DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 88

[Docket No. CDC–2016–0072; NIOSH–291]

RIN 0920–AA56, 0920–AA44, 0920–AA48, 0920–AA50

World Trade Center Health Program; Amendments to Definitions, Appeals, and Other Requirements

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Final rule.

SUMMARY: In 2011 and 2012, the Secretary, Department of Health and Human Services (HHS), promulgated regulations designed to govern the World Trade Center (WTC) Health Program (Program), including the processes by which eligible responders and survivors may apply for enrollment in the Program, obtain health monitoring and treatment for WTC-related health conditions, and appeal enrollment and treatment decisions, as well as a process to add new conditions to the List of WTC-Related Health Conditions (List). After using the regulations for a number of years, the Administrator of the WTC Health Program identified potential improvements to certain existing provisions, including, but not limited to, appeals of enrollment, certification, and treatment decisions, as well as the procedures for the addition of health conditions for WTC Health Program coverage. He also identified the need to add new regulatory provisions, including, but not limited to, standards for the disenrollment of a WTC Health Program member and decertification of a certified WTC-related health condition. A notice of proposed rulemaking was published on August 17, 2016; this action addresses public comments received on that proposed rulemaking, as well as three interim final rules promulgated since 2011, and finalizes the proposed rule and three interim final rules.

DATES: This rule is effective on January 17, 2017.

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I. Executive Summary

A. Purpose of Regulatory Action

On August 17, 2016, the Secretary, HHS, and the Administrator of the WTC Health Program published a notice of proposed rulemaking proposing amendments to some provisions in part 88 in Title 42 and the addition of others (August 2016 NPRM).[1] This final rule includes the Administrator's response to public comments received on the August 2016 NPRM, as well as public comments received in response to three interim final rules establishing portions of 42 CFR part 88, published in 2011, 2013, and 2014, respectively.[2] The amendments to part 88 are intended to benefit both the WTC Health Program and its members by clarifying requirements and improving administrative processes.

B. Summary of Major Provisions

In this action, the Administrator finalizes amendments to a number of existing sections in part 88, including provisions for appeals of enrollment decisions, appeals of certification, decertification, or treatment authorization decisions, and the addition of health conditions to the List of WTC-Related Health Conditions. Some existing language is moved into new sections for clarity. Finally, new language on disenrollment, decertification, appeals of reimbursement denials, and coordination of benefits and recoupment is added to part 88.

C. Costs

The revisions to part 88 proposed in the August 2016 NPRM and finalized in this action are expected to result in approximately $42,742 in costs to the WTC Health Program associated with updating existing Program policies and developing new policies. As explained below, the Program estimates that total costs of the WTC Health Program were $240.5 million in FY 2015 and may range from $265.5 to $388.6 million in FY 2025. Cumulative costs associated with WTC Health Program administration and monitoring and treatment services for all health conditions for fiscal years (FY) 2016 through 2025 are projected to range from $2.9 billion (7% discount rate) to $3.6 billion (3% discount rate).[3]

II. Public Participation

Interested persons or organizations were invited to participate in the August 2016 NPRM by submitting written views, opinions, recommendations, and/or data on any topic related to the proposed rule. All communications received on or before the closing date for comments were fully considered by the Administrator of the WTC Health Program. The August 2016 NPRM as well as public comments received are available in the docket for this rulemaking. Public comments received on the three interim final rules are available in those respective dockets.[4]

Submissions to the August 2016 NPRM docket were received from three commenters, including a labor organization, a joint labor/management trust fund, and the contractor providing care for survivors in the WTC Health Program.

III. Background

This final rule includes the Administrator's response to public comments received on the August 2016 NPRM, as well as public comments received in response to three interim final rules (IFRs). The first IFR was published on July 1, 2011 to establish part 88 and implement the Program, and included all of the original sections establishing eligibility criteria and enrollment processes, health condition certification and treatment requirements, mechanisms to appeal Program decisions, and reimbursement

[1] 81 FR 55086 (Aug. 17, 2016).

[2] These include the July 2011 IFR (establishing part 88 and implementing the Program), 76 FR 38914 (July 1, 2011); the March 2013 IFR (establishing eligibility criteria for Shanksville and Pentagon responders), 78 FR 18855 (Mar. 28, 2013); and the February 2014 IFR (clarifying the definition of ''childhood cancers'' and revising the definition of ''rare cancers''), 79 FR 9100 (Feb. 18, 2014).

[3] Costs for FY 2016–2025 have been evaluated for all health conditions covered by the Program, both those conditions included in the PHS Act at sec. 3312(a)(3) and 3322(b) and those added to the List of WTC-Related Health Conditions in § 88.15, including cancer, new-onset chronic obstructive pulmonary disease, and WTC-related acute traumatic injury.

[4] *See infra* note 9.

(July 2011 IFR).[5] A second IFR was published on March 28, 2013 to establish new eligibility criteria for Pentagon and Shanksville, Pennsylvania responders (March 2013 IFR).[6] A third IFR was published on February 18, 2014 to clarify the definition of ''childhood cancers'' and revise the definition of ''rare cancers,'' resulting in cancers of the brain, the pancreas, and the testes, and invasive cervical cancer becoming eligible for Program coverage (February 2014 IFR).[7] The Administrator addressed some of the public comments submitted on the three IFRs in the August 2016 NPRM; this final rule includes the Administrator's responses to the remainder of public comments on the IFRs.

IV. WTC Health Program Statutory Authority

Title I of the James Zadroga 9/11 Health and Compensation Act of 2010 (Pub. L. 111–347, as amended by Pub. L. 114–113), added Title XXXIII to the Public Health Service Act (PHS Act), establishing the WTC Health Program within HHS. The WTC Health Program provides medical monitoring and treatment benefits to eligible firefighters and related personnel, law enforcement officers, and rescue, recovery, and cleanup workers who responded to the September 11, 2001, terrorist attacks in New York City, at the Pentagon, and in Shanksville, Pennsylvania (responders), and to eligible persons 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 (survivors).

All references to the Administrator of the WTC Health Program (Administrator) in this notice mean the WTC Program Administrator, the Director of the National Institute for Occupational Safety and Health (NIOSH), or his or her designee. Section 3301(j) of the PHS Act authorizes the Administrator to promulgate such regulations as are necessary to administer the WTC Health Program.

V. Summary of Final Rule and Response to Comments

This rule adopts and finalizes all amendments to 42 CFR part 88 promulgated by the July 2011, March 2013, and February 2014 IFRs and proposed in the August 2016 NPRM. Amendments to the regulatory text in part 88 are finalized in accordance with the discussion provided in the August 2016 NPRM[8] and below, responding to public comments received on all four rulemakings. All public comments are available in the dockets for the four respective rulemakings.[9]

Section 88.1 Definitions

The Administrator revised pre-existing definitions and established new definitions for terms commonly used in the WTC Health Program in 42 CFR 88.1.

Comment: One July 2011 IFR commenter asked the Program to amend three definitions. The commenter asked that the definition of ''aggravating'' include any health condition that requires medical treatment ''more intensive than'' would have been required for such a condition in the absence of 9/11 exposure; that ''medically necessary treatment'' include treatment modalities and protocols developed specifically for children; and that ''New York City disaster area'' include 14th Street as the northern boundary.

Administrator's response: The term ''aggravating'' is defined in sec. 3306(1) of the PHS Act and cannot be expanded in the regulatory definition.

The Administrator also declines to amend ''medically necessary treatment'' because the medical treatment protocols developed by the Data Centers already include treatment modalities developed for children. The existing definition is sufficiently broad to include all types of patients treated by physicians affiliated with the Clinical Centers of Excellence (CCEs) or the Nationwide Provider Network (NPN). No changes are made to the regulatory text in response to these comments.

Finally, ''New York City disaster area'' is also defined in the PHS Act, at sec. 3306(7), and cannot be expanded in the regulatory definitions. No change is made to the regulatory text in response to the public comments.

The term ''designated representative'' is revised to clarify that an individual applying for enrollment in the WTC Health Program may designate a representative. A new definition of ''WTC,'' meaning ''World Trade Center,'' is added to this section; all existing definitions beginning with ''World Trade Center'' are revised accordingly to streamline the regulatory text.

Section 88.2 General Provisions

This section establishes the appointment process for an applicant's or WTC Health Program member's designated representative and the parameters of the representative's authority.

Comment: One July 2011 IFR commenter asked that the Program allow a parent or guardian to be the designated representative for a mentally impaired screening- or certified-eligible survivor.

Administrator's response: The Administrator agrees with the comment and has added a new paragraph (a)(7) to address the concern. In addition, paragraph (a)(6) has been revised to clarify that a parent or guardian of a minor applicant, as well as the parent or guardian of a screening-eligible or certified-eligible survivor who is a minor, may act on behalf of the minor.

Comment: One July 2011 IFR commenter asked that the Program offer reimbursement to members in the NPN for whom the cost of travel to the provider is less than 250 miles but nevertheless poses a financial burden, which is a barrier to care.

Administrator's response: PHS Act, sec. 3312(b)(4)(C) allows the Program to provide transportation expenses for medically necessary treatment through the NPN involving ''travel of more than 250 miles.'' The statutory language only authorizes reimbursement of travel expenses where travel exceeds 250 miles. No change is made to the regulatory text in response to this comment.

Section 88.3 Eligibility—Currently Identified Responders

No public comment was received on this section. No revisions are made to this section, although it is included in the regulatory text, below, for completeness.

Section 88.4 Eligibility Criteria—WTC Responders

This section establishes eligibility criteria for individuals who participated in response and recovery activities at the New York City area sites, at the Pentagon site, and at the Shanksville, Pennsylvania site.

Comment: One July 2011 IFR commenter asked the Program to develop eligibility criteria for responders engaged in the cleanup or demolition of buildings at or near Ground Zero, including 130 Liberty Street (Deutsche Bank) and 245 Greenwich Street (Fiterman Hall), which were heavily contaminated with WTC dust. In the case of those buildings

[5] 76 FR 38914 (July 1, 2011).

[6] 78 FR 18855 (Mar. 28, 2013.

[7] 79 FR 9100 (Feb. 18. 2014).

[8] *See* 81 FR 55086 at 55087–96.

[9] *See* July 2011 IFR, docket CDC–2011–0009; March 2013 IFR, docket CDC–2013–0002; February 2014 IFR, docket CDC–2014–0004; and August 2016 NPRM, docket CDC–2016–0072.

and others across Lower Manhattan, cleanup took place years after September 11, 2001 (*e.g.,* cleanup of the Deutsche Bank building began in 2007; Fiterman Hall in 2008). Workers exposed to the re-suspension of WTC dust caused by cleanup activities ''had the potential to become ill from those exposures and should be eligible under modified criteria for monitoring and treatment.''

Administrator's response: Workers who engaged in cleanup or demolition of buildings contaminated by WTC dust outside of the eligibility criteria identified in PHS Act, sec. 3311(a)(2) cannot be included in the eligibility criteria for WTC responders in § 88.4 without promulgating modified eligibility criteria by rulemaking. At this time, the Administrator is not aware of any scientific evidence to support such a rulemaking. No change is made to the regulatory text in response to this comment.

Comment: One March 2013 IFR commenter suggested that the addition of eligibility criteria for Pentagon and Shanksville responders is unnecessary because, the commenter believes, there were no real hazards at the Shanksville, Pennsylvania site, and the Pentagon site was quickly cleaned up.

Administrator's response: The Administrator does not agree with the sentiments expressed by this commenter. The eligibility criteria for Pentagon and Shanksville responders were developed after consideration of a report produced by NIOSH that reviewed published literature and other authoritative sources and consultations with participating responders from both sites.[10] The report summarized the results of environmental sampling at the Pentagon and Shanksville, Pennsylvania sites; estimated the length of time that each of the various responder groups participated in rescue, recovery, demolition, debris cleanup, and other related response activities; and identified the types of exposures potentially experienced by the site responders. Based on the report's findings, the Administrator found it reasonable to establish eligibility criteria for Pentagon and Shanksville responders.[11] No change is made to the regulatory text in response to this comment.

Section 88.5 Application Process—WTC Responders

This section describes the application process for individuals who participated in response and recovery activities at any of the three sites. Language from § 88.6(b), concerning notification of deficient applications, is moved into a new § 88.5(c). The word ''shall'' is replaced with ''must'' throughout the section, and ''WTC Program Administrator'' is replaced with ''WTC Health Program.''

Comment: One July 2011 IFR commenter asked that the Program contact an applicant by telephone to notify the individual of deficiencies in an application or supporting documentation.

Administrator's response: The Program makes every effort to contact applicants to correct any deficiencies in the application and conducts follow-up by telephone, mail, and/or email. No change is made to the regulatory text in response to this comment.

Section 88.6 Enrollment Decision—WTC Responders

This section describes the basis for enrollment and enrollment denial decisions and explains the Program's notification procedures. Language from § 88.6(b), concerning notification of deficient applications, is moved into a new § 88.5(c) where it is better placed. A sentence is added to paragraph (d) to clarify that the 60-day time period for Program enrollment decisions will be tolled during any days in which the applicant is correcting deficiencies, as in § 88.10(a).

Comment: Two July 2011 IFR commenters expressed concerns about the requirement regarding use of the terrorist watch list. Specifically, the commenters asked about information sharing protections and redress procedures, and stated that the terrorist watch list must not be used to harass, jeopardize, and/or deport immigrants.

Administrator's response: The Program is required to screen applicants against the terrorist watch list (*see* PHS Act, secs. 3311(a)(5) and 3321(a)(4)). Program applications as well as the System of Records Notice (SORN) for the WTC Health Program [12] state that information will only be disclosed to the Department of Justice (DOJ) and others for the limited purposes of ascertaining enrollment eligibility and qualification. HHS does not conduct terrorist watch list screening; the Program submits limited information collected from applications to DOJ, and DOJ's Terrorist Screening Center conducts the screening. DOJ is a signatory to the 2007 *Memorandum of Understanding on Terrorist Watchlist Redress Procedures* (MOU).[13] There is no change to the regulatory language in response to these comments.

Comment: One July 2011 IFR commenter asked that the Program notify the applicant of an enrollment decision within 30 calendar days of the Program's receipt of the application.

Administrator's response: The Program is required by statute to respond to applications within 60 calendar days of receipt of the application and makes every effort to respond in less time; average response time is approximately 4 weeks. Applicants can impact the length of the eligibility review process by submitting a complete application. No change is made to the regulatory text in response to this comment.

Section 88.7 Eligibility—Currently-Identified Survivors

No public comment was received on this section. No revisions are made to this section, although it is included in the regulatory text, below, for completeness.

Section 88.8 Eligibility Criteria—WTC Survivors

This section establishes eligibility criteria for individuals who do not meet the eligibility criteria for WTC responders.

Comment: One July 2011 IFR commenter asked that the language in § 88.8(a)(1)(iii), regarding ''extensive exposure,'' be interpreted liberally because ''this population may be least likely to have employment related documents or the ability to obtain them.''

Administrator's response: This eligibility criteria is based on section 3321(a)(1)(B)(iii) of the PHS Act, which requires extensive exposure to WTC dust for this specific population. However, the Program takes an applicant-favorable approach to eligibility criteria. There is no change made to the regulatory text in response to this comment.

Comment: One July 2011 IFR commenter pointed out that the

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[10] Robert McCleery, *Summary of Evidence for Establishing Dates on which Cleanup of the Pentagon and Shanksville, Pennsylvania Sites of the Terrorist-Related Aircraft Crashes of September 11, 2001 Concluded,* Prepared for the Administrator, WTC Health Program, February 8, 2012, *http://www.cdc.gov/niosh/docket/archive/pdfs/NIOSH–248/0248–041312-ShanksvilleResponse.pdf.*

[11] *See generally* 78 FR 18855.

[12] *Occupational Health Epidemiological Studies and EEOICPA Program Records and WTC Health Program Records,* HHS/CDC/NIOSH, Privacy Act System Notice 09–20–0147, *https://www.gpo.gov/fdsys/pkg/FR-2011-06-14/html/2011-14807.htm.*

[13] *See* DOJ press release, *Federal Inter-Agency Partners Sign Government-wide Watchlisting Redress MOU,* October 24, 2007, *https://www.justice.gov/archive/opa/pr/2007/October/ustsc-102407.html.*

regulatory language in § 88.8(a)(1)(iv)(C) implies that the individual must have lived in the New York City disaster area residence from September 11, 2001 through May 31, 2003 but asserts that the Lower Manhattan Development Corporation Residential Grant Program did not begin until August 2002 and participation requirements state that ''renters must have leases commencing on or after June 1, 2001 and on or prior to May 31, 2003. Owners must purchase apartments on or prior to May 31, 2003.'' The commenter requests that the text of the regulation indicate that the individual was in residence for part of that period.

Administrator's response: The Administrator appreciates the comment, however, the language in this section mirrors the eligibility language in PHS Act, sec. 3321(a)(1)(B)(iv). No change is made to the regulatory text in response to this comment.

Comment: Similar to comments made on § 88.4, one July 2011 IFR commenter suggested that the section be amended to include survivors who conducted cleanup or demolition of buildings at or near Ground Zero which were heavily contaminated with WTC dust. In some cases, cleanup took place years after September 11, 2001 and workers were exposed to the re-suspension of WTC dust caused by cleanup activities.

Administrator's response: As discussed above, workers who engaged in cleanup or demolition of buildings contaminated by WTC dust outside of the eligibility criteria identified in PHS Act, sec. 3321(a)(1)(B) cannot be included in the eligibility criteria for WTC survivors in § 88.8 without promulgating modified eligibility criteria by rulemaking. At this time, the Administrator is not aware of any scientific evidence to support such a rulemaking. There is no change made to the regulatory text in response to this comment.

Comment: One July 2011 IFR commenter asked the Program to establish modified eligibility criteria for the ''full cohort of affected children,'' including those who were exposed in utero (mothers who lived or worked in the New York City disaster area); those exposed to WTC dust brought home by responder parents; those born after September 11, 2001, to responder or survivor parents and suffering mental health impacts due to the parents' WTC-related mental health condition; and those born to exposed responders or survivors if evidence of environmental reproductive health impacts is available.

Administrator's response: Individuals who were children at the time of the terrorist attack in New York City or its aftermath may be enrolled WTC survivors if they meet the eligibility criteria for screening-eligible survivors. Children who were exposed in-utero, who experienced 'take-home' exposures, who suffer from mental health conditions resulting from their parents' WTC-related mental health conditions, and who suffer from health effects resulting from parental exposures were not identified in the PHS Act's eligibility criteria for survivors. To the extent that language could be added to the eligibility criteria to permit some or all such cohorts of children to be enrolled as WTC survivors under § 88.8, the Administrator would be required to promulgate modified eligibility criteria. The Administrator is not contemplating such modified criteria at this time. Developmental disorders cannot be added to the List without rulemaking supported by scientific or medical evidence, pursuant to the procedures established in § 88.16 for adding new WTC-related health conditions to the List. There is no change made to the regulatory text in response to this comment.

Section 88.9 Application Process—WTC Survivors

This section describes the application process for individuals in the New York City disaster area who did not participate in response and recovery activities.

Comment: One July 2011 IFR commenter suggested that the application process should allow statements written under penalty of perjury from fellow workers, neighbors, and fellow students or teachers, and allow a sworn statement of facts by the applicant before a notary if no other documentation is available.

Administrator's response: The Program accepts a wide range of documentation to verify an applicant's status. Statements from co-workers and others used as evidence of an individual's presence in the New York City disaster area are contemplated by § 88.9(a)(1), which has been slightly revised for clarity by replacing a comma with a semi-colon, to state that ''[d]ocumentation may include but is not limited to: Proof of residence, such as a lease or utility bill; attendance roster at a school or daycare; or pay stub, other employment documentation, or written statement, under penalty of perjury, by an employer indicating employment location during the relevant time period; or similar documentation.'' ''Similar documentation'' could include written statements from co-workers and fellow students or neighbors. The types of written statements suggested by the commenter are among those that are routinely accepted by the Program. This section is not changed in response to this comment.

A new paragraph (a)(3), comprising language concerning the notification of deficiencies in an application, is moved from § 88.10(a). ''Shall'' is replaced with ''must'' throughout the section, and ''WTC Program Administrator'' is replaced with ''WTC Health Program'' in paragraph (b).

Section 88.10 Enrollment Decision—Screening-Eligible Survivors

This section describes the basis for enrollment as a screening-eligible survivor and enrollment denial decisions, and explains the Program's notification procedures.

Comment: One July 2011 IFR comment asked that the Program shorten the time frame for notifying applicants of screening-eligible status from 60 calendar days to no more than 30 days from NIOSH's receipt of the application. The commenter also asked that the Program use telephone outreach to follow up with applicants when documentation is absent or deficient.

Administrator's response: The Program is required by statute to respond to applications within 60 calendar days of receipt of the application and makes every effort to respond in less time; the average response time is approximately 4 weeks. Applicants can impact the length of the eligibility review process by submitting a complete application. The Program makes every effort to contact applicants to correct any deficiencies in the application, and conducts follow-up by telephone, mail, and/or email. This section is not changed in response to this comment.

Language in paragraph (a) concerning notification of deficiencies in an application is moved to § 88.9(a)(3).

Section 88.11 Initial Health Evaluation for Screening-Eligible Survivors

This section describes the initial health evaluation process for screening-eligible survivors.

Comment: One August 2016 NPRM commenter shared a concern that the language may permit survivors to obtain an initial health evaluation and treatment from any CCE.

Administrator's response: The language in this section is essentially unchanged from the original language of § 88.10(d)(1), which reads ''A WTC Health Program Clinical Center of Excellence or a member of the nationwide network provider [sic] will provide the screening-eligible survivor

an initial health evaluation to determine if the individual has a WTC-related health condition. . . .'' Although the names are changed to acronyms for the sake of brevity and clarity, the Administrator's intent is unchanged and the language in this section continues to mean that an initial health evaluation will be provided by the Program. No change is made to the regulatory text in response to this comment.

Section 88.12 Enrollment Decision—Certified-Eligible Survivors

This section describes the basis for enrollment as a certified-eligible survivor and enrollment denial decisions, and explains the Program's notification procedures.

Comment: One July 2011 IFR commenter asked that the Program specify a time frame for notification of certified-eligible status, no more than 30 days from receipt by the Program of a physician determination.

Administrator's response: Although the WTC Health Program makes every effort to provide certification decisions in a timely manner, the establishment of a deadline for notification of certified-eligible status or a deadline for the Program's decision whether to certify a WTC-related health condition (pursuant to § 88.18) could impede the Program's ability to conduct a thorough analysis of the member's health condition and exposure history. This could especially be the case where the Administrator has added a health condition to the List but the Program has not yet established implementation guidelines. Moreover, a deadline may create confusion if stakeholders believe that a certification request not granted or denied within the period is deemed to be either granted or denied. No change is made to the regulatory text in response to this comment.

Section 88.13 Disenrollment

This section clarifies the process for disenrolling a member from the WTC Health Program.

Comment: One August 2016 NPRM commenter agreed that the disenrollment (and decertification, pursuant to § 88.18) provisions are important to ''ensure program integrity.''

Comment: One August 2016 NPRM commenter stated that there is no language included in this section to address grandfathered members (those enrolled pursuant to §§ 88.3 and 88.7) and stated the opinion that such members should be ''immune from disenrollment.''

Administrator's response: It is important to the integrity of the WTC Health Program to maintain the authority to disenroll any member if evidence indicates that the enrollment was based on incorrect or fraudulent information. The provisions in paragraph (a)(1) only apply to members enrolled under the eligibility criteria in §§ 88.4 or 88.8 (which do not include grandfathered members) and permit disenrollment where there is insufficient proof of meeting the eligibility criteria required by those sections. The provisions in paragraph (a)(2) apply to all members (including grandfathered members) and permit disenrollment where the enrollment was based on incorrect or fraudulent information. No change to the regulatory text is made in response to this comment.

Section 88.14 Appeal of Enrollment or Disenrollment Decision

This section establishes procedures for the appeal of a WTC Health Program decision to deny enrollment of an applicant or disenroll a Program member.

Comment: One August 2016 NPRM commenter agreed that the proposed extension of the deadline for filing an appeal, from 60 to 90 days, is an improvement but is still too short a time frame for obtaining necessary records. According to the commenter, the deadline for filing an appeal should be extended to at least 4 months (120 days).

Administrator's response: The Administrator agrees and extends the deadline for appeal submission to 120 days. The regulatory text in paragraph (b)(1) is amended accordingly.

Comment: One August 2016 NPRM commenter requested that the Program allow applicants and members to make an oral statement during the appeal, as is allowed in § 88.21.

Administrator's response: Although applicants and members are allowed to submit new information in support of Program enrollment denial or disenrollment appeals, the Administrator has determined that, in the context of enrollment and disenrollment appeals, the administrative burden associated with oral statements outweighs the benefits. The factual bases and documentation requirements for enrollment and disenrollment decisions can be more efficiently considered through a paper-based review. No changes to the regulatory text are made in response to this comment.

Comment: One July 2011 IFR commenter asked that the Program indicate from where the Federal Official will be drawn and what expertise that individual may have with the monitoring and treatment of WTC-related health conditions.

Administrator's response: The Federal Officials appointed to hear appeals are chosen from Centers, Institutes, or Offices within the Centers for Disease Control and Prevention. They have relevant knowledge but do not work within the WTC Health Program. No change is made to the regulatory text in response to this comment.

Comment: One August 2016 NPRM commenter stated that the NPRM provides no justification for having the Administrator make final decisions on appeals and appears unfair to the claimant making the appeal.

Administrator's response: To clarify the processes by which certain decisions are made within the Program, language throughout Part 88 is changed to indicate that some decisions are made directly by the Administrator, while he has designated WTC Health Program staff to make other Program decisions, such as certifications. In the case of enrollment or disenrollment appeals, the Administrator is reviewing decisions made by Program staff. The Program finds it important to shift the final appeal decision-making authority to the Administrator because the final decision on eligibility appeals (and the certification and treatment authorization appeals in § 88.21) should be made by the Administrator, who has a thorough understanding of the WTC cohorts and matters related to eligibility and exposures and is best able to apply the laws, policies, and procedures governing the WTC Health Program. No change is made to the regulatory text in response to this comment.

Comment: One August 2016 NPRM commenter expressed concern that some appeals may take longer than the average 45 days, and recommended a final decision deadline of 120 days, with a contingency for justifying longer delays based on specific circumstances.

Administrator's response: As discussed above, the establishment of a deadline for notification of a decision such as a final appeal decision could impede the Program's ability to conduct a thorough review of the prospective member's application and documentation of eligibility. The section is not changed in response to this comment.

Section 88.15 List of WTC-Related Health Conditions

This section contains the List previously placed in § 88.1 Definitions. No public comments were received on this section and no substantive revisions are made to the text. Some punctuation

is corrected and the names of two types of cancer are pluralized.

Section 88.16 Addition of Health Conditions to the List of WTC-Related Health Conditions

This section establishes the process by which interested parties may petition the Administrator to add a health condition to the List. No public comments were received on this section and no revisions are made to the text.

Section 88.17 Physician's Determination of WTC-Related Health Conditions

This section establishes the basis for a CCE or NPN-affiliated physician's determination that a member has a health condition that can be certified. No public comments were received on this section and no revisions are made to the text.

Section 88.18 Certification

This section establishes that the WTC Health Program will promptly assess physician determinations submitted by a CCE or NPN-affiliated physician and, if the Program concurs with the determination and decides that a health condition is a WTC-related health condition or a health condition medically associated with a WTC-related health condition, will certify the condition as eligible for coverage under the WTC Health Program.

Comment: One August 2016 NPRM commenter recommended the establishment of a deadline for Program decisions concerning the certification of WTC-related health conditions.

Administrator's response: As discussed above with regard to certified-eligible status notification, the establishment of a deadline for a final appeal decision could impede the Program's ability to conduct a thorough analysis of the member's health condition and exposure history. Certification decisions may be particularly time-consuming to resolve if a condition has been added to the List but the Program has not yet established implementation guidelines. Moreover, a deadline may create confusion if stakeholders believe that a certification request not granted or denied within the period is deemed granted. The section is not changed in response to this comment.

Comment: Four July 2011 IFR commenters stated their belief that PHS Act, sec. 3312(b)(2) permits certification of individual primary conditions determined to be WTC-related that are not on the List and the regulatory text should be revised accordingly.

Administrator's response: The Administrator has reviewed PHS Act, sec. 3312(b)(2)(A)–(B) and finds that the meaning of the text ''determination based on medically associated WTC-related health conditions'' and ''if a . . . WTC responder has a health condition described in subsection (a)(1)(A) that is not in the list in subsection (a)(3) but which is medically associated with a WTC-related health condition . . .'' is plain—the medically associated health condition must be related to a health condition listed in sec. 3312(a)(3). The language of the enacted statute does not permit physicians to recommend a health condition for certification that is not causally related to a listed WTC-related health condition. The Administrator finds the language of the Act is clear, and the legislative history is consistent with the Administrator's interpretation. While the language in the introduced bill did give physicians the authority requested by commenters, subsequent amendments to the bill changed the language and the intent of the enacted Act is different from that which was introduced. The regulatory text in this section is not changed in response to these comments.

Section 88.19 Decertification

This section clarifies the process for decertification of a WTC-related health condition or health condition medically associated with a WTC-related health condition.

Comment: One August 2016 NPRM commenter asked that language be added to this section ''to clarify that a member whose health condition has been decertified retains the right to seek recertification'' in some circumstances. For example, where new information about the member's exposure or evidence of association between 9/11 exposure and the decertified condition was previously not considered by the Program.

Administrator's response: In addition to a right to appeal a WTC Health Program decision to decertify a certified WTC-related health condition, a member who believes the decision was made in error may ask the CCE or NPN physician to resubmit the certification request; the physician may include new information to support the case for certification. The Administrator finds it unnecessary to revise the regulatory text in § 88.19(b) and may address this matter administratively.

Comment: Similar to a comment on § 88.13, one August 2016 NPRM commenter expressed concern that there is no language in this section addressing grandfathered members (those enrolled pursuant to §§ 88.3 and 88.7), who should be ''immune from decertification.''

Administrator's response: It is important to the integrity of WTC Health Program that any health condition may be decertified if the available evidence indicates that the certification is based on inadequate exposure or was otherwise certified in error. This includes grandfathered Program members. The section is not changed in response to this comment.

Section 88.20 Authorization of Treatment

This section describes the provision of medically necessary treatment.

Comment: One July 2011 IFR commenter asked the Program to use a variety of mental health modalities to treat mental health conditions. The commenter recommended that such treatment must be culturally sensitive and allow patients to be treated by private, community-based mental health professionals.

Administrator's response: The Program allows a variety of treatment modalities to address various diagnoses, especially posttraumatic stress disorder (PTSD) and other mental health conditions. Many of the practitioners affiliated with CCEs or the NPN have community-based mental health practices where they see Program members and should be able to render culturally-sensitive care. No change is made to the regulatory text in response to this comment.

Comment: One August 2016 NPRM commenter recommended the addition of flexibility to the regulatory text in paragraph (b) to ''accommodate complex care situations'' like cancer treatment or organ transplant in medical protocols developed by the Data Centers.

Administrator's response: The Program finds that the regulatory text in paragraph (b) is sufficiently broad to allow for the development of medical protocols of any appropriate complexity. No change is made to the regulatory text in response to this comment.

Comment: One August 2016 NPRM commenter expressed concern that a strict interpretation of the language in paragraph (c) requires the Administrator personally to authorize treatment pending certification before any treatment is provided (except for emergency care). According to the commenter, ''[g]iven the growing length of time between submission of certification requests and the receipt of decisions, a strict interpretation of this language would be detrimental to member wellbeing.''

Administrator's response: The Administrator agrees with the commenter and changes the regulatory text to replace ''Administrator of the WTC Health Program'' with ''WTC Health Program.''

Section 88.21 Appeal of Certification, Decertification, or Treatment Authorization Decision

This section establishes that a WTC Health Program member or the designated representative of such a member may appeal the Program's decision to deny certification of a health condition as WTC-related or medically associated with a WTC-related health condition, decertify a WTC-related health condition or medically associated health condition, or deny authorization of treatment for a certified health condition.

In response to public comment on § 88.14, concerning appeal of enrollment decisions, the Administrator agreed to extend enrollment appeal submission deadlines to 120 days. To maintain parity with that process, the deadline for the submission of appeals of certification, decertification, and treatment authorization decisions is also extended to 120 calendar days.

Section 88.24 Coordination of Benefits and Recoupment

This section addresses the matter of coordination of benefits, including recoupment from workers' compensation settlements.

Comment: One August 2016 NPRM commenter stated that the language in paragraph (e) ''does not address the growing use of restricted networks by health insurers which can make it very difficult for a participant to find a provider in their network for the complicated specialty treatment required for their medical condition. Would they be forced to go to an in-network provider which is not in the WTC program?''

Administrator's response: The Program is aware of the concern raised by the commenter, especially in the cancer care context. In very rare circumstances, the Program may allow for members who require ''specialty treatment,'' such as cancer care and transplants, to receive care from providers outside of their insurance networks. Otherwise, the CCE or NPN will coordinate care through providers within the members' insurance networks. The Program may provide more specific administrative guidance on this issue, as necessary. No changes are made to the regulatory text in response to this comment.

General Comments

Comment: One July 2011 IFR commenter asked that the Part 88 regulations address outreach, and include radio, TV, newspaper advertising, community meetings; fund effective, culturally competent outreach; partnership with community-based social service providers; re-fund de-funded outreach programs; and offer in-person assistance for completing application for non-English speakers and the mentally impaired.

Administrator's response: Section 3303 of the PHS Act authorizes the Administrator to conduct the following outreach and education activities: establish a public Web site with information about the Program; hold meetings with potentially eligible populations; develop and disseminate outreach and education materials about the Program; and establish telephone information services. The Act further specifies that these activities will be conducted in a manner intended to reach all affected populations and include materials for culturally and linguistically diverse populations. The WTC Health Program meets these requirements by funding outreach and education activities (including culturally appropriate and diverse programs) to be conducted by the CCEs as well as community and labor groups. These groups are able to provide face-to-face enrollment assistance. Furthermore, the WTC Health Program has a New York Field Coordinator who also conducts outreach and provides application assistance. No change is made to Part 88 in response to this comment.

VI. Regulatory Assessment Requirements

A. Executive Order 12866 and Executive Order 13563

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

This final rule has been determined to be a ''significant regulatory action'' under section 3(f) of Executive Order 12866.

This final rule includes changes proposed in the August 2016 NPRM and final revisions made in response to public comment and to clarify the Program's intent; it also finalizes three IFRs issued in July 2011, March 2013, and February 2014, respectively. This final rule includes revisions to §§ 88.14 and 88.21 (enrollment and medical appeals) and § 88.16 (addition of health conditions) that will result in necessary updates to several existing WTC Health Program policies; novel regulatory provisions in § 88.13 (disenrollment), § 88.19 (decertification), and § 88.23 (reimbursement appeals) will require the revision of existing policies or development of new policies. The Administrator estimates that amending the existing *Policy and Procedures for Handling Submissions and Petitions to Add a Health Condition to the List of WTC-Related Health Conditions* and the Web page containing frequently asked questions regarding appeals, and developing new disenrollment, decertification, and reimbursement appeal policies will require approximately 568 hours of staff time. The average WTC Health Program staff member responsible for updating these policies is a GS 14–5, earning $125,221 annually, pursuant to OPM's Salary Table 2016–DCB (Washington DC), or $75.25 hourly, adjusted to include benefits. Accordingly, the revisions to Part 88 finalized in this final rule are expected to cost the WTC Health Program approximately $42,742 and that amount is included in the administrative costs discussed below. This rulemaking is not expected to change the number of applicants or Program members; the Administrator has not identified any other potential impacts associated with this final rule.

In addition to the costs associated with the August 2016 NPRM, this rule also updates the regulatory impact analyses for the July 2011, March 2013, and February 2014 IFRs, which are all finalized in this action. In the original cost analysis conducted for the Part 88 WTC Health Program regulations,[14] HHS estimated the aggregate cost of medical monitoring and treatment to be provided and administrative expenses associated with implementing the WTC Health Program for a period of 5 years. HHS developed those estimates for the health conditions included for Program coverage in sections 3312 and 3321 of the PHS Act, using data from the health programs that were in place for WTC responders and survivors prior to the establishment of the WTC Health Program. Since that original July 2011 rulemaking and cost analysis, the WTC Health Program has expanded the list of

[14] July 2011 IFR, 76 FR 38914 at 38921.

health conditions eligible to receive coverage in the Program through regulations, as permitted by section 3312(a)(6) of the PHS Act; in addition to the original statutory conditions of specified aerodigestive disorders, mental health conditions, and, for certain responders, musculoskeletal disorders, the WTC Health Program now also provides coverage for numerous types of cancer, new-onset chronic obstructive pulmonary disease (COPD), and WTC-related acute traumatic injury. Data used to update this regulatory impact analysis include data derived from WTC Health Program health services claims data as well as administrative and infrastructure cost data collected between FY 2012, the first full year for which data are available, and the end of FY 2015, the last full year for which data are available.

The Program estimates that total cumulative costs associated with the WTC Health Program over the next 10 years will be $4,223,209,653, undiscounted (from $2,874,481,628 at 7 percent discount rate to $3,553,658,528 at 3 percent discount rate). The cost of the rule in FY 2025 is estimated to be $522,307,538 (present value between $265,514,667 and $388,645,860, at 7 percent and 3 percent discounts rates, respectively).[15]

TABLE 1—SUMMARY OF WTC HEALTH PROGRAM COSTS *

	FY 2015	FY 2025	Cumulative FY 2016–2025
Total Costs			
Undiscounted	$240,571,579	$522,307,537	$4,223,209,653
7% discount rate		265,514,667	2,874,481,628
3% discount rate		388,645,860	3,553,658,528
Program Administration			
Undiscounted	96,414,964	134,485,132	1,194,966,221
7% discount rate		68,365,421	825,867,165
3% discount rate		100,069,568	1,012,191,361
Medical Monitoring and Treatment			
Initial health evaluation (survivors only):			
Undiscounted	887,401	2,387,362	18,641,297
7% discount rate		1,213,614	12,610,885
3% discount rate		1,776,421	15,644,794
Annual medical monitoring:			
Undiscounted	17,583,046	47,303,408	369,360,390
7% discount rate		24,046,654	249,873,253
3% discount rate		35,198,178	309,987,399
Diagnostic evaluation/cancer screening:			
Undiscounted	13,131,585	35,327,709	275,850,234
7% discount rate		17,958,816	186,613,392
3% discount rate		26,287,133	231,508,572
Medical Treatment:			
Undiscounted	112,554,583	302,803,927	2,364,391,511
7% discount rate		153,930,162	1,599,516,932
3% discount rate		225,314,560	1,984,326,403
All Medical Monitoring and Treatment			
Undiscounted	144,156,615	387,822,405	3,028,243,432
7% discount rate		197,149,246	2,048,614,463
3% discount rate		288,576,292	2,541,467,168
Prior Rulemaking Cost Estimates			
Cancer, September 2012 final rule (non-add)		Estimated cost per year FY 2013–2016 ($mil) 12.5–33.3.	
Pentagon/Shanksville responders, March 2013 IFR (non-add)		Estimated cost per year FY 2013–2016 ($mil) .9–3.2.	
Prostate cancer, September 2013 final rule (non-add)		Estimated cost per year FY 2014–2016 ($mil) 3.5–7.0.	
Brain, invasive cervical pancreatic, testicular cancers, February 2014 IFR (non-add)		Estimated cost per year FY 2014–2016 ($mil) 2.2–5.0.	
COPD and acute traumatic injury, July 2016 final rule (non-add)		Estimated cost per year FY 2016–2019 ($mil) 4.6–5.7.	

* Due to rounding, some totals may not correspond with the sum of the separate figures.

[15] These estimates represent only a 60 percent increase over the cost estimates provided in the July 2011 IFR, where the Program found that costs in 2015 could range from $106,800,000 to $151,000,000. That estimate was based not on WTC Health Program experience, but on health programs that pre-dated the current WTC Health Program. The estimate in the July 2011 IFR was carried out until only FY 2015; the current analysis projects Program costs through FY 2025 based on WTC Health Program experience to date.

Enrollment

As of the end of FY 2015, WTC Health Program membership included 64,008 WTC responders and 9,144 screening- and certified-eligible survivors. Based on enrollment numbers since FY 2012, the first full year for which data are available, responders (including Pentagon and Shanksville responders) enroll at an approximate rate of 2,087 per year, screening- and certified-eligible survivors at an approximate rate of 1,077 per year. Table 2 displays the past annual enrollment of members, the projected enrollment over the 10 years between FY 2016 and FY 2025, and the projected total number of members by FY 2025.[16]

TABLE 2—WTC HEALTH PROGRAM ANNUAL ENROLLMENT

	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016–2025	Total members by 2025
WTC responders	886	1,539	3,096	2,205	20,873	84,545
Screening- and certified-eligible survivors	1,017	736	1,451	1,170	10,770	19,809
Total	1,903	2,275	4,547	3,375	31,643	104,354

Administrative Costs

The annual cost to the WTC Health Program of conducting administrative functions was approximately $96,414,964 in FY 2015. Given the aggregate rate of enrollment of WTC responders and screening- and certified-eligible survivors, a rise in operations costs by 1.7 percent and a rise in infrastructure costs of 3.3 percent, annual administrative costs for FY 2025 are expected to be $134,485,132. Such costs include program management, enrollment, certification of health conditions, pre-authorization of medical care, payment services, administration of appeals, education and outreach, administration of the advisory and steering committees, and infrastructure costs for the CCEs/NPN.

Infrastructure costs for the CCEs/NPN include the retention of participants, case management, medical review, benefits counseling, quality management, data transfer, interpreter services, and assisting with the development of treatment protocols.

TABLE 3—WTC HEALTH PROGRAM ADMINISTRATIVE COSTS

[Undiscounted]

	FY 2015	FY 2025
Administrative costs (not including CCE/NPN infrastructure—see below)	$39,672,004	$57,193,270
CCE/NPN infrastructure cost	56,742,690	77,291,862
Total	96,414,694	134,485,132

Costs of Medical Monitoring and Treatment

In FY 2015, the total cost to the WTC Health Program for medical monitoring and treatment was $144,156,615, and the breakdown by type of service is shown in Table 1. Initial health evaluations are for WTC screening-eligible survivors only. Diagnostic evaluation and cancer screening is for WTC screening- and certified-eligible survivors and WTC responders. The other two categories of services are for WTC certified-eligible survivors and WTC responders. These costs are based on claims paid during FY 2015. The FY 2015 costs do not include costs associated with monitoring and treatment of new-onset COPD and WTC-related acute traumatic injury because the rulemaking adding those conditions to the List was not completed until July 2016.[17]

For FY 2025, the WTC Health Program estimated the total cost for all health care service categories based on linear cost projections from prior fiscal years, with an adjustment (increase) to account conservatively for statistical uncertainty in the estimate. Also included in the estimate are increases for the treatment and monitoring of new-onset COPD and WTC-related acute traumatic injury, added to the List in July 2016. The FY 2025 total for all health care service categories is $387,822,406. This estimate accounts for an increase in enrollment, more members receiving health care benefits, higher-cost care related to cancer and complications of other illnesses, and general medical care cost increases. In order to determine the breakout by health care service category for FY 2025, the WTC Health Program calculated the percentage of the total cost in FY 2015 for each category and applied those percentages to the total estimate for FY 2025.

Examination of Benefits

Through FY 2015, the last full year for which Program data are available, 35,523 members (49 percent) have been certified for at least one WTC-related health condition. The number of certifications of WTC-related health conditions identified in the categories of health conditions included in the List of WTC-Related Health Conditions is in Table 4, below. Based on the projected FY 2025 enrollment number of 104,354 and an increase of 3 percent annually of the number of members who are estimated to be certified, there would be 158,415 certifications for 68,103 Program members in FY 2025.

[16] These enrollment numbers do not include grandfathered members, the majority of whom were automatically enrolled in the Program in July 2011.

[17] 81 FR 43510 (July 5, 2016).

TABLE 4—NUMBER OF CERTIFIED WTC-RELATED HEALTH CONDITIONS AMONG WTC HEALTH PROGRAM MEMBERS

Health condition category	FY 2015	FY 2025
Aerodigestive disorders	58,782	112,694
Mental health conditions	18,868	36,173
Musculoskeletal disorders	535	1,026
Cancers	4,445	8,522
Total certifications	82,630	158,415

An evaluation of the health and quality of life improvements associated with medical treatment of several of the most commonly-certified health conditions is based on the prevalence of certified WTC-related health conditions. Quality-adjusted life year (QALY) is a common metric of expected treatment effectiveness for the health conditions evaluated. For the purpose of this evaluation, the Administrator assumes that each health condition will continue to be represented among new Program members at the same rate at which it occurs in current members. The health benefits provided by the WTC Health Program are compared with the effect of no Program at all.

The Administrator assumes that WTC Health Program members receive the best care available, as CCE and NPN providers are experts in treating the types of health conditions on the List eligible for certification. In order to compare the benefits provided by the WTC Health Program to a scenario with no WTC Health Program, the Administrator further assumes that the 9/11-exposed population of responders and survivors would instead receive some but not optimal treatment for their health conditions. Accordingly, the estimated benefits (QALYs) represent the incremental improvement in health that WTC Health Program members can expect from receiving the optimal treatment provided by the CCEs and NPN versus standard treatments that are commonly received outside of the Program.

Below are summarized QALY estimates for morbidity improvements for aero-digestive conditions, PTSD and depression, and cancer.[18]

Aerodigestive Disorders

- Gastroesophageal Reflux Disorder (GERD)

In the July 2011 IFR, an estimated 0.012 QALYs were gained per year per patient under treatment for GERD in the Program compared with patients treated outside the Program. Multiplying the WTC Health Program's GERD population for each year during FY 2016–2025 by 0.012 results in 3,311 total undiscounted QALYs gained. Discounting future health benefits at 3 and 7 percent results in 2,781 and 2,244 total QALYs gained, respectively.

- Chronic Rhinosinusitis and other Upper Respiratory Diseases

In the July 2011 IFR, an estimated 0.0145 QALYs were gained per year per patient under treatment for chronic rhinosinusitis and other upper respiratory diseases in the Program compared with patients treated outside the Program. Assuming the same gain is achieved for patients treated for other upper respiratory diseases, treating patients for all upper respiratory diseases would result in 4,877 total undiscounted QALYs gained. Discounting future health benefits at 3 and 7 percent results in 4,095 and 3,304 total QALYs gained, respectively.

- Asthma

In the July 2011 IFR, an estimated 0.029 QALYs were gained per year per patient under treatment for asthma in the Program resulting in 6,002 total undiscounted QALYs gained. Discounting future benefits at a rate of 3 percent and 7 percent results in 5,040 and 4,066 total QALYs, respectively.

- Chronic Obstructive Pulmonary Disease (COPD)[19]

In the July 2011 IFR, an estimated 0.077 QALYs were gained per year per patient under treatment in the program for WTC-exacerbated COPD in the Program resulting in 3,320 total undiscounted QALYs gained. Discounting future health benefits at 3 and 7 percent results in 2,788 and 2,249 total QALYs gained, respectively.

- Reactive Airways Dysfunction Syndrome (RADS) and other Aerodigestive Conditions

In the July 2011 IFR, an estimated medical treatment similar to that for asthma was discussed for patients suffering from RADS. Assuming that treating one patient results in 0.029 QALYs gained and that treating all other aerodigestive conditions not examined above would also result in 0.029 QALYs gained would result in a total of 4,877 undiscounted QALYs gained. Discounting future health benefits at 3 and 7 percent, results in 4,094 and 3,204 total QALYs gained, respectively.

Posttraumatic Stress Disorder (PTSD) and Depression

In the July 2011 IFR, an estimated 0.013 QALYs were gained per year per patient under treatment for PTSD and depression in the Program resulting in a total of 3,598 undiscounted QALYs gained. Discounting future health benefits at 3 and 7 percent results in 3,022 and 2,438 total QALYs gained, respectively.

Cancer

It was assumed that all patients in FY 2016–2025 will live at a health-related quality of life level similar overall to that reported in Cutler and Richardson[20] and Tengs and Wallace[21] for patients with cancer. A QALY for a person living with cancer, without specifying treatment, stage of disease, or other specifics is approximately 0.7, with 1 representing perfect health and 0 death. For comparison, Sullivan and Ghushchyan[22] estimated the health-related quality of life for the age group 50–69 in the general U.S. population at 0.827.

[18] Estimates for mental disorders other than PTSD and depression and for musculoskeletal disorders are not provided because these conditions only account for approximately 9 percent of the total certifications; estimates for WTC-related acute traumatic injuries are not included because the FY 2015 data used to conduct this analysis pre-dates the July 2016 rulemaking that added WTC-related acute traumatic injuries to the List.

[19] Data used to develop QALYs for COPD were derived from FY 2015 Program data regarding WTC-exacerbated COPD; estimates for new-onset COPD are not included because the FY 2015 data pre-dates the addition of new-onset COPD to the List in the July 2016 rulemaking.

[20] David Cutler and Elizabeth Richardson, *Your Money and Your Life: The Value of Health and What Affects It,* in *Frontiers in Health Policy Research, vol. 2,* 99–132 (National Bureau of Economic Research, 1999).

[21] Tammy Tengs and Amy Wallace, *One-Thousand Health-Related Quality of Life Estimates,* Med Care 2000;38(6):583–637.

[22] Patrick Sullivan and Vahram Ghushchyan, *Preference-Based EQ–5D Index Scores for Chronic Conditions in the United States,* Med Decis Making 2006;26:410–420.

Using the expected number of prevalent cancer cases for FY 2016–2025 and published information in Tengs and Wallace on the health-related quality of life of cancer patients who respond to treatment for their cancer, a rough estimate of 0.06 for the increase in patients' quality of life was estimated for cancers treated in the WTC Health Program compared to those not treated in the Program.[23] Using the prevalence of cancers and an assumed difference in health-related quality of life of 0.06 among patients treated in the Program and those not treated in the Program for the years FY 2016–2025 results in a total of 3,913 undiscounted QALYs gained. Discounting future benefits at 3 percent and 7 percent, results in 3,285 and 2,651 total QALYs gained, respectively.

In summary, available information indicates the WTC Health Program is likely to provide substantial improvements in health to responders and survivors. The QALY estimates discussed above and summarized and annualized in Table 5 below are illustrative of these benefits.

TABLE 5—POTENTIAL QALYS GAINED FROM THE WTC HEALTH PROGRAM TREATMENT OF SELECT WTC-RELATED HEALTH CONDITIONS: FY 2016–2025 SUMMARY

Health condition	Total undiscounted QALYs gained by treatment	Present value of QALYs gained by treatment discounted at 7%	Present value of QALYs gained by treatment discounted at 3%
Aerodigestive disorders	17,510	11,863	14,704
PTSD & Depression	3,598	2,438	3,022
Cancers	3,913	2,651	3,285
Total	25,021	16,952	21,011
Annualized	2,502	2,414	2,463

The cost analysis above is subject to a number of limitations, some but not all of which have been identified by the Program. The enrollment, administrative, and medical monitoring and treatment cost estimates are based on historical cost experience from the first full year of the WTC Health Program (FY 2012) to the end of FY 2015 and do not anticipate the costs of WTC-related health conditions added to the List in the future. The annual rate of increase takes into account the growth of the Program's membership based on enrollment data from the start of the Program to present and does not consider natural population mortality and mortality due to the WTC-related health conditions. The medical monitoring and treatment cost estimates are based on a combination of linear regression analysis of aggregate medical costs and adjustments for factors described above.

The Program has also identified some, but not all, limitations in deriving the health benefits estimate. Some new Program members, if they have not received treatment for a certified WTC-related health condition prior to enrollment, may present in worse health and may benefit less from medical treatment than members who received more timely treatment in the Program. Furthermore, many Program members may have more than one concurrent certified WTC-related health condition for which they are receiving treatment in the Program, which can impact the effectiveness of medical treatment for any given condition.

This rule does not interfere with State, local, or Tribal governments in the exercise of their governmental functions.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.,* requires each agency to consider the potential impact of its regulations on small entities including small businesses, small governmental units, and small not-for-profit organizations. The Administrator certifies that this proposed rule has ''no significant economic impact upon a substantial number of small entities'' within the meaning of the RFA.

C. Paperwork Reduction Act

The Paperwork Reduction Act, 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. This final action continues to impose the same information collection requirements as under the July 2011, March 2013, and February 2014 IFRs, including the submission of the following forms and other information listed in the table below.

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. September 30, 2018). HHS has determined that substantive changes are needed to the information collection already approved by OMB. Accordingly, HHS has published a notice of the proposed changes to the existing approved information collection and invites comment from the public during the 60-day comment period. The 60-day notice, published in the **Federal Register** on October 24, 2016, is open for comment through December 23, 2016 (*see* 81 FR 73108); the 60-day notice will be followed by a 30-day notice, after which the revised information collection request will be finalized and approved by OMB. Revisions to the approved information collection include the following:

- *Disenrollment Letter and Appeal Notification—Eligibility:* Of the over 70,000 Program members, we expect that 0.014 percent (10) will be subsequently disenrolled from the Program. Of those, we expect that 30 percent (3) will appeal the disenrollment decisions. We estimate that the appeal requests will take no more than 0.5 hours per respondent. The annual burden estimate is 1.5 hours.
- *Decertification Letter and Appeal Notification—Health Condition:* Of the projected 51,472 enrollees who have at least

[23] Tengs and Wallace, *supra* note 15, reports ranges of differences in QALYs according to different treatments for ovarian cancer patients and whether these patients responded to these treatments. The ranges of these differences varied from 0.06 to 0.17. We used the low end of the range as a conservative estimate. We are not aware of data available with which to estimate the possible effect more reliably.

one health condition certification, it is estimated that 0.02 percent (10) will be decertified, and 50 percent (5) of those will appeal a decertification. We estimate that the appeal request will take no more than 0.5 hours per respondent and providing additional information and/or an oral statement will take no more than 1 hour per respondent. The annual burden estimate is 7.5 hours.

- *Denial Letter and Appeal Notification—Health Condition Certification:* This information collection, including the submission of appeal requests, is currently approved by OMB for 60 respondents (0.5 hours per respondent) and is expanded by this final rule to include the provision of new information and/or an oral statement. We do not expect the OMB-approved estimated number of respondents to change. We estimate that the additional burden will be no more than 1 hour per respondent. The total burden estimate (1.5 hours) includes both 0.5 hours per respondent for the submission of an appeal request (currently approved by OMB) as well as 1 hour per respondent for new information and/or an oral statement. The annual burden estimate is 90 hours.
- *Denial Letter and Appeal Notification—Treatment Authorization:* This information collection, including the submission of appeal requests, is currently approved by OMB for 26 respondents (0.5 hours per respondent) and is expanded by this final rule to include the provision of new information and/or an oral statement. We do not expect the OMB-approved estimated number of respondents to change. We estimate that the additional burden will be no more than 1 hour per respondent. The total burden estimate (1.5 hours) includes both 0.5 hours per respondent for the submission of an appeal request (currently approved by OMB) as well as 1 hour per respondent for new information and/or an oral statement. The annual burden estimate is 39 hours.
- *Reimbursement Denial Letter and Appeal Notification—Providers:* Of the nearly 52,000 providers affiliated with the Program, it is estimated that 1.15 percent (600) annually will appeal a denial of reimbursement for treatment found to be not medically necessary or in accordance with treatment protocols. We estimate that the appeal request will take no more than 0.5 hours per respondent to compile. The annual burden estimate is 300 hours.
- *Designated Representative HIPAA Authorization:* The Program also finds it necessary to add a new form to allow applicants and Program members to grant permission to share protected health information with an individual who has been properly appointed the applicant's or member's designated representative pursuant to 42 CFR 88.2. We estimate that 10 applicants and members will submit the Designated Representative Health Insurance Portability and Accountability Act (HIPAA) Authorization form annually. The form is expected to take no longer than 0.25 hours to complete. The burden estimate for the HIPAA Authorization form is 2.5 hours.

The Program estimates that the total annual paperwork burden associated with this rulemaking, including the revised and new burden hour estimates, is 14,178.95 hours.[24]

Type of respondent	Form name	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
FDNY Responder	World Trade Center Health Program FDNY Responder Eligibility Application.	45	1	0.5	22.5
General Responder	World Trade Center Health Program Responder Eligibility Application (Other than FDNY).	2,475	1	0.5	1,237.5
Pentagon/Shanksville Responder.	World Trade Center Health Program Pentagon/Shanksville Responder.	630	1	0.5	315
WTC Survivor	World Trade Center Health Program Survivor Eligibility Application.	1,350	1	0.5	675
General Responder	Postcard for new general responders in NY/NJ to select a clinic.	2,475	1	0.25	618.75
Program Medical Provider.	WTC–3 Request for Certification	20,000	1	0.5	10,000
Responder/Survivor	Denial Letter and Appeal Notification—Enrollment.	45	1	0.5	22.5
Responder/Survivor	Disenrollment Letter and Appeal Notification—Eligibility.	3	1	0.5	1.5
Responder/Survivor	Decertification Letter and Appeal Notification	5	1	1.5	7.5
Responder/Survivor	Denial Letter and Appeal Notification—Health Condition Certification.	60	1	1.5	90
Responder/Survivor	Denial Letter and Appeal Notification—Treatment Authorization.	26	1	1.5	39
Responder/Survivor	WTC Health Program Medical Travel Refund Request.	10	1	0.17	1.7
Responder/Survivor	Designated Representative form	10	1	0.25	2.5
Pharmacy	Outpatient prescription pharmaceuticals	150	261	0.02	783
Program Medical Provider.	Reimbursement Denial Letter and Appeal Notification.	600	1	0.5	300
Responder/Survivor	Designated Representative HIPAA Authorization	10	1	0.25	2.5
Responder/Survivor/Advocate (physician).	Petition for the addition of health conditions	60	1	1	60
Total					14,178.95

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*

[24] The burden estimates provided here are subject to change in the final approved information collection revision request, pending the collection and review of public comments.

seq., directs agencies to assess the effects of Federal regulatory actions on State, local, and Tribal governments, and the private sector ''other than to the extent that such regulations incorporate requirements specifically set forth in law.'' For purposes of the Unfunded Mandates Reform Act, this final rule does not include any Federal mandate that may result in increased annual expenditures in excess of $100 million by State, local, or Tribal governments in the aggregate, or by the private sector.

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.

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 and requests public comment on this effort.

List of Subjects in 42 CFR Part 88

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

Final rule

■ For the reasons discussed in the preamble, the Administrator revises 42 CFR part 88 to read as follows:

PART 88—WORLD TRADE CENTER HEALTH PROGRAM

Sec.
88.1 Definitions.
88.2 General provisions.
88.3 Eligibility—currently-identified responders.
88.4 Eligibility criteria—WTC responders.
88.5 Application process—WTC responders.
88.6 Enrollment decision—WTC responders.
88.7 Eligibility—currently-identified survivors.
88.8 Eligibility criteria—WTC survivors.
88.9 Application process—WTC survivors.
88.10 Enrollment decision—screening-eligible survivors.
88.11 Initial health evaluation for screening-eligible survivors.
88.12 Enrollment decision—certified-eligible survivors.
88.13 Disenrollment.
88.14 Appeal of enrollment or disenrollment decision.
88.15 List of WTC-Related Health Conditions.
88.16 Addition of health conditions to the List of WTC-Related Health Conditions.
88.17 Physician's determination of WTC-related health conditions.
88.18 Certification.
88.19 Decertification.
88.20 Authorization of treatment.
88.21 Appeal of certification, decertification, or treatment authorization decision.
88.22 Reimbursement for medical treatment and services.
88.23 Appeal of reimbursement denial.
88.24 Coordination of benefits and recoupment.
88.25 Reopening of WTC Health Program final decisions.

Authority: 42 U.S.C. 300mm to 300mm-61, Pub. L. 111–347, 124 Stat. 3623, as amended by Pub. L. 114–113, 129 Stat. 2242.

§ 88.1 Definitions.

Act means Title XXXIII of the Public Health Service Act, as amended, 42 U.S.C. 300mm through 300mm–61 (codifying Title I of the James Zadroga 9/11 Health and Compensation Act of 2010, Pub. L. 111–347, as amended by Pub. L. 114–113), which created the World Trade Center (WTC) Health Program.

Aggravating means a health condition that existed on September 11, 2001, and that, as a result of exposure to airborne toxins, any other hazard, or any other adverse condition resulting from the September 11, 2001, terrorist attacks, requires medical treatment that is (or will be) in addition to, more frequent than, or of longer duration than the medical treatment that would have been required for such condition in the absence of such exposure.

Certification means WTC Health Program review of a health condition in a particular WTC Health Program member for the purpose of identification and approval of a WTC-related health condition, as defined in this section and included on the List of WTC-Related Health Conditions in 42 CFR 88.15, or a health condition medically associated with a WTC-related health condition.

Certified-eligible survivor means (1) an individual who has been identified as eligible for medical monitoring and treatment as of January 2, 2011; or (2) a screening-eligible survivor who is eligible for follow-up monitoring and treatment pursuant to § 88.12(b).

Clinical Center of Excellence (CCE) means a center or centers under contract with the WTC Health Program. A CCE:

(1) Uses an integrated, centralized health care provider approach to create a comprehensive suite of health services that are accessible to enrolled WTC responders, screening-eligible survivors, or certified-eligible survivors;

(2) Has experience in caring for WTC responders and screening-eligible survivors, or includes health care providers who have received WTC Health Program training;

(3) Employs health care provider staff with expertise that includes, at a minimum, occupational medicine, environmental medicine, trauma-related psychiatry and psychology, and social services counseling; and

(4) Meets such other requirements as specified by the Administrator of the WTC Health Program.

Data Center means a center or centers under contract with the WTC Health Program to:

(1) Receive, analyze, and report to the Administrator of the WTC Health Program on data that have been collected and reported to the Data Center by the corresponding CCE(s);

(2) Develop monitoring, initial health evaluation, and treatment protocols with respect to WTC-related health conditions;

(3) Coordinate the outreach activities of the corresponding CCE;

(4) Establish criteria for credentialing of medical providers participating in the Nationwide Provider Network;

(5) Coordinate and administer the activities of the WTC Health Program Steering Committees; and

(6) Meet periodically with the corresponding CCE(s) to obtain input on the analysis and reporting of data and on development of monitoring, initial health evaluation, and treatment protocols.

Designated representative means an individual selected by an applicant, WTC responder, or a screening-eligible or certified-eligible survivor to represent his or her interests to the WTC Health Program.

Ground Zero means a site in Lower Manhattan bounded by Vesey Street to the north, the West Side Highway to the west, Liberty Street to the south, and Church Street to the east in which stood the former World Trade Center complex.

Health condition medically associated with a WTC-related health condition means a condition that results from treatment of a WTC-related health condition or results from progression of a WTC-related health condition.

Initial health evaluation means assessment of one or more symptoms that may be associated with a WTC-related health condition and includes a medical and exposure history, a physical examination, and additional medical testing as needed to evaluate whether the individual has a WTC-related health condition and is eligible for treatment under the WTC Health Program.

Interested party means a representative of any organization representing WTC responders, a nationally recognized medical association, a WTC Health Program CCE or Data Center, a State or political subdivision, or any other interested person.

List of WTC-Related Health Conditions means those conditions eligible for coverage in the WTC Health Program as identified in § 88.15 of this part.

Medical emergency means a physical or mental health condition for which immediate treatment is necessary.

Medically necessary treatment means the provision of services to a WTC Health Program member by physicians and other health care providers, including diagnostic and laboratory tests, prescription drugs, inpatient and outpatient hospital services, and other care that is appropriate, to manage, ameliorate, or cure a WTC-related health condition or a health condition medically associated with a WTC-related health condition, and which conforms to medical treatment protocols developed by the Data Centers, with input from the CCEs, and approved by the Administrator of the WTC Health Program.

Monitoring means periodic physical and mental health assessment of a WTC responder or certified-eligible survivor in relation to exposure to airborne toxins, any other hazard, or any other adverse condition resulting from the September 11, 2001, terrorist attacks and which includes a medical and exposure history, a physical examination and additional medical testing as needed for surveillance or to evaluate symptom(s) to determine whether the individual has a WTC-related health condition.

Nationwide Provider Network (NPN) means a network of providers throughout the United States under contract with the WTC Health Program to provide an initial health evaluation, monitoring, and treatment to enrolled WTC responders, screening-eligible survivors, or certified-eligible survivors who live outside the New York metropolitan area.

New York City disaster area means an area within New York City that is the area of Manhattan that is south of Houston Street and any block in Brooklyn that is wholly or partially contained within a 1.5-mile radius of the former World Trade Center complex.

New York metropolitan area means the combined statistical areas comprising the Bridgeport-Stamford-Norwalk, CT Metropolitan Statistical Area; Kingston, NY Metropolitan Statistical Area; New Haven-Milford, CT Metropolitan Statistical Area; New York-Northern New Jersey-Long Island, NY-NJ-PA Metropolitan Statistical Area; Poughkeepsie-Newburgh-Middletown, NY Metropolitan Statistical Area; Torrington, CT Micropolitan Statistical Area; Trenton-Ewing, NJ Metropolitan Statistical Area, as defined in OMB Bulletin 10–02, December 1, 2009.

NIOSH means the National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

One (1) day means the length of a standard work shift, or at least 4 hours but less than 24 hours.

Pentagon site means any area of the land (consisting of approximately 280 acres) and improvements thereon, located in Arlington, Virginia, on which the Pentagon Office Building, Federal Building Number 2, the Pentagon heating and sewage treatment plants, and other related facilities are located, including various areas designated for the parking of vehicles, vehicle access, and other areas immediately adjacent to the land or improvements previously described that were affected by the terrorist-related aircraft crash on September 11, 2001; and those areas at Fort Belvoir in Fairfax County, Virginia and at the Dover Port Mortuary at Dover Air Force Base in Delaware involved in the recovery, identification, and transportation of human remains for the incident.

Police department means any law enforcement department or agency, whether under Federal, state, or local jurisdiction, responsible for general police duties, such as maintenance of public order, safety, or health, enforcement of laws, or otherwise charged with prevention, detection, investigation, or prosecution of crimes.

Scientific/Technical Advisory Committee means the WTC Health Program Scientific/Technical Advisory Committee whose members are appointed by the Administrator of the WTC Health Program to review scientific and medical evidence and to make recommendations to the Administrator on additional WTC Health Program eligibility criteria and on additional WTC-related health conditions.

Screening-eligible survivor means an individual who is not a WTC responder and who claims symptoms of a WTC-related health condition and meets the eligibility criteria for a survivor specified in § 88.8 of this part.

September 11, 2001, terrorist attacks means the terrorist attacks that occurred on September 11, 2001, in New York City, at Shanksville, Pennsylvania, and at the Pentagon, and includes the aftermath of such attacks.

Shanksville, Pennsylvania site means the property in Stonycreek Township, Somerset County, Pennsylvania, which is bounded by Route 30 (Lincoln Highway), State Route 1019 (Buckstown Road), and State Route 1007 (Lambertsville Road); and those areas at the Pennsylvania National Guard Armory in Friedens, Pennsylvania involved in the recovery, identification, and transportation of human remains for the incident.

Staten Island Landfill means the landfill in Staten Island, NY called ''Fresh Kills.''

Terrorist watch list means the lists maintained by the Federal government that will be utilized to screen for known terrorists.

WTC means World Trade Center.

WTC Health Program means the program established by Title XXXIII of the Public Health Service Act as amended, 42 U.S.C. 300mm to 300mm–61 (codifying Title I of the James Zadroga 9/11 Health and Compensation Act of 2010, Pub. L. 111–347, as amended by Pub. L. 114–113) to provide

medical monitoring and treatment benefits for eligible responders to the September 11, 2001, terrorist attacks and initial health evaluation, monitoring, and treatment benefits for residents and other building occupants and area workers in New York City who were directly impacted and adversely affected by such attacks.

WTC Health Program member means any responder, screening-eligible survivor, or certified-eligible survivor enrolled in the WTC Health Program.

WTC Program Administrator (Administrator of the WTC Health Program, or Administrator) means, for the purposes of this part, the Director of the National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Department of Health and Human Services, or his or her designee.

WTC-related acute traumatic injury means a health condition eligible for coverage in the WTC Health Program as described in § 88.15(e)(1) of this part.

WTC-related health condition means 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 expertise in treating or diagnosing the health conditions in the List of WTC-Related Health Conditions, is substantially likely to be a significant factor in aggravating, contributing to, or causing the illness or health condition, including a mental health condition. Only those conditions on the List of WTC-Related Health Conditions codified in 42 CFR 88.15 may be considered WTC-related health conditions.

WTC-related musculoskeletal disorder means a health condition eligible for coverage in the WTC Health Program as described in § 88.15(c)(1) of this part.

WTC responder means an individual who has been identified as eligible for monitoring and treatment as described in § 88.3 or who meets the eligibility criteria in § 88.4.

§ 88.2 General provisions.

(a) *Designated representative.* (1) An applicant or WTC Health Program member may appoint one individual to represent his or her interests under the WTC Health Program. The appointment must be made in writing and consistent with all relevant Federal laws and regulations in order for the designated representative to receive personal health information.

(2) There may be only one designated representative at any time. After one designated representative has been properly appointed, the WTC Health Program will not recognize another individual as the designated representative until the appointment of the previously designated representative is withdrawn in a signed writing.

(3) A properly appointed designated representative who is recognized by the WTC Health Program may make a request or give direction to the WTC Health Program regarding the eligibility, certification, or any other administrative issue pertaining to the applicant or WTC Health Program member under the WTC Health Program, including appeals. Any notice requirement contained in this part or in the Act is fully satisfied if sent to the designated representative.

(4) An applicant or WTC Health Program member may authorize any individual to represent him or her in regard to the WTC Health Program, unless that individual's service as a representative would violate any applicable provision of law (such as 18 U.S.C. 205 or 18 U.S.C. 208) or is otherwise prohibited by WTC Health Program policies and procedures or contract provisions.

(5) A Federal employee may act as a representative only on behalf of the individuals specified in, and in the manner permitted by, 18 U.S.C. 203 and 18 U.S.C. 205.

(6) If an applicant or screening-eligible or certified-eligible survivor is a minor, a parent or guardian may act on his or her behalf.

(7) If an applicant or WTC Health Program member is a mentally incompetent adult, an individual authorized under state or other applicable law to act on the applicant's or member's behalf may act as his or her designated representative as described in this section.

(b) *Transportation and travel expenses.* The WTC Health Program may provide for necessary and reasonable transportation and expenses incident to the securing of medically necessary treatment through the NPN, involving travel of more than 250 miles.

§ 88.3 Eligibility—currently identified responders.

(a) Responders who were identified as eligible for monitoring and treatment under the arrangements as in effect on January 2, 2011, between NIOSH and the consortium administered by Mount Sinai School of Medicine in New York City and the Fire Department, City of New York, are enrolled in the WTC Health Program.

(1) No individual who is determined to be a positive match to the terrorist watch list maintained by the Federal government will be considered to be enrolled in the WTC Health Program.

(2) [Reserved]

(b) WTC responders identified as enrolled under this section are not required to submit an application to the WTC Health Program.

§ 88.4 Eligibility criteria—WTC responders.

(a) Responders to the New York City disaster area who have not been previously identified as eligible as provided for under § 88.3 of this part may apply for enrollment in the WTC Health Program on or after July 1, 2011. Such individuals must meet the criteria in one of the following categories to be considered eligible for enrollment:

(1) Firefighters and related personnel must meet the criteria specified in paragraph (a)(1)(i) or (ii) of this section:

(i) The individual was an active or retired member of the Fire Department, City of New York (whether firefighter or emergency personnel), and participated at least 1 day in the rescue and recovery effort at any of the former World Trade Center sites (including Ground Zero, the Staten Island Landfill, or the New York City Chief Medical Examiner's Office), during the period beginning on September 11, 2001, and ending on July 31, 2002; or

(ii) The individual is:

(A) A surviving immediate family member of an individual who was an active or retired member of the Fire Department, City of New York (whether firefighter or emergency personnel), who was killed at Ground Zero on September 11, 2001, and

(B) Received any treatment for a WTC-related mental health condition on or before September 1, 2008.

(2) Law enforcement officers and WTC rescue, recovery, and cleanup workers must meet the criteria specified in paragraph (a)(2)(i) or (ii) of this section:

(i) The individual worked or volunteered onsite in rescue, recovery, debris cleanup, or related support services in lower Manhattan (south of Canal Street), the Staten Island Landfill, or the barge loading piers, for at least:

(A) 4 hours during the period beginning on September 11, 2001, and ending on September 14, 2001; or

(B) 24 hours during the period beginning on September 11, 2001, and ending on September 30, 2001; or

(C) 80 hours during the period beginning on September 11, 2001, and ending on July 31, 2002.

(ii) The individual was an active or retired member of the New York City Police Department or an active or retired member of the Port Authority Police of the Port Authority of New York and

New Jersey who participated onsite in rescue, recovery, debris cleanup, or related support services, for at least:

(A) 4 hours during the period beginning September 11, 2001, and ending on September 14, 2001, in lower Manhattan (south of Canal Street), including Ground Zero, the Staten Island Landfill, or the barge loading piers; or

(B) 1 day beginning on September 11, 2001, and ending on July 31, 2002, at Ground Zero, the Staten Island Landfill, or the barge loading piers; or

(C) 24 hours during the period beginning on September 11, 2001, and ending on September 30, 2001, in lower Manhattan (south of Canal Street); or

(D) 80 hours during the period beginning on September 11, 2001, and ending on July 31, 2002, in lower Manhattan (south of Canal Street).

(3) Office of the Chief Medical Examiner of New York City employee. The individual was an employee of the Office of the Chief Medical Examiner of New York City involved in the examination and handling of human remains from the WTC attacks, or other morgue worker who performed similar post-September 11 functions for such Office staff, during the period beginning on September 11, 2001, and ending on July 31, 2002.

(4) Port Authority Trans-Hudson Corporation Tunnel worker. The individual was a worker in the Port Authority Trans-Hudson Corporation Tunnel for at least 24 hours during the period beginning on February 1, 2002, and ending on July 1, 2002.

(5) Vehicle-maintenance worker. The individual was a vehicle-maintenance worker who was exposed to debris from the former World Trade Center while retrieving, driving, cleaning, repairing, and maintaining vehicles contaminated by airborne toxins from the September 11, 2001, terrorist attacks; and conducted such work for at least 1 day during the period beginning on September 11, 2001, and ending on July 31, 2002.

(b) Responders to the Pentagon site of the September 11, 2001, terrorist attacks, may apply for enrollment in the WTC Health Program on or after April 29, 2013. Individuals must meet the criteria below to be considered eligible for enrollment:

(1) The individual was an active or retired member of a fire or police department (fire or emergency personnel), worked for a recovery or cleanup contractor, or was a volunteer; and

(2) Performed rescue, recovery, demolition, debris cleanup, or other related services at the Pentagon site of the September 11, 2001, terrorist attacks, for at least 1 day beginning September 11, 2001, and ending on November 19, 2001.

(c) Responders to the Shanksville, Pennsylvania site of the September 11, 2001, terrorist attacks, may apply for enrollment in the WTC Health Program on or after April 29, 2013. Individuals must meet the criteria below to be considered eligible for enrollment:

(1) The individual was an active or retired member of a fire or police department (fire or emergency personnel), worked for a recovery or cleanup contractor, or was a volunteer; and

(2) Performed rescue, recovery, demolition, debris cleanup, or other related services at the Shanksville, Pennsylvania site of the September 11, 2001, terrorist attacks, for at least 1 day beginning September 11, 2001, and ending on October 3, 2001.

(d) [Reserved]

(e) The WTC Health Program will maintain a list of WTC responders.

§ 88.5 Application process—WTC responders.

(a) An application to the WTC Health Program based on the criteria in § 88.4 must be submitted with documentation of the applicant's employment affiliation (if relevant) and work activity during the dates, times, and locations specified in § 88.4

(1) Documentation may include but is not limited to a pay stub; official personnel roster; a written statement, under penalty of perjury by an employer; site credentials; or similar documentation.

(2) An applicant who is unable to submit the required documentation must instead offer a written explanation of how he or she tried to obtain proof of presence, residence, or work activity and why the attempt was unsuccessful. The applicant must attest, under penalty of perjury, that he or she meets the criteria specified in § 88.4.

(b) The application and supporting documentation must be submitted to the WTC Health Program for consideration.

(c) The WTC Health Program will notify the applicant in writing (or by email if an email address is provided by the applicant) of any deficiencies in the application or the supporting documentation.

§ 88.6 Enrollment decision—WTC responders.

(a) *Enrollment priority.* The WTC Health Program will prioritize applications in the order in which they are received.

(b) *Enrollment eligibility.* The WTC Health Program will decide if the applicant meets the eligibility criteria provided in § 88.4.

(c) *Denial of enrollment.* (1) The WTC Health Program will deny enrollment if the applicant fails to meet the applicable eligibility requirements.

(2) The WTC Health Program may deny enrollment of a responder who is otherwise eligible and qualified if the Act's numerical limitations for newly enrolled responders have been met.

(i) No more than 25,000 WTC responders, other than those enrolled pursuant to §§ 88.3 and 88.4(a)(1)(ii), may be enrolled at any time. The Administrator of the WTC Health Program may decide, based on the best available evidence, that sufficient funds are available under the WTC Health Program Fund to provide treatment and monitoring only for individuals who are already enrolled as WTC responders at that time.

(ii) [Reserved]

(3) No individual who is determined to be a positive match to the terrorist watch list maintained by the Federal government may qualify to be enrolled or be determined to be eligible for the WTC Health Program.

(d) *Notification of enrollment decision.* (1) The WTC Health Program will decide if the applicant meets the current eligibility criteria for WTC responders in § 88.4 and is qualified, and notify the applicant of the enrollment decision in writing within 60 calendar days of the date of receipt of the application. The 60-day time period will not include any days during which the applicant is correcting deficiencies in the application or supporting documentation.

(2) If the WTC Health Program decides that an applicant is denied enrollment, the written notification will include an explanation, as appropriate, for the decision to deny enrollment and inform the applicant of the right to appeal the initial denial of eligibility and provide instructions on how to file an appeal.

§ 88.7 Eligibility—currently identified survivors.

(a) Survivors who have been identified as eligible for medical treatment and monitoring as of January 2, 2011, are considered certified-eligible in the WTC Health Program.

(1) No individual who is determined to be a positive match to the terrorist watch list maintained by the Federal government will be considered to be a certified-eligible survivor in the WTC Health Program.

(2) [Reserved]

(b) Survivors identified as certified-eligible under this section are not

required to submit an application to the WTC Health Program.

§ 88.8 Eligibility criteria—WTC survivors.

(a) Criteria for status as a screening-eligible survivor. An individual who is not a WTC responder, claims symptoms of a WTC-related health condition, and who has not been previously identified as eligible under § 88.7 may apply to the WTC Health Program on or after July 1, 2011, for a determination of eligibility for an initial health evaluation.

(1) The WTC Health Program will determine an applicant's eligibility for an initial health evaluation based on one of the following criteria:

(i) The screening applicant was present in the dust or dust cloud in the New York City disaster area on September 11, 2001.

(ii) The screening applicant worked, resided, or attended school, childcare, or adult daycare in the New York City disaster area, for at least:

(A) 4 days during the period beginning on September 11, 2001, and ending on January 10, 2002; or

(B) 30 days during the period beginning on September 11, 2001, and ending on July 31, 2002.

(iii) The screening applicant worked as a cleanup worker or performed maintenance work in the New York City disaster area during the period beginning on September 11, 2001, and ending on January 10, 2002, and had extensive exposure to WTC dust as a result of such work.

(iv) The screening applicant:

(A) Was deemed eligible to receive a grant from the Lower Manhattan Development Corporation Residential Grant Program;

(B) Possessed a lease for a residence or purchased a residence in the New York City disaster area; and

(C) Resided in such residence during the period beginning on September 11, 2001, and ending on May 31, 2003.

(v) The screening applicant is an individual whose place of employment—

(A) At any time during the period beginning on September 11, 2001, and ending on May 31, 2003, was in the New York City disaster area; and

(B) Was deemed eligible to receive a grant from the Lower Manhattan Development Corporation WTC Small Firms Attraction and Retention Act program or other government incentive program designed to revitalize the lower Manhattan economy after the September 11, 2001, terrorist attacks.

(2) [Reserved]

(b) Criteria for status as a certified-eligible survivor. Survivors who have been determined to have screening-eligible status under § 88.10(a), may seek status as a certified-eligible survivor. Status as a certified-eligible survivor is based on a certification by the WTC Health Program that, pursuant to an initial health evaluation, the screening-eligible survivor has a WTC-related health condition and is eligible for follow-up monitoring and treatment.

(c) The WTC Health Program will maintain a list of screening-eligible and certified-eligible survivors.

§ 88.9 Application process—WTC survivors.

(a) *Application for status as a screening-eligible survivor.* An application to the WTC Health Program based on the criteria in § 88.8(a) must be submitted with documentation of the applicant's location, presence or residence, and/or work activity during the relevant time period.

(1) Documentation may include but is not limited to: Proof of residence, such as a lease or utility bill; attendance roster at a school or daycare; or pay stub, other employment documentation, or written statement, under penalty of perjury, by an employer indicating employment location during the relevant time period; or similar documentation. The applicant must also attest to symptoms of a WTC-related health condition.

(2) An applicant who is unable to submit the required documentation must instead offer a written explanation of how he or she tried to obtain proof of location, presence, or residence, and/or work activity and why the attempt was unsuccessful. The applicant must attest, under penalty of perjury, that he or she meets the criteria specified in § 88.8.

(3) The applicant will be notified of any deficiencies in the application or the supporting documentation.

(b) *Status as a certified-eligible survivor.* No additional application is required for status as a certified-eligible survivor. If, based upon the screening-eligible survivor's initial health evaluation (*see* § 88.11), the WTC Health Program certifies the diagnosis of a WTC-related health condition, then the survivor will automatically receive the status of a certified-eligible survivor.

§ 88.10 Enrollment decision—screening-eligible survivors.

(a) The WTC Health Program will decide if the applicant meets the screening-eligible survivor criteria pursuant to § 88.8(a) and is qualified, and notify the applicant of the enrollment decision in writing within 60 calendar days of the date of receipt of the application. The 60-day time period will not include any days during which the applicant is correcting deficiencies in the application or supporting documentation.

(b) If the WTC Health Program decides that an applicant is denied enrollment, the written notification will include an explanation for the decision to deny enrollment and inform the applicant of the right to appeal the enrollment denial and provide instructions on how to file an appeal.

(1) The WTC Health Program may deny screening-eligible survivor status if the applicant is ineligible under the criteria specified in § 88.8(a).

(2) The WTC Health Program may deny screening-eligible survivor status if the numerical limitation on certified-eligible survivors in § 88.12(b)(3)(i) has been met.

(3) No individual who is determined to be a positive match to the terrorist watch list maintained by the Federal government may qualify to be a screening-eligible survivor in the WTC Health Program.

§ 88.11 Initial health evaluation for screening-eligible survivors.

(a) A CCE or an NPN-affiliated physician will provide the screening-eligible survivor an initial health evaluation to determine if the individual has a WTC-related health condition.

(b) The WTC Health Program will provide only one initial health evaluation per screening-eligible survivor. The individual may request additional health evaluations at his or her own expense.

(c) If the physician determines that the screening-eligible survivor has a WTC-related health condition, the physician will promptly transmit to the WTC Health Program his or her determination, consistent with the requirements of § 88.17(a).

§ 88.12 Enrollment decision—certified-eligible survivors.

(a) The WTC Health Program will prioritize certification requests in the order in which they are received.

(b) The WTC Health Program will review the physician's determination, render a decision regarding certification of the individual's WTC-related health condition, and notify the individual of the decision and the reason for the decision in writing, pursuant to §§ 88.17 and 88.18.

(1) If the individual is a screening-eligible survivor and the individual's condition is certified as a WTC-related health condition, the individual will automatically receive the status of a certified-eligible survivor.

(2) If a screening-eligible survivor's condition is not certified as a WTC-related health condition pursuant to §§ 88.17 and 88.18, the WTC Health Program will deny certified-eligible status. The screening-eligible survivor may appeal the decision to deny certification, as provided under § 88.21.

(3) The WTC Health Program may deny certified-eligible survivor status of an otherwise eligible and qualified screening-eligible survivor if the Act's numerical limitations for certified-eligible survivors have been met.

(i) No more than 25,000 individuals, other than those described in § 88.7, may be determined to be certified-eligible survivors at any time. The Administrator of the WTC Health Program may decide, based on the best available evidence, that sufficient funds are available under the WTC Health Program Fund to provide treatment and monitoring only for individuals who have already been certified as certified-eligible survivors at that time.

(ii) [Reserved]

(4) No individual who is determined to be a positive match to the terrorist watch list maintained by the Federal government may qualify to be a certified-eligible survivor in the WTC Health Program.

§ 88.13 Disenrollment.

(a) The disenrollment of a WTC Health Program member may be initiated by the WTC Health Program in the following circumstances:

(1) The WTC Health Program mistakenly enrolled an individual under § 88.4 (WTC responders) or § 88.8 (screening-eligible survivors) who did not provide sufficient proof of eligibility consistent with the required eligibility criteria; or

(2) The WTC Health Program member's enrollment was based on incorrect or fraudulent information.

(b) The disenrollment of a WTC Health Program member may be initiated by the enrollee for any reason.

(c) A disenrolled WTC Health Program member will be notified in writing by the WTC Health Program of a disenrollment decision, provided an explanation, as appropriate, for the decision, and provided information on how to appeal the decision. A disenrolled WTC Health Program member disenrolled pursuant to paragraph (a) may appeal the disenrollment decision in accordance with § 88.14.

(d) A disenrolled WTC Health Program member who has been disenrolled in accordance with paragraphs (a) or (b) of this section may seek to re-enroll in the WTC Health Program using the application and enrollment procedures, provided that the application is supported by new information.

§ 88.14 Appeal of enrollment or disenrollment decision.

(a) *Right to appeal.* An applicant denied WTC Health Program enrollment, a disenrolled WTC Health Program member, or the applicant's or member's designated representative (appointed pursuant to § 88.2(a)) may appeal the enrollment denial or disenrollment decision.

(b) *Appeal request.* (1) A letter requesting an appeal must be postmarked within 120 calendar days of the date of the letter from the Administrator notifying the denied applicant or disenrolled WTC Health Program member of the adverse decision. Electronic versions of a signed letter will be accepted if transmitted within 120 calendar days of the date of the Administrator's notification letter.

(2) A valid request for an appeal must:

(i) Be made in writing and signed;

(ii) Identify the denied applicant or disenrolled WTC Health Program member and designated representative (if applicable);

(iii) Describe the decision being appealed and state the reasons why the denied applicant, disenrolled WTC Health Program member, or designated representative believes the enrollment denial or disenrollment was incorrect and should be reversed. The appeal request may include relevant new information not previously considered by the WTC Health Program; and

(iv) Be sent to the WTC Health Program at the address specified in the notice of denial or disenrollment.

(3) Where the denial or disenrollment is based on information from the terrorist watch list, the appeal will be forwarded to the appropriate Federal agency.

(c) *Appeal process.* Upon receipt of a valid appeal, the Administrator will appoint a Federal Official independent of the WTC Health Program to review the case. The Federal Official will review all available records relevant to the WTC Health Program's decision not to enroll the applicant or to disenroll the WTC Health Program member and assess whether the appeal should be granted. In conducting the review, the Federal Official's consideration will include the following: Whether the WTC Health Program substantially complied with all relevant WTC Health Program policies and procedures; whether the information supporting the WTC Health Program's decision was factually accurate; and whether the WTC Health Program's decision was reasonable as applied to the facts of the case.

(1) The Federal Official may consider additional relevant new information submitted by the denied applicant, disenrolled WTC Health Program member, or designated representative.

(2) The Federal Official will provide his or her recommendation regarding the disposition of the appeal, including his or her findings and any supporting materials, to the Administrator.

(d) *Final decision and notification.* The Administrator will review the Federal Official's recommendation and any relevant information and make a final decision on the appeal. The Administrator will notify the denied applicant or disenrolled WTC Health Program member and/or designated representative of the following in writing:

(1) The recommendation and findings made by the Federal Official as a result of the review;

(2) The Administrator's final decision on the appeal;

(3) An explanation of the reason(s) for the Administrator's final decision on the appeal; and

(4) Any administrative actions taken by the WTC Health Program in response to the Administrator's final decision.

§ 88.15 List of WTC-Related Health Conditions.

WTC-related health conditions include the following disorders and conditions:

(a) Aerodigestive disorders:

(1) Interstitial lung diseases.

(2) Chronic respiratory disorder—fumes/vapors.

(3) Asthma.

(4) Reactive airways dysfunction syndrome (RADS).

(5) WTC-exacerbated and new-onset chronic obstructive pulmonary disease (COPD).

(6) Chronic cough syndrome.

(7) Upper airway hyperreactivity.

(8) Chronic rhinosinusitis.

(9) Chronic nasopharyngitis.

(10) Chronic laryngitis.

(11) Gastroesophageal reflux disorder (GERD).

(12) Sleep apnea exacerbated by or related to a condition described in preceding paragraphs (a)(1) through (11) of this section.

(b) Mental health conditions:

(1) Posttraumatic stress disorder (PTSD).

(2) Major depressive disorder.

(3) Panic disorder.

(4) Generalized anxiety disorder.

(5) Anxiety disorder (not otherwise specified).

(6) Depression (not otherwise specified).

(7) Acute stress disorder.

(8) Dysthymic disorder.

(9) Adjustment disorder.

(10) Substance abuse.

(c) Musculoskeletal disorders:

(1) WTC-related musculoskeletal disorder is a chronic or recurrent disorder of the musculoskeletal system caused by heavy lifting or repetitive strain on the joints or musculoskeletal system occurring during rescue or recovery efforts in the New York City disaster area in the aftermath of the September 11, 2001, terrorist attacks. For a WTC responder who received any treatment for a WTC-related musculoskeletal disorder on or before September 11, 2003, such a health condition includes:

(i) Low back pain.

(ii) Carpal tunnel syndrome (CTS).

(iii) Other musculoskeletal disorders.

(2) [Reserved].

(d) Cancers:

(1) Malignant neoplasms of the lip; tongue; salivary gland; floor of mouth; gum and other mouth; tonsil; oropharynx; hypopharynx; and other oral cavity and pharynx.

(2) Malignant neoplasm of the nasopharynx.

(3) Malignant neoplasms of the nose; nasal cavity; middle ear; and accessory sinuses.

(4) Malignant neoplasm of the larynx.

(5) Malignant neoplasm of the esophagus.

(6) Malignant neoplasm of the stomach.

(7) Malignant neoplasms of the colon and rectum.

(8) Malignant neoplasms of the liver and intrahepatic bile duct.

(9) Malignant neoplasms of the retroperitoneum and peritoneum; omentum; and mesentery.

(10) Malignant neoplasms of the trachea; bronchus and lung; heart, mediastinum and pleura; and other ill-defined sites in the respiratory system and intrathoracic organs.

(11) Mesothelioma.

(12) Malignant neoplasms of the peripheral nerves and autonomic nervous system; and other connective and soft tissue.

(13) Malignant neoplasms of the skin (melanoma and non-melanoma), including scrotal cancer.

(14) Malignant neoplasm of the female breast.

(15) Malignant neoplasm of the ovary.

(16) Malignant neoplasm of the prostate.

(17) Malignant neoplasm of the urinary bladder.

(18) Malignant neoplasm of the kidney.

(19) Malignant neoplasms of the renal pelvis; ureter; and other urinary organs.

(20) Malignant neoplasms of the eye and orbit.

(21) Malignant neoplasm of the thyroid.

(22) Malignant neoplasms of the blood and lymphoid tissues (including, but not limited to, lymphoma, leukemia, and myeloma).

(23) *Childhood cancers:* any type of cancer diagnosed in a person less than 20 years of age.

(24) *Rare cancers:* any type of cancer [1] that occurs in less than 15 cases per 100,000 persons per year in the United States.

(e) Acute traumatic injuries:

(1) WTC-related acute traumatic injury is physical damage to the body caused by and occurring immediately after a one-time exposure to energy, such as heat, electricity, or impact from a crash or fall, resulting from a specific event or incident. For a WTC responder or screening-eligible or certified-eligible survivors who received any medical treatment for a WTC-related acute traumatic injury on or before September 11, 2003, such a health condition includes:

(i) Eye injury.

(ii) Burn.

(iii) Head trauma.

(iv) Fracture.

(v) Tendon tear.

(vi) Complex sprain.

(vii) Other similar acute traumatic injuries.

(2) [Reserved]

§ 88.16 Addition of health conditions to the List of WTC-Related Health Conditions.

(a) Any interested party may submit a request to the Administrator of the WTC Health Program to add a condition to the List of WTC-Related Health Conditions in § 88.15. The Administrator will evaluate the submission to decide whether it is a valid petition.

(1) Each valid petition must include the following:

(i) An explicit statement of an intent to petition the Administrator to add a health condition to the List of WTC-Related Health Conditions;

(ii) Name, contact information, and signature of the interested party petitioning for the addition;

(iii) Name and/or description of the condition(s) to be added;

(iv) Reasons for adding the condition(s), including the medical basis for the association between the September 11, 2001, terrorist attacks and the condition(s) to be added.

(2) Not later than 90 calendar days after the receipt of a valid petition, the Administrator will take one of the following actions:

(i) Request a recommendation of the WTC Health Program Scientific/Technical Advisory Committee;

(ii) Publish in the **Federal Register** a proposed rule to add such health condition;

(iii) Publish in the **Federal Register** the Administrator's decision not to publish a proposed rule and the basis for that decision; or

(iv) Publish in the **Federal Register** a decision that insufficient evidence exists to take action under paragraph (a)(2)(i) through (iii) of this section.

(3) The 90-day time period will not include any days during which the Administrator is consulting with the interested party to clarify the submission.

(4) The Administrator may consider more than one petition simultaneously when the petitions propose the addition of the same health condition. Scientific/Technical Advisory Committee recommendations and **Federal Register** notices initiated by the Administrator pursuant to paragraph (a)(2) of this section may respond to more than one petition.

(5) The Administrator will be required to consider a submission for a health condition previously reviewed by the Administrator and found not to qualify for addition to the List of WTC-Related Health Conditions as a valid new petition only if the submission presents a new medical basis (*i.e.,* a basis not previously reviewed) for the association between the September 11, 2001, terrorist attacks and the condition to be added. A submission that provides no new medical basis and is received after the publication of a response in the **Federal Register** to a petition requesting the addition of the same health condition will not be considered a valid petition and will not be answered in a **Federal Register** notice pursuant to paragraph (a)(2), above. The interested party will be informed of the WTC Health Program's decision in writing.

(b) The Administrator may propose to add a condition to the List of WTC-Related Health Conditions in § 88.15 of this part by publishing a proposed rule in the **Federal Register** and providing interested parties a period of 30 calendar days to submit written comments. The Administrator may

[1] Based on 2005–2009 average annual data age-adjusted to the 2000 U.S. population. *See* Glenn Copeland, Andrew Lake, Rick Firth, *et al.* (eds), *Cancer in North America: 2005–2009. Volume One: Combined Cancer Incidence for the United States, Canada and North America,* Springfield, IL: North American Association of Central Cancer Registries, Inc., June 2012.

extend the comment period for good cause.

(1) If the Administrator requests a recommendation from the WTC Health Program Scientific/Technical Advisory Committee, the Advisory Committee will submit its recommendation to the Administrator no later than 90 calendar days after the date of the transmission of the request or no later than a date specified by the Administrator (but not more than 180 calendar days after the request). The Administrator will publish a proposed rule or a decision not to publish a proposed rule in the **Federal Register** no later than 90 calendar days after the date of transmission of the Advisory Committee recommendation.

(2) Before issuing a final rule to add a health condition to the List of WTC-Related Health Conditions, the Administrator will provide for an independent peer review of the scientific and technical evidence that would be the basis for issuing such final rule.

§ 88.17 Physician's determination of WTC-related health conditions.

(a) A physician affiliated with either a CCE or NPN will promptly transmit to the WTC Health Program a determination that a member's exposure to airborne toxins, any other hazard, or any other adverse condition resulting from the September 11, 2001, terrorist attacks is substantially likely to be a significant factor in aggravating, contributing to, or causing the illness or health condition, including a mental health condition. The transmission will also include the basis for such determination. The physician's determination will be made based on an assessment of the following:

(1) The individual's exposure to airborne toxins, any other hazard, or any other adverse condition resulting from the September 11, 2001, terrorist attacks.

(2) The type of symptoms experienced by the individual and the temporal sequence of those symptoms.

(b) For a health condition medically associated with a WTC-related health condition, the physician's determination must contain information establishing how the health condition has resulted from treatment of a previously certified WTC-related health condition or how it has resulted from progression of the certified WTC-related health condition.

§ 88.18 Certification.

(a) *WTC-related health condition.* The WTC Health Program will review each physician determination and render a decision regarding certification of the condition as a WTC-related health condition. The WTC Health Program will notify the WTC Health Program member of the decision and the reason for the decision in writing.

(b) *Health condition medically associated with a WTC-related health condition.* The WTC Health Program will review each physician determination and render a decision regarding certification of the condition as a health condition medically associated with a WTC-related health condition. The WTC Health Program will notify the WTC Health Program member in writing of the decision and the reason for the decision within 60 calendar days after the date the physician's determination is received.

(1) In the course of review, the WTC Health Program may seek a recommendation about certification from a physician panel with appropriate expertise for the condition.

(2) [Reserved]

(c) *Appeal right.* If certification of a condition as a WTC-related health condition or a health condition medically associated with a WTC-related health condition is denied, the WTC Health Program member may appeal the WTC Health Program's decision to deny certification, as provided under § 88.21.

§ 88.19 Decertification.

(a) The decertification of a WTC Health Program member's certified WTC-related health condition or health condition medically associated with a WTC-related health condition may be initiated by the WTC Health Program in the following circumstances:

(1) The WTC Health Program finds that the member's exposure is inadequate or is otherwise not covered;

(2) The WTC Health Program finds that the member's certified WTC-related health condition was certified in error or erroneously considered to have been aggravated, contributed to, or caused by exposure to airborne toxins, any other hazard, or any other adverse condition resulting from the September 11, 2001, terrorist attacks, pursuant to § 88.17(a); or

(3) The WTC Health Program finds that the member's health condition was erroneously determined to be medically associated with a WTC-related health condition, pursuant to § 88.17(b).

(b) A WTC Health Program member will be notified in writing by the WTC Health Program of a decertification decision, provided an explanation, as appropriate, for the decision, and provided information on how to appeal the decision. A WTC Health Program member whose WTC-related health condition or health condition medically associated with a WTC-related health condition is decertified may appeal the decertification decision in accordance with § 88.21 of this part.

§ 88.20 Authorization of treatment.

(a) *Generally.* Medically necessary treatment of certified WTC-related health conditions and certified health conditions medically associated with WTC-related health conditions will be provided through the CCEs or the NPN as permitted under WTC Health Program treatment protocols and in accordance with all applicable WTC Health Program policies and procedures.

(b) *Standard for determining medical necessity.* All treatment provided under the WTC Health Program will adhere to a standard which is reasonable and appropriate; based on scientific evidence, professional standards of care, expert opinion or any other relevant information; and which has been included in the medical treatment protocols developed by the Data Centers, with input from the CCEs, and approved by the Administrator of the WTC Health Program.

(c) *Treatment pending certification.* While certification of a condition is pending, authorization for treatment of a WTC-related health condition or a health condition medically associated with a WTC-related health condition must be obtained from the WTC Health Program before treatment is provided, except for the provision of treatment for a medical emergency.

§ 88.21 Appeal of certification, decertification, or treatment authorization decision.

(a) *Right to appeal.* A WTC Health Program member or the member's designated representative (appointed pursuant to § 88.2(a)) may appeal the following four types of decisions made by the WTC Health Program:

(1) To deny certification of a health condition as a WTC-related health condition;

(2) To deny certification of a health condition as medically associated with a WTC-related health condition;

(3) To decertify a WTC-related health condition or a health condition medically associated with a WTC-related health condition; or

(4) To deny authorization of treatment for a certified health condition based on a finding that the treatment is not medically necessary.

(b) *Appeal request.* (1) A letter requesting an appeal must be postmarked within 120 calendar days of the date of the letter from the

Administrator of the WTC Health Program notifying the member of the adverse decision. Electronic versions of a signed letter will be accepted if transmitted within 120 calendar days of the date of the Administrator's notification letter.

(2) A valid request for an appeal must:

(i) Be made in writing and signed;

(ii) Identify the member and designated representative (if applicable);

(iii) Describe the decision being appealed and the reason(s) why the member or designated representative believes the decision is incorrect and should be reversed. The description may include, but is not limited to, the following: Scientific or medical information correcting factual errors that may have been submitted to the WTC Health Program by the CCE or NPN; information demonstrating that the WTC Health Program did not correctly follow or apply relevant WTC Health Program policies or procedures; or any information demonstrating that the WTC Health Program's decision was not reasonable given the facts of the case. The basis provided in the appeal request must be sufficiently detailed and supported by information to permit a review of the appeal. Any new information not previously considered by the WTC Health Program must be included with the appeal request, unless later requested by the WTC Health Program; and

(iv) Be sent to the WTC Health Program at the address specified in the notice of denial.

(3) The appeal request may also state an intent to make a 15-minute oral statement by telephone. The WTC Health Program member or designated representative will have a second opportunity to schedule an oral statement after being contacted by the WTC Health Program regarding the appeal.

(c) *Appeal process.* Upon receipt of a valid appeal, the Administrator will appoint a Federal Official independent of the WTC Health Program to review the case. The Federal Official will review all available records relevant to the WTC Health Program's decision to deny certification of a health condition as a WTC-related health condition, deny certification of a health condition as medically associated with a WTC-related health condition, decertify the WTC-related health condition or health condition medically associated with a WTC-related health condition, or deny treatment authorization, and assess whether the appeal should be granted. The Federal Official's consideration will include the following: Whether the WTC Health Program substantially complied with all relevant WTC Health Program policies and procedures; whether the information supporting the WTC Health Program's decision was factually accurate; and whether the WTC Health Program's decision was reasonable as applied to the facts of the case.

(1) In conducting his or her review, the Federal Official will review the case record, including any oral statement made by the WTC Health Program member or the member's designated representative, as well as additional relevant new information submitted with the appeal request or provided by the WTC Health Program member or the member's designated representative at the request of the WTC Health Program.

(2) The Federal Official may consult one or more qualified experts to review the WTC Health Program's decision and any additional information provided by the WTC Health Program member or the member's designated representative. The expert reviewer(s) will submit their findings to the Federal Official.

(3) The Federal Official will provide his or her recommendation regarding the disposition of the appeal, including his or her findings and any supporting materials (including the transcript of any oral statement and any expert reviewers' findings), to the Administrator.

(d) *Final decision and notification.* The Administrator will review the Federal Official's recommendation and any relevant information and make a final decision on the appeal. The Administrator will notify the WTC Health Program member and/or the member's designated representative of the following in writing:

(1) The recommendation and findings made by the Federal Official as a result of the review;

(2) The Administrator's final decision on the appeal;

(3) An explanation of the reason(s) for the Administrator's final decision on the appeal; and

(4) Any administrative actions taken by the WTC Health Program in response to the Administrator's final decision.

§ 88.22 Reimbursement for medical treatment and services.

(a) *Review of claims.* Each claim for reimbursement for treatment will be reviewed by the WTC Health Program. Claims that cannot be validated by that process will be further assessed by the Administrator of the WTC Health Program.

(b) *Initial health evaluations, medical monitoring, and medically necessary treatment.* (1) The costs incurred by a CCE or NPN-affiliated provider for providing a WTC Health Program member an initial health evaluation, medical monitoring, and/or medically necessary treatment or services for a WTC-related health condition or a health condition medically associated with a WTC-related health condition will be reimbursed according to the payment rates that apply to the provision of such treatment and services under the Federal Employees Compensation Act (FECA), 5 U.S.C. 8101 *et seq.,* 20 CFR part 10.

(i) The Administrator will reimburse a CCE or NPN-affiliated provider for treatment for which FECA rates have not been established pursuant to the applicable Medicare fee for service rate, as determined appropriate by the Administrator.

(ii) The Administrator will reimburse a CCE or NPN-affiliated provider for treatment for which neither FECA nor Medicare fee for service rates have been established, at rates as determined appropriate by the Administrator.

(2) If the treatment is determined not to be medically necessary or is inconsistent with WTC Health Program protocols, the Administrator will withhold reimbursement.

(c) *Outpatient prescription pharmaceuticals.* Payment for costs of medically necessary outpatient prescription pharmaceuticals for a WTC-related health condition or health condition medically associated with a WTC-related health condition will be reimbursed by the WTC Health Program under a contract with one or more pharmaceutical benefit management services.

§ 88.23 Appeal of reimbursement denial.

After exhausting procedural and/or contractual administrative remedies, a CCE or NPN medical director or affiliated provider may submit a written appeal of a WTC Health Program decision to withhold reimbursement or payment for treatment found to be not medically necessary or not in accordance with approved WTC Health Program medical treatment protocols pursuant to § 88.20 of this part. Appeal procedures are published on the WTC Health Program Web site.

§ 88.24 Coordination of benefits and recoupment.

The WTC Health Program will attempt to recover the cost of payment for treatment, including pharmacy benefits, for a WTC Health Program member's certified WTC-related health condition or health condition medically associated with a WTC-related health condition by coordinating benefits with any workers' compensation insurance

available [2] for members' work-related health conditions, and with any public or private health insurance available [3] for members' non-work-related health conditions.

(a) Where a WTC Health Program member's WTC-related health condition or health condition medically associated with a WTC-related health condition is eligible for workers' compensation or another illness or injury benefit plan to which New York City is obligated to pay, the WTC Health Program is the primary payer.

(b) Where a WTC Health Program member has filed a workers' compensation claim for a WTC-related health condition or health condition medically associated with a WTC-related health condition and the claim is pending, the WTC Health Program is the primary payer; however, if the claim is ultimately accepted by the workers' compensation board, the workers' compensation insurer in question is responsible for reimbursing the WTC Health Program for any treatment provided and/or paid for during the pendency of the claim.

(c) Where a WTC Health Program member has filed a workers' compensation claim for a WTC-related health condition or health condition medically associated with a WTC-related health condition, but a final decision is issued denying the compensation for the claim, the WTC Health Program is the primary payer.

(d) Where a WTC Health Program member has filed a workers' compensation claim for a WTC-related health condition or health condition medically associated with a WTC-related health condition with a workers' compensation plan to which New York City is not obligated to pay, the workers' compensation insurer is the primary payer. The WTC Health Program is the secondary payer.

(1) If a WTC Health Program member settles a workers' compensation claim by entering into a settlement agreement that releases the employer or insurance carrier from paying for future medical care, the settlement must protect the interests of the WTC Health Program. This may include setting aside adequate funds to pay for future medical expenses, as required by the WTC Health Program, which would otherwise have been paid by workers' compensation. In such situations, the WTC Health Program may require reimbursement for treatment services of a WTC-related health condition or health condition medically associated with a WTC-related health condition directly from the member.

(2) The WTC Health Program will pay providers for treatment in accordance with § 88.22(b); to the extent that the workers' compensation insurance pays for treatment at a lower rate, the WTC Health Program will recoup treatment costs at the workers' compensation insurance rate.

(e) Where a WTC Health Program member's WTC-related health condition or health condition medically associated with a WTC-related health condition is not work-related, the WTC Health Program member's public or private health insurance plan is the primary payer. The WTC Health Program will pay costs not reimbursed by the public or private health insurance plan due to the application of deductibles, co-payments, co-insurance, other cost sharing arrangements, or payment caps up to and in accordance with the rates described in § 88.22(b).

(f) Any coordination of benefits or recoupment situation not described in paragraphs (a) through (e) of this section will be handled pursuant to WTC Health Program policies and procedures, as found on the WTC Health Program Web site.

§ 88.25 Reopening of WTC Health Program final decisions.

At any time, and without regard to whether new evidence or information is provided or obtained, the Administrator of the WTC Health Program may reopen any final decision made by the WTC Health Program pursuant to the provisions of this part. The Administrator may affirm, vacate, or modify such decision, or take any other action he or she deems appropriate.

Dated: November 22, 2016.

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.

Dated: November 28, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

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[2] As described in PHS Act, sec. 3331(b). To the extent that payment for treatment of the member's work-related condition has been made, or can reasonably be expected to be made, under any other work-related injury or illness benefit plan of the member's employer, the WTC Health Program will also attempt to recover the costs associated with treatment, including pharmacy benefits, for the member's certified WTC-related health condition or health condition medically associated with a WTC-related health condition. *See* PHS Act, sec. 3331(b)(1). For purposes of this regulation, ''workers' compensation law or plan'' or ''workers' compensation insurance'' includes any other work-related injury or illness benefit plan of the WTC Health Program member's employer.

[3] As described in PHS Act, sec. 3331(c).