STATE OF WASHINGTON NONREGULATORY PROVISIONS AND QUASI-REGULATORY MEASURES—Continued

Name of SIP provision	Applicable geographic or nonattainment area	State submittal date	EPA approval date	Comments
Approval of Motor Vehicle Emission Budgets and Determination of Attainment for the 2006 24-Hour Fine Particulate Standard.	Tacoma, Pierce County	11/28/12	9/19/13, [Insert page number where the document begins].	

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 88

[Docket No. CDC–2013–0012; NIOSH–267]

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: Final rule.

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. In this final rule, the Administrator adds malignant neoplasm of the prostate (prostate cancer) to the List in the WTC Health Program regulations.

DATES: This final rule is effective October 21, 2013.

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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 citing a study of over 25,000 WTC responders enrolled in the WTC Health Program as scientific evidence.

B. Summary of Major Provisions

The rule adds 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 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

On July 2, 2013, the Administrator of the WTC Health Program published a notice of proposed rulemaking (78 FR 39670) proposing to add prostate cancer (malignant neoplasm of the prostate) to the List of WTC-Related Health Conditions. The Administrator invited interested persons or organizations to participate in this rulemaking by submitting written views, opinions, recommendations, and/or data. Comments were invited on any topic related to the proposed rule.

The Administrator received 11 substantive submissions to the docket for this rulemaking. Commenters included the following: relatives of Fire Department of New York (FDNY) members who responded at Ground Zero; a FDNY responder; a New York Police Department responder; a survivor of the attacks in New York; two labor unions that represent WTC responders; the WTC Health Program Survivor Steering Committee; and three elected officials. A summary of those comments and the Administrator's responses are found in Section VII (Summary of the Final Rule and Response to Public Comments) of this document.

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

[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.

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 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. 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 preamble to a final rule published on 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.[2] 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.[3] 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 [4] 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,[5] then the criteria of Method 4 are applied. Under Method 4, the Administrator determines whether the WTC Health Program Scientific/Technical Advisory Committee (STAC), if consulted, has provided a reasonable basis for adding the type of cancer, aside from Methods 1, 2, or 3 mentioned above. 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.

C. Consideration of Evidence for Adding Prostate Cancer to the List

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 referenced, and relied 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*.[6] Petition 002 asserted that the Solan study:

> affirms 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.[7]

The ''prior published studies'' referenced in Petition 002 were authored by Zeig-Owens *et al.,* published in *The Lancet* in September 2011,[8] and by Li *et al.,* published in the *Journal of the American Medical Association* (*JAMA*) in December 2012.[9] The Zeig-Owens, Li, and Solan studies were reviewed and analyzed by the Administrator in the notice of proposed rulemaking published July 2, 2013.[10] 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. A summary of the Administrator's findings regarding the three studies is offered below, followed by the Administrator's final determination on the addition of prostate cancer to the List.

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 described above.[11] The Administrator's determination to not add prostate cancer in the 2012 rulemaking is superseded by his new evaluation, discussed in the notice of proposed rulemaking. 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 cancer in its recommendation. The subsequently published Li and Solan studies present new 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 determine 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 adequate 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. Because no relationship

[2] 77 FR 56138, 56142.

[3] 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).

[4] 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 August 12, 2013.

[5] World Health Organization International Agency for Research on Cancer (IARC). *http://monographs.iarc.fr/.* Accessed August 12, 2013.

[6] 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. Environmental Health Perspectives 121(6):699–704.

[7] 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.

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

[9] 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.

[10] 78 FR 39670, 39674–39675.

[11] *See* pages 39674–39675 of the notice of proposed rulemaking (78 FR 39670, July 2, 2013).

has been identified between prostate cancer and a condition on the List of WTC-Related Health Conditions (Method 2), the review turned to evaluating the evidence of carcinogenicity provided by NTP and IARC under Method 3. The Administrator has determined that, based on the evidence provided in Method 3, prostate cancer will be added to the List of WTC-Related Health Conditions on the effective date for this final rule.

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.[12] 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 Final Rule and Response to Public Comments

The Administrator received 11 public comments on the notice of proposed rulemaking. Ten comments support inclusion of prostate cancer on the List of WTC-Related Health Conditions.

One commenter does not support the proposal to add prostate cancer to the List. The commenter finds that, because the epidemiologic studies published to date are inconclusive with regard to the relationship between 9/11 exposures and prostate cancer, adding prostate cancer is inappropriate at this time. Further, the commenter states that the proposal to add prostate cancer using Method 3 ''threatens the integrity of the decision-making process in the future by utilizing unclear science.'' According to the commenter, the Administrator did not ''rigorously analyze[ ] the presence and concentration of arsenic and cadmium at the attack sites.'' In addition, the commenter asserts that the review of evidence by IARC does not conclusively support the idea that arsenic and cadmium are carcinogenic for prostate cancer. Finally, the commenter believes that the addition of prostate cancer will create a strain on the financial resources available to both the WTC Health Program and the VCF administered by the Department of Justice.

The Administrator concurs that Method 1 of the Administrator's methodology, which evaluates the available epidemiologic evidence, is the preferred method for deciding whether to add a cancer to the List of WTC-Related Health Conditions. However, epidemiologic studies are substantially limited in their ability to provide timely guidance on which types of cancer should be added to the List to allow the WTC Health Program to provide services to the responders and survivors currently suffering from cancers related to 9/11 exposures. Due to the traditionally long latency period between exposure and cancer diagnosis, many epidemiologic studies of cancer and findings on health effects 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 be less than ideal given the immediate need for treatment of many WTC Health Program members and prospective members. In addition, other factors make it difficult to establish positive associations using traditional epidemiologic methods within a short time frame. The number of potentially exposed individuals is small, so the statistical power of any study will be substantially limited. Detecting traditional statistically significant increases will be difficult and may only be definitively established through a retrospective cohort mortality study conducted decades from now.

While Method 1 is the preferred method, section 3312(a)(6) of the PHS Act does not limit the Administrator's methodology to the use of traditional epidemiologic methods to add conditions to the List (Method 1). Upon thorough review of all available information, including peer-reviewed and unpublished studies, expert opinion, the STAC recommendation solicited by the Administrator for the 2012 rulemaking, and comments from the public, the Administrator determined in the September 2012 final rule that it is reasonable to acknowledge the limitations of traditional epidemiologic methods. As the Administrator concluded, ''[r]equiring evidence of positive associations from epidemiologic studies of 9/11-exposed populations exclusively does not serve the best interests of WTC Health Program members.'' [13] Accordingly, the three additional hierarchical methods were established to incorporate additional scientific sources of information in the evaluation process.

Method 3 of the Administrator's methodology incorporates qualitative exposure information and established relationships between exposure agents and types of cancer. 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. Reliance on the concentrations found in settled dust samples or observations several days or weeks after the attacks does not provide a complete understanding of the exposures. While the concentrations of arsenic and cadmium in settled dust samples collected from around the WTC site were relatively low, the qualitative exposure conditions of thick dust clouds, the likely ingestion of dust by individuals at or near the site, and the large deposits of dust in homes are likely to result in large, short-term exposures.

Analysis under Method 3 also includes identifying those agents categorized (1) by NTP as *known* or *reasonably anticipated* to be human carcinogens, and (2) by IARC as *known, probable,* or *possible* human carcinogens and having *sufficient* or *limited* evidence for causing specific types of cancer in humans. NTP and IARC findings have undergone substantial peer review and/or scientific scrutiny in their development. These authoritative bodies have categorized arsenic and inorganic arsenic

[12] U.S. Preventive Services Task Force. Recommendation: Screening for Prostate Cancer (2012). *http://www.uspreventiveservicestaskforce.org/prostatecancerscreening.htm.* Accessed August 12, 2013.

[13] 77 FR 56138, 56156 (September 12, 2012).

compounds as well as cadmium and cadmium compounds as known human carcinogens, and IARC has determined there is *limited* evidence that arsenic and inorganic arsenic compounds as well as cadmium and cadmium compounds cause cancer of the prostate.[14] Thus, the criteria in Method 3, established to add a type of cancer based on relevant exposure and an established relationship to a specific type of cancer, have been met and prostate cancer is added to the List of WTC-Related Health Conditions.

The Administrator understands the concerns about the lack of certainty in these methods and potential adverse impact on the VCF. However, the Administrator notes that individuals who are not currently enrolled in the WTC Health Program must first be determined to be eligible and qualified to enroll. The Administrator also 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 diagnosed by a Program physician 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 the individual's cancer meets the statutory definition of a WTC-related health condition.[15] The use of individual medical history and exposure assessment as part of the determination and certification process will reduce the uncertainties inherent in the methods used to determine which cancers to add to the List. Guidelines for determination and certification of a WTC-related health condition have been jointly developed by the WTC Health Program and the Clinical Centers of Excellence (CCE) for conditions on the List. With this input from the CCEs, the WTC Health Program will develop additional instructions to assess, for purposes of certification, whether an individual's 9/11 exposure may have contributed to, aggravated, or caused their prostate cancer. Similarly, the VCF employs rigorous standards used to determine individual compensation awards. The Administrator is not in a position to comment on the budget impact that this regulation will have on the VCF as matters concerning VCF administration are outside the scope of this rulemaking.

For the reasons discussed above and in the notice of proposed rulemaking published July 2, 2013, the Administrator amends 42 CFR 88.1, paragraph (4), Table 1, to add malignant neoplasm of the prostate (prostate cancer) and to add the corresponding medical diagnostic codes.[16]

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 final rule has been determined not to be a ''significant regulatory action'' under sec. 3(f) of E.O. 12866, and therefore has not been reviewed by the Office of Management and Budget (OMB). The addition of prostate cancer by this rulemaking is estimated to cost the WTC Health Program between $3,462,675 [17] and $6,995,817 [18] 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. The rule would not interfere with State, local, and Tribal governments in the exercise of their governmental functions.

Cost Estimates

The WTC Health Program has, to date, enrolled approximately 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.[19] 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).[20] 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 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

[14] Cogliano VJ, Baan R, Straif K, Grosse Y, Lauby-Secretan B, El Ghissassi F, Bouvard B, Benbrahim-Tallaa L, Guha N, Freeman C, Galichet L, Wild CP [2011]. Preventable Exposures Associated with Human Cancers. Journal of the National Cancer Institute 103:1827–1839.

IARC (International Agency for Research on Cancer) [2012]. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans: Vol. 100—A Review of Human Carcinogens. Part C: Arsenic, Metals, Fibres, and Dusts. IARC, Lyon, France. *http://monographs.iarc.fr/ENG/Monographs/vol100C/index.php.* Accessed August 7, 2013.

[15] ''An illness or health condition for which exposure to airborne toxins, any other hazard, or any other adverse condition resulting from the September 11, 2001, terrorist attacks, based on an examination by a medical professional with experience in treating or diagnosing the health conditions included in the applicable list of WTC-related health conditions, is substantially likely to be a significant factor in aggravating, contributing to, or causing the condition.'' PHS Act, sec. 3312(a)(1)(A)(i).

[16] ICD–9 code 185 and ICD–10 code C61. See, respectively, WHO (World Health Organization) [1978]. International Classification of Diseases, Ninth Edition; WHO [1997]. International Classification of Diseases, Tenth Edition.

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

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

[19] 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.''

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

exposure),[21] 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.[22] Given the challenges associated with interpreting the Zeig-Owens findings,[23] 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 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.[24] 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.[25] 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 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.[26] The average costs of treatment described above are given in 2011 prices adjusted using the Medical Consumer Price Index for all urban consumers.[27]

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 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:[28] 57 percent non-

[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. The Lancet 378(9794):898–905.

[22] *Id.*

[23] 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.

[24] 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 of the National Cancer Institute 100(9):630–41.

[25] *Id.*

[26] 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.

[27] Bureau of Labor Statistics. Consumer Price Index. Available at *https://research.stlouisfed.org/fred2/series/CPIMEDSL/downloaddata?cid=32419.* Accessed August 12, 2013.

[28] Jordan HT, Brackbill RM, Cone JE, Debchoudhury I, Farfel MR, Greene CM, Hadler JL, Kennedy J, Li J, Liff J, Stayner L, Stellman SD [2011]. Mortality Among Survivors of the Sept 11,

Continued

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).[29] A life-table analysis program, LTAS.NET, was used to estimate the expected number of incident cancers for prostate cancer.[30] 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.[31] 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 2002 and estimated the prevalence of cancer using survival rate statistics for each incident cancer group through 2016.[32] 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).[33] 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.[34] Therefore the number of deceased persons in 2002 would be $34.22 \times (1 - 0.9944) = 0.19$. 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.

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

2001, Word Trade Center Disaster: Results from the World Trade Center Health Registry Cohort. The Lancet 378:879–887. Note: percentages may not sum to 100 percent due to rounding.

[29] 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 August 12, 2013.

[30] 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.

[31] National Cancer Institute, Surveillance Epidemiology and End Results (SEER). *http://seer.cancer.gov/.* Accessed August 12, 2013.

[32] *Id.*

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

[34] National Cancer Institute, Surveillance Epidemiology and End Results (SEER). *http://seer.cancer.gov/.* Accessed August 12, 2013.

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$

Year	Years covered by the WTC Health Program		
	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.[35]

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

TABLE E—ESTIMATED PREVALENCE 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

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

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 final 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.*[36] 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.[37] 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 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 final rule does not include any Federal mandate that may result in increased annual expenditures in excess of $100 million in 1995 dollars by State, local or Tribal governments in the aggregate, or by the private sector. However, the rule may result in an increase in the contribution made by New York City for treatment and monitoring, as required by Title XXXIII, Sec. 3331(d)(2). For 2013, the inflation adjusted threshold is $150 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)

The Administrator 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, the Administrator has evaluated the environmental health and safety effects of this final 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 final rule on energy supply, distribution or use, and has determined that the rule will not have a significant adverse effect.

[36] 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 Journal for Clinicians 58:9–31.

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

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 final rule consistent with the Federal Plain Writing Act guidelines.

List of Subjects in 42 CFR Part 88

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

Final Rule

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

PART 88—WORLD TRADE CENTER HEALTH PROGRAM

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

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

§ 88.1 [Amended]

■ 2. In § 88.1, under paragraph (4) of the definition ''List of WTC-Related Health Conditions,'' revise Table 1 to read as follows:

§ 88.1 Definitions.

* * * * *

List of WTC-related health conditions

* * *

(4)* * *

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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
	• Ill-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	• 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 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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Dated: September 10, 2013.

John Howard,

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

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 64

[Docket ID FEMA–2013–0002; Internal Agency Docket No. FEMA–8301]

Suspension of Community Eligibility

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule.

SUMMARY: This rule identifies communities where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP) that are scheduled for suspension on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will not occur and a notice of this will be provided by publication in the **Federal Register** on a subsequent date. Also, information identifying the current participation status of a community can be obtained from FEMA's Community Status Book (CSB). The CSB is available at *http://www.fema.gov/fema/csb.shtm.*

DATES: *Effective Dates:* The effective date of each community's scheduled suspension is the third date (''Susp.'') listed in the third column of the following tables.

FOR FURTHER INFORMATION CONTACT: If you want to determine whether a particular community was suspended on the suspension date or for further information, contact David Stearrett, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2953.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase Federal flood insurance that is not otherwise generally available from private insurers. In return, communities agree to adopt and administer local floodplain management measures aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits the sale of NFIP flood insurance unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR Part 59. Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. We recognize that some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue to be eligible for the sale of NFIP flood insurance. A notice withdrawing the suspension of such communities will be published in the **Federal Register**.

In addition, FEMA publishes a Flood Insurance Rate Map (FIRM) that identifies the Special Flood Hazard Areas (SFHAs) in these communities. The date of the FIRM, if one has been published, is indicated in the fourth column of the table. No direct Federal financial assistance (except assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act not in connection with a flood) may be provided for construction or acquisition of buildings in identified SFHAs for communities not participating in the NFIP and identified for more than a year on FEMA's initial FIRM for the community as having flood-prone areas (section 202(a) of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4106(a), as amended). This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column. The Administrator finds that notice and public comment procedures under 5 U.S.C. 553(b), are impracticable and unnecessary because communities listed in this final rule have been adequately notified.