse non-Hodgkin lymphoma	**C83**	*
	• Small cell (diffuse)	• C83.0	• 200.8
	• Small cleaved cell (diffuse)	• C83.1	• 202.4
	• Mixed small and large cell (diffuse)	• C83.2	• 200.8
	• Large cell (diffuse)	• C83.3	• 200.0
	• Immunoblastic (diffuse)	• C83.4	• 200.8
	• Lymphoblastic (diffuse)	• C83.5	• 200.1
	• Undifferentiated (diffuse)	• C83.6	• 202.8
	• Burkitt's tumor	• C83.7	• 200.2
	• Other types of diffuse non-Hodgkin lymphoma	• C83.8	• 200.8
	• Diffuse non-Hodgkin lymphoma, unspecified	• C83.9	• 202.0
	Peripheral and cutaneous T-cell lymphomas	**C84**	*
	• Mycosis fungoides	• C84.0	• 202.1
	• Sezary's disease	• C84.1	• 202.2
	• T-zone lymphoma	• C84.2	• 202.8
	• Lymphoepithelioid lymphoma	• C84.3	• 202.8
	• Peripheral T-cell lymphoma	• C84.4	• 202.0
	• Other and unspecified T-cell lymphomas	• C84.5	• 202.0
	Other and unspecified types of non-Hodgkin lymphoma	**C85**	*
	• Lymphosarcoma	• C85.0	• 200.1
	• B-cell lymphoma, unspecified	• C85.1	• 202.8
	• Other specified types of non-Hodgkin lymphoma	• C85.7	• 202.8
	• 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,~~	• ~~C96.7~~	• ~~202.8~~

	hematopoietic and related tissue		
	• 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 the populations smaller than 200,000 individuals in the Unites 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.

+ For the purposes of this rule, ICD-10 C50 is limited to cancer of the breast in females.

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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