

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**42 CFR Part 88**

[Docket No. CDC-2016-0072; NIOSH-291]

RIN 0920-AA56

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

**AGENCY:** Centers for Disease Control and Prevention, HHS.

**ACTION:** Notice of proposed rulemaking.

**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. After using the regulations for a number of years, the Administrator of the WTC Health Program has 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 has 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.

**DATES:** The Administrator of the WTC Health Program invites comment on this proposed rule from interested parties. Comments must be received by September 16, 2016.

**ADDRESSES:** Interested parties may submit comments by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Mail:* NIOSH Docket Office, 1090 Tusculum Avenue, MS C-34, Cincinnati, OH 45226-1998.

*Instructions:* All submissions received should include the agency name (Centers for Disease Control and Prevention, HHS) and docket number (CDC-2016-0072; NIOSH-291) or Regulation Identifier Number (0920-AA56) for this rulemaking. All relevant comments, including any personal information provided, will be posted

without change to <http://www.regulations.gov>. For detailed instructions on submitting public comments, see the "Public Participation" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket:* For access to the docket to read background documents, go to <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** Rachel Weiss, Program Analyst; 1090 Tusculum Ave, MS: C-46, Cincinnati, OH 45226; telephone (855) 818-1629 (this is a toll-free number); email [NIOSHregs@cdc.gov](mailto:NIOSHregs@cdc.gov).

**SUPPLEMENTARY INFORMATION:** This preamble is organized as follows:

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  - I. Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use)
  - J. Plain Writing Act of 2010

**I. Executive Summary**

*A. Purpose of Regulatory Action*

The Secretary, HHS, promulgated regulations designed to implement the WTC Health Program in a 2011 interim final rule establishing Part 88 in Title 42 of the Code of Federal Regulations,<sup>1</sup> and in a 2012 final rule adding procedures for the submission of petitions to add health conditions for Program coverage.<sup>2</sup> These regulations in 42 CFR part 88 include the processes by which eligible responders and survivors may apply for enrollment in the WTC Health Program, obtain health monitoring and treatment for WTC-related health conditions, and appeal enrollment and treatment decisions. The Administrator of the WTC Health Program (Administrator) has determined that

amending some provisions in Part 88 and adding others will benefit both the WTC Health Program and its members by clarifying requirements and improving administrative processes.

*B. Summary of Major Provisions*

Although the Administrator proposes to amend a number of existing sections in part 88, many of the changes would be non-substantive. Some existing language would be moved into new sections for clarity. Substantive amendments would be made to the following existing provisions:

- *§ 88.11 Appeals regarding eligibility determinations—responders and survivors*—this section would be amended to clarify appeal procedures and to allow the Administrator to make a final decision on the appeal.
  - *§ 88.15 Appeals regarding treatment*—this section would be significantly modified to clarify the appeal process, including allowing a WTC Health Program member or his/her designated representative to submit new evidence in support of the appeal and make an oral statement to the Federal Official reviewing the case, and allow the Administrator to make a final decision on the appeal.
    - *§ 88.17 Addition of health conditions to the list of WTC-related health conditions*—this section would be amended to extend the deadline for the Administrator's response to a petition for the addition of a health condition from 60 to 90 calendar days, consistent with current law. Another amendment to this section would allow the Administrator to consider a petition to be invalid if it presents the same scientific evidence supporting the addition of the health condition that was previously considered by the Administrator in a response published in the **Federal Register**.

New language on the following topics would be added to Part 88:

- *Disenrollment*—this new section would describe the WTC Health Program's procedures for disenrolling a Program member and the circumstances under which disenrollment would be applicable.
  - *Decertification*—this new section would describe the WTC Health Program's ability to decertify a WTC-related health condition or health condition medically associated with a WTC-related health condition and the circumstances under which decertification would be applicable.
    - *Appeal of reimbursement denial*—this new section would clarify the statutory appeal right for Program medical providers in cases in which the WTC Health Program has denied

<sup>1</sup> 76 FR 38914 (July 1, 2011).

<sup>2</sup> 77 FR 24628 (Apr. 25, 2012).

reimbursement for treatment found not to be medically necessary.

- *Coordination of benefits and recoupment*—this new section would be added to reflect the statutory requirement that payment for treatment, including pharmaceuticals, must be reduced or recouped as appropriate when the WTC Health Program finds that payment has been made by workers' compensation, public, or private health insurance.

### C. Costs

This rulemaking is expected to result in approximately \$42,742 in costs to the WTC Health Program associated with updating existing Program policies and developing new policies in accordance with amendments proposed in this action.

## II. Public Participation

Interested persons or organizations are invited to participate in this rulemaking by submitting written views, opinions, recommendations, and/or data. Comments are invited on any topic related to this proposed rule. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Any information in the comment or supporting materials considered confidential or inappropriate for public disclosure should not be included.

Comments submitted electronically or by mail should be titled "Docket No. CDC-2016-0072" and should identify the author(s) and contact information in case clarification is needed. Electronic and written comments can be submitted to the addresses provided in the **ADDRESSES** section, above. All communications received on or before the closing date for comments will be fully considered by the Administrator of the WTC Health Program.

## III. Background

This action proposes to amend certain regulatory provisions established in Part 88 of Title 42 of the Code of Federal Regulations and add new provisions to the part.

### A. History and Scope of Rulemaking

On July 1, 2011, HHS published an interim final rule (July 2011 IFR) to establish Part 88 in Title 42 of the Code of Federal Regulations and implement the WTC Health Program as administered by the Director of the National Institute for Occupational Safety and Health (NIOSH) (76 FR

38914). Provisions established in Part 88 include the following: WTC Health Program definitions; general provisions; eligibility and application requirements for WTC responders and screening- and certified-eligible survivors; initial health evaluations for screening-eligible survivors; enrollment, certification, and treatment appeals; physician determinations; the process for certifying WTC-related health conditions; the medical necessity standard; and reimbursement for health care providers.

A section describing the process for adding new health conditions to the List of WTC-Related Health Conditions (List) was finalized on April 25, 2012 (77 FR 24628).

Regulations establishing the eligibility criteria for Shanksville, Pennsylvania and Pentagon responders were established in an interim final rule published on March 28, 2013 (78 FR 18855).

Certain types of cancer, including rare cancers and childhood cancers, were added to the List in a September 12, 2012 final rule (77 FR 56138). Another cancer rulemaking, adding prostate cancer to the List, was finalized on September 19, 2013 (78 FR 57505). An IFR was published on February 18, 2014 (February 2014 IFR) to clarify the definition of "childhood cancers" and revise the definition of "rare cancers" (79 FR 9100). As a result of this IFR, cancers of the brain, the pancreas, and the testes, and invasive cervical cancer are also considered covered conditions.

Finally, on September 11, 2015, a notice of proposed rulemaking (NPRM) was published proposing the addition of new-onset chronic obstructive pulmonary disease (COPD) and WTC-related acute traumatic injury to the List (80 FR 54746). A final rule adding the two health conditions to the List was published on July 5, 2016 (81 FR 43510).

Regulatory text promulgated through an IFR, such as Part 88, is effective prior to the consideration of public comments and may be amended just as if it had been promulgated by normal notice-and-comment rulemaking. In this proposed rule, the Administrator proposes amendments to certain sections of Part 88, responds to public comments on those sections received in response to the July 2011 IFR and the February 2014 IFR, and seeks public comment on the amendments proposed in this notice.

This NPRM and all of the interim final rules described above,<sup>3</sup> as well as any public comments to any of the interim final rules not addressed in this NPRM, will be addressed in a final rule.

### B. 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 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.

## IV. Summary of Proposed Rule

The Administrator finds it necessary to amend certain existing sections of 42 CFR part 88, to rearrange others, and to add new sections. The rationales for each proposed amendment are offered below, along with summaries of the proposed rule text. This action answers only those public comments relevant to the provisions that the Administrator is proposing to amend in this action.

The Administrator proposes to amend the title of certain Part 88 sections referenced below; the new titles used in the preamble correspond with the proposed regulatory text found at the end of this document.

The table below matches the proposed reorganization of Part 88 with the originating sections in the existing regulation. No changes are proposed to §§ 88.3 and 88.7; although they are included in the table for completeness, they are not referenced again in this notice. The regulatory text with

<sup>3</sup> These include the July 2011 IFR (establishing Part 88 and implementing the Program), the March 2013 IFR (establishing eligibility criteria for

Shanksville and Pentagon responders), and the February 2014 IFR (clarifying the definition of

"childhood cancers" and revising the definition of "rare cancers").

proposed amendments is found in the last section of this notice.

PROPOSED REORGANIZATION AND SECTION TITLE AMENDMENTS

Proposed section	Originating section
88.1 Definitions	88.1 Definitions.
88.2 General provisions	88.2 General provisions.
88.3 Eligibility—currently-identified responders*	88.3 Eligibility—currently-identified responders.
88.4 Eligibility criteria—WTC responders	88.4 Eligibility criteria—status as a WTC responder.
88.5 Application process—WTC responders	88.5 Application process—status as a WTC responder.
88.6 Enrollment decision—WTC responders	88.6 Enrollment determination—status as a WTC responder.
88.7 Eligibility—currently-identified survivors *	88.7 Eligibility—currently-identified survivors.
88.8 Eligibility criteria—WTC survivors	88.8 Eligibility criteria—status as a WTC survivor.
88.9 Application process—WTC survivors	88.9 Application process—status as a WTC survivor.
88.10 Enrollment decision—screening-eligible survivors	88.10 Enrollment determination—status as a WTC survivor.
88.11 Initial health evaluation for screening-eligible survivors	88.10 Enrollment determination—status as a WTC survivor.
88.12 Enrollment decision—certified-eligible survivors	88.10 Enrollment determination—status as a WTC survivor.
88.13 Disenrollment	New.
88.14 Appeal of enrollment or disenrollment decision	88.11 Appeals regarding eligibility determinations—responders and survivors.
88.15 List of WTC-Related Health Conditions	relocated from 88.1.
88.16 Addition of health conditions to the List of WTC-Related Health Conditions.	88.17 Addition of health conditions to the list of WTC-related health conditions.
88.17 Physician’s determination of WTC-related health conditions	88.12 Physician’s determinations of WTC-related health conditions.
88.18 Certification	88.13 WTC Program Administrator’s certification of health conditions.
88.19 Decertification	New.
88.20 Authorization of treatment	88.14 Standard for determining medical necessity.
88.21 Appeal of certification, decertification, or treatment authorization decision.	88.15 Appeals regarding treatment.
88.22 Reimbursement for medical treatment and services	88.16 Reimbursement for medically necessary treatment, outpatient prescription pharmaceuticals, monitoring, and initial health evaluations, and travel expenses.
88.23 Appeal of reimbursement denial	New.
88.24 Coordination of benefits and recoupment	New.
88.25 Reopening of WTC Health Program final decisions	88.11 Appeals regarding eligibility determinations—responders and survivors and 88.15 Appeals regarding treatment.

\* No amendments are proposed for this section.

Section 88.1 Definitions

The Administrator established definitions of the terms commonly used in the WTC Health Program in 42 CFR 88.1. For reasons discussed below, amendments are proposed to the definitions of the following terms: “Act,” “Certification,” “Certified-eligible survivor,” “Clinical Center of Excellence,” “List of World Trade Center (WTC)-related health conditions,” “Medically necessary treatment,” “Nationwide provider network,” “World Trade Center (WTC) Health Program,” “World Trade Center (WTC) Program Administrator,” “World Trade Center (WTC)-related health condition,” and “World Trade Center (WTC)-related musculoskeletal disorder.” New definitions of “World Trade Center (WTC) Health Program member” and “World Trade Center (WTC)-related acute traumatic injury,” would also be added.

Act

The Administrator proposes to amend the current definition of “Act” to reference the 2016 reauthorization of the

WTC Health Program in Public Law 114–113.

Certification

The Administrator proposes to amend the current definition of “certification” to better characterize the role of certification in the WTC Health Program. Certification would mean the WTC Health Program review and approval of a health condition as eligible for medically necessary treatment. A certified WTC-related health condition or a certified health condition medically associated with a certified WTC-related health condition is eligible for medically necessary treatment in the WTC Health Program.

Certified-Eligible Survivor

The current definition of “certified-eligible survivor” references enrollment of certified-eligible survivors under § 88.10(f). This reference is incorrect and, in any event, should be amended to reflect the reorganization of Part 88 in this action, placing the enrollment of certified-eligible survivors in § 88.12(b).

Clinical Center of Excellence (CCE)

The Administrator proposes to amend the current definition of “Clinical Center of Excellence” to add the acronym “CCE.” An amendment to paragraph (2) would strike reference to certified-eligible survivors and indicate that a CCE may include health care providers who have received WTC Health Program training, as described in the PHS Act.<sup>4</sup> The term “WTC Program Administrator” is replaced with “Administrator of the WTC Health Program” in paragraph (4) of this definition.

List of WTC-Related Health Conditions

The Administrator proposes non-substantive amendments to the existing definition of “List of World Trade Center (WTC)-related health conditions” (List) to allow for easier reference to the health conditions covered by the WTC Health Program, to simplify future amendments to the List, and to give the List more prominence by moving it into its own section. The term “List of WTC-

<sup>4</sup> See PHS Act, sec. 3305(b)(1)(A)(ii).

Related Health Conditions” would be capitalized to reflect common usage by the Program. Furthermore, the Administrator proposes to move the List from the § 88.1 Definitions section to a new § 88.15. The definition of “List of WTC-related health conditions” would be replaced in the § 88.1 Definitions section with a marker to point the reader to the new § 88.15.

#### Medically Necessary Treatment

The Administrator proposes to amend the existing definition of “medically necessary treatment” to add the term “WTC Health Program members” to clarify that the standard applies to the provision of health care services to a particular member. The definition would also be amended to indicate that the medical treatment protocols are also developed with input from the CCEs. This language would be added to reflect the language in section 3305(a)(2)(A)(vi) of the PHS Act.

#### Nationwide Provider Network

The existing definition of “Nationwide provider network” would be slightly amended to capitalize the name Nationwide Provider Network and include the acronym “NPN.”

#### World Trade Center (WTC) Health Program

The Administrator proposes to amend the existing definition of “World Trade Center (WTC) Health Program” to update the reference to the authorizing statute, 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).

#### World Trade Center (WTC) Health Program Member

The Administrator proposes to add a new definition for the term “World Trade Center (WTC) Health Program member.” This term is often used in Program publications and refers generally to any responder, screening-eligible survivor, or certified-eligible survivor enrolled in the WTC Health Program. The phrase “responder, screening-eligible survivor, or certified-eligible survivor” is replaced with “WTC Health Program member” as appropriate in this Part.

#### World Trade Center (WTC) Program Administrator

The Administrator proposes to amend the existing definition of “WTC Program Administrator” to clarify the title and to allow flexibility in how the Administrator is addressed in WTC

Health Program documents. This non-substantive amendment to the existing definition would allow the use of the identical terms “Administrator of the WTC Health Program” and “Administrator.”

#### World Trade Center (WTC)-Related Acute Traumatic Injury

The Administrator proposes to add “WTC-related acute traumatic injury” to direct the reader to the List of WTC-Related Health Conditions in 42 CFR 88.15.

#### World Trade Center (WTC)-Related Health Condition

“World Trade Center (WTC)-related health condition” would be amended to clarify that WTC-related health conditions are those that are found in the WTC Health Program regulations. The Administrator has added new health conditions to the statutory list, found in sections 3312 and 3322 of the PHS Act, through rulemaking;<sup>5</sup> the expanded List is currently codified in § 88.1 of Part 88. Because the Administrator is proposing to move the List from § 88.1 to § 88.15, amendments to this definition would direct the reader to its location.

#### World Trade Center (WTC)-Related Musculoskeletal Disorder

The Administrator proposes to amend the existing definition of “WTC-related musculoskeletal disorder” to direct the reader to the List of WTC-Related Health Conditions in 42 CFR 88.15.

#### Section 88.2 General Provisions

This existing 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. In response to public comments submitted to the July 2011 IFR docket regarding this section,<sup>6</sup> the Administrator declines to amend this section to add “organization” to the types of eligible representatives in paragraph (a) or to allow the designation of an alternate representative. Only one individual at a time is permitted to be the designated representative; if the applicant or member wishes to select a different representative, he or she may do so by notifying the WTC Health

<sup>5</sup> See final rule, 77 FR 56138 (Sept. 12, 2012) (adding certain types of cancer); final rule, 78 FR 57505 (Sept. 19, 2013) (adding prostate cancer); interim final rule, 79 FR 9100 (Feb. 18, 2014) (clarifying the definition of “childhood cancers” and revising the definition of “rare cancers”); and final rule, 81 FR 43510 (July 5, 2016) (adding new-onset chronic obstructive pulmonary disease and WTC-related acute traumatic injury).

<sup>6</sup> NIOSH Docket 235, CDC–2011–0009.

Program in writing, signed by the applicant or member and either submitted in hard copy or scanned and submitted electronically, of the intent to withdraw the previous representative and name a new one. Accordingly, the Administrator proposes to amend paragraph (a)(2) of this section to clarify that a designated representative must be withdrawn in writing. Paragraph (a)(3) would be amended to clarify that the designated representative may represent the WTC Health Program member on any other administrative matter, in addition to eligibility and certification matters. Paragraph (a)(4) would be amended to indicate that an applicant or Program member may designate a representative unless that individual’s service is prohibited by law, WTC Health Program policies and procedures, or contract provisions.

Finally, because of proposed amendments to existing § 88.16, the Administrator would move provisions regarding reimbursement for transportation and travel expenses into reserved paragraph (b).

#### Section 88.4 Eligibility Criteria—WTC Responders

This section title would be amended from “Eligibility criteria—status as a WTC responder” to the title above, for clarity.

#### Section 88.5 Application Process—WTC Responders

This section title would be amended from “Application process—status as a WTC responder” to the title above, for clarity.

#### Section 88.6 Enrollment Decision—WTC Responders

This section title would be amended from “Enrollment determination—status as a WTC responder” to the title above, for clarity. The Administrator also finds that the term “determination” or “determine” should be replaced with “decision” or “decide” in this section and throughout Part 88 where the text refers to a WTC Health Program action. Although these terms were used interchangeably in the July 2011 IFR, the word “determination” is used in the Program to describe the finding made by a CCE or NPN physician that a member’s diagnosed health condition meets the PHS Act standards to be considered a WTC-related health condition or a health condition medically-associated with a WTC-related health condition; such determination is submitted to the Administrator for a certification decision (see § 88.18). Finally, language in existing paragraph (c)(2)(i) and

(c)(2)(i)(A) would be consolidated into one paragraph at (c)(2)(i).

*Section 88.8 Eligibility Criteria—WTC Survivors*

This section title would be amended from “Eligibility criteria—status as a WTC survivor” to the title above, for clarity.

*Section 88.9 Application Process—WTC Survivors*

This section title would be amended from “Application process—status as a WTC survivor” to the title above, for clarity.

*Section 88.10 Enrollment Decision—Screening-Eligible Survivors*

The Administrator proposes to simplify the existing provisions in § 88.10, titled “Enrollment determination—status as a WTC survivor,” by splitting the section into three separate sections: Enrollment decision—screening-eligible survivors; initial health evaluation for screening-eligible survivors; and enrollment decision—certified-eligible survivors. The screening-eligible survivor status decision provisions would remain in § 88.10; the initial health evaluation provisions would be moved into a new § 88.11, and the certified-eligible survivor status provisions would be moved into a new § 88.12.

For the reasons discussed above, the Administrator proposes to amend the title of this existing section from “Enrollment determination—status as a WTC survivor” to “Enrollment decision—screening-eligible survivors.” The new title would clarify that enrollment “decisions” are made by the WTC Health Program, to avoid confusion with “determinations” made by CCE and NPN physicians regarding a member’s health condition. Amendments to this section would retain and combine the substance of existing paragraphs (a), (b), and (c) into new paragraphs (a) and (b). Proposed revisions to the language concerning the 60-day deadline for the WTC Health Program’s decision would clarify that the date would be calculated in calendar days and extend the notification deadline to be no later than 60 days of receipt of the application, rather than the date of transmission of the application, which can be difficult to determine. The 60-day notification deadline would be tolled while the applicant is correcting deficiencies in the application or supporting documents. Existing paragraph (d), described below, would be removed to a new § 88.11. Existing paragraphs (e),

(f), and (g), described below, would be removed to a new § 88.12.

*Section 88.11 Initial Health Evaluation for Screening-Eligible Survivors*

A new § 88.11 comprises language formerly found in § 88.10(d). Minor amendments to this new section would include replacing “diagnoses” with “determines” to align the rule text with terms commonly used by the WTC Health Program.

In response to public comments submitted to the July 2011 IFR docket regarding these provisions,<sup>7</sup> the Administrator declines to allow a screening-eligible survivor to obtain an additional health evaluation at no cost or to specify that the cost of an additional evaluation would be the same as is paid by the WTC Health Program. The Administrator is constrained by section 3321(b)(3) of the PHS Act, which explicitly limits screening-eligible survivors to a single initial health evaluation at no cost. The member could request more than one health evaluation, but the Administrator has no legal obligation or authority to pay for subsequent health evaluations. The Administrator does not propose any substantive changes to this text.

*Section 88.12 Enrollment Decision—Certified-Eligible Survivors*

A new § 88.12 would comprise the former § 88.10(e), describing certification determinations; § 88.10(f), describing denials of certification; and § 88.10(g), describing notification of the certified-eligible survivor status decision. The new title would clarify that enrollment “decisions” are made by the WTC Health Program, to avoid confusion with “determinations” made by CCE or NPN physicians regarding a member’s health condition. Proposed amendments to this new section would include removing redundant language and clarifying certification status language. Existing language in § 88.10(e) states that “[i]f the individual’s condition is certified as a WTC-related health condition, the individual will also be certified as a certified-eligible survivor.” The use of “also” may incorrectly suggest the WTC Health Program member retains two statuses, as both a screening-eligible and a certified-eligible survivor, simultaneously. Amendments would clarify that if the Program member’s condition is certified as a WTC-related health condition, the member’s status will automatically change to that of a certified-eligible survivor. The Administrator does not

propose any substantive changes to this text.

*Section 88.13 Disenrollment*

The Administrator proposes to add a new section to Part 88 to clarify the process for disenrolling a member from the WTC Health Program. To date, only 12 enrolled members have been found to have been wrongly enrolled due to Program error or inaccurate eligibility information. Allowing individuals who do not meet WTC Health Program enrollment eligibility criteria to stay in the Program may result in those individuals improperly receiving medical benefits. Moreover, individuals who are erroneously enrolled may fill the statutory limits on the number of WTC responders and certified-eligible survivors enrolled in the WTC Health Program,<sup>8</sup> thereby preventing qualified individuals from enrolling.

Pursuant to this section, a WTC Health Program member enrolled pursuant to § 88.4 or § 88.8 may be disenrolled if the member did not provide sufficient proof of eligibility and was mistakenly enrolled in the Program, or the member’s location, activities, and/or duration are inconsistent with the eligibility criteria for newly enrolled WTC responders or screening-eligible survivors; additionally, a member may be disenrolled if his or her enrollment was based on inaccurate or fraudulent information. A member may be disenrolled following a periodic audit conducted by the Program to ensure that enrollment decisions are proper or when the Program is made aware of new information that would impact the enrollment decision. A member could also choose to disenroll from the Program at his or her own discretion.

A member who has been disenrolled from the WTC Health Program would be notified in writing of the disenrollment decision and given the opportunity to appeal that decision, within 90 days of the date of the Administrator’s notification letter, in accordance with § 88.14. Finally, a member who is disenrolled may reapply for enrollment in the WTC Health Program if new information is available to support the application.

*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 to an applicant or disenroll a Program member. The Administrator proposes to amend the section heading from

<sup>7</sup> NIOSH Docket 235, CDC–2011–0009.

<sup>8</sup> See PHS Act, secs. 3311(a)(4) and 3321(a)(3).

“Appeals regarding eligibility determinations—responders and survivors” to “Appeal of enrollment or disenrollment decision,” to provide greater clarity.

The Administrator has identified the need to make substantive amendments to this existing section due to other proposed revisions in this notice and in response to public comment on the July 2011 IFR.<sup>9</sup> Commenters asserted that the existing 60-day deadline for filing an appeal of an enrollment denial is too short and requested that applicants be given from 180 days to a year to file an appeal. The Administrator agrees that the current requirement that an applicant file an appeal within 60 days of the date on the notification letter explaining the enrollment denial may not provide enough time for the applicant to gather necessary documentation or other information for the appeal. Therefore, the Administrator proposes amendments to this section to permit consideration of a denied applicant’s appeal letter that is postmarked<sup>10</sup> within 90 calendar days of the date of the Administrator’s denial notification letter. The Administrator similarly finds that allowing 90 days for submission of an appeal request subsequent to a disenrollment of a Program member should allow ample time for a disenrolled Program member to gather any necessary information. However, the Administrator requests further public comment on the appropriateness of allowing 90 days for appeal of a disenrollment decision.

The Administrator also proposes to amend this section to recognize appeals of a WTC Health Program decision to disenroll a Program member, as described in the proposed new disenrollment provisions in § 88.13.

Because of the reorganization of this part, the current number of this section, § 88.11, would be changed to § 88.14. Existing paragraph (b) would be redesignated paragraph (c). New language for paragraph (b) would establish the appeal request process and mirror the appeal process for certification, decertification, and treatment authorization decisions in § 88.21. The new language would specify that an appeal request must be made in writing, identify the denied applicant or disenrolled Program member and the designated representative, if any, and state the reasons why the WTC Health Program’s

action was incorrect and should be reversed. As currently permitted, the appeal request may include relevant new information not previously considered by the Program. Existing paragraph (c), which allows the Administrator to reopen and reconsider an enrollment denial, would be removed from this section and placed in a new section, § 88.25 described below, regarding reopenings generally. A new paragraph (c) would describe the appeal process, which would consist of the appointment of a Federal Official, who will be an HHS employee independent of the WTC Health Program, to review the case and submit a recommendation to the Administrator.

Finally, a new paragraph (d) would change the existing appeal process to result in the Federal Official making a recommendation to the Administrator, who would then make a final decision on the appeal. This paragraph would also clarify that the Administrator will share the results of the Federal Official’s review and any administrative actions taken by the WTC Health Program with the denied applicant, disenrolled Program member, or designated representative who filed the appeal. The Administrator declines to offer a deadline for the final decision on an enrollment appeal, as requested by public comment on the July 2011 IFR.<sup>11</sup> Given the potentially complex nature of appeals decisions, the Administrator is concerned that limiting the amount of time available to the Federal Official and/or the Administrator to review the denied applicant’s or disenrolled Program member’s file (including any new information submitted) could result in undue burden on the Federal Official and/or Program staff and not allow for a thorough review of the appeal. In the Program’s experience, final decisions on enrollment appeals typically occur within 45 days of receipt of the applicant’s appeal request.

#### *Section 88.15 List of WTC-Related Health Conditions*

This new section contains the health conditions enumerated in the PHS Act at sections 3312(a)(3) and 3322(b) as well as those additional WTC-related health conditions promulgated through rulemaking by the Administrator.<sup>12</sup> The Administrator proposes moving the List of WTC-related health conditions from § 88.1, the definitions section, to a new § 88.15 in order to better clarify and emphasize for stakeholders the conditions that are covered by the WTC Health Program. The Administrator also

proposes to capitalize the section title as well as the name “List of WTC-Related Health Conditions,” as it appears throughout Part 88, to reflect the terminology commonly used in most Program publications. The health conditions that would be included in this new section are the same health conditions named in the definition, “List of WTC-related health conditions” currently found in § 88.1. The reference to “interstitial lung disease” in paragraph (a)(1) should be plural and would be corrected in this action, the reference to “upper airway hyperreactivity” in paragraph (a)(7) is misspelled in the current regulation and would be corrected in this action, and the acronym “PTSD” would be added to the existing WTC-related health condition, “Posttraumatic stress disorder” in (b)(1).

The definition of “WTC-related musculoskeletal disorder,” also currently found in § 88.1, would be incorporated into paragraph (c) of the new § 88.15. No other substantive changes to the rule text regarding the List are proposed.

In response to the July 2011 IFR, one commenter requested that ‘musculoskeletal disorders’ be available to survivors for certification.<sup>13</sup> The PHS Act limits the coverage of musculoskeletal disorders to responders to the terrorist attacks in New York City. The same commenter requested the addition of “developmental disorders and any disorder linked specifically to children’s WTC exposures, including those that occurred in utero.” Individuals who were children at the time of the terrorist attacks may be considered survivors if they meet the eligibility criteria for screening- or certified-eligible survivors. Health conditions cannot be added to the List without rulemaking, supported by scientific or medical evidence, pursuant to the PHS Act and procedures established under Part 88 for adding new WTC-related health conditions to the List.

Public comments submitted to the docket for the February 2014 IFR (clarifying the definition of “childhood cancers” and revising the definition of “rare cancers”) relevant to this section<sup>14</sup> are addressed here, including questions regarding the availability of a list of rare cancers identified by the Program, and requests that the WTC Health Program reach out to members who were denied certification of brain and pancreatic cancers prior to

<sup>9</sup> NIOSH Docket 235, CDC–2011–0009.

<sup>10</sup> For appeal letters submitted electronically via fax or email, the date of the electronic transmission is understood to be the date the letter is ‘postmarked.’

<sup>11</sup> NIOSH Docket 235, CDC–2011–0009.

<sup>12</sup> See *supra* note 5.

<sup>13</sup> NIOSH Docket 235, CDC–2011–0009.

<sup>14</sup> NIOSH Docket 268, CDC–2014–0004.

publication of the February 2014 IFR.<sup>15</sup> The WTC Health Program published a list of the cancers considered rare on the Policies & Procedures Web page;<sup>16</sup> the full list of cancer types covered by the Program is found on the List of WTC-Related Health Conditions. Further, when a new health condition is added to the List or when WTC Health Program policy regarding a condition on the List changes, it is Program practice to communicate directly with members or their CCE or NPN regarding conditions previously denied certification, to determine if the condition should be re-evaluated for certification. No amendments to the List are proposed in response to public comment.

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

A new § 88.16 would comprise language formerly found in § 88.17. This section establishes the process for adding a new health condition to the List of WTC-Related Health Conditions in § 88.15. The Administrator has determined that these existing provisions should be revised to clarify the circumstances under which the Administrator is required to consider a new submission requesting the addition of a health condition that has been previously considered. Amending this section would promote administrative efficiency by not requiring WTC Health Program staff to devote time to reviewing and responding to a submission that, in substance, was already considered.

The Administrator proposes to change the number of this existing section from § 88.17 to § 88.16. The Administrator further proposes minor amendments to clarify that the List would be moved to § 88.15 and to replace “determination” with “decision,” as explained above. Paragraph (a) describes the criteria for a valid petition, including the following: An explicit statement of an intent to petition; the name, contact information, and signature of the petitioning party; the name and/or description of the condition(s) to be added; and the 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. The paragraph would be amended to clarify that the Administrator accepts all submissions from interested parties and then evaluates the submissions to decide whether they are valid petitions. Paragraph (a)(1) would be amended slightly to clarify in paragraph (a)(1)(i) that the petition must state an intent to petition the Administrator to add a health condition to the List. Paragraph (a)(1)(ii) would be amended to require that the petitioner provide a signature on the petition. Requiring a signature aligns the regulation with the petition form offered by the Program, which requires that the petitioner provide a signature. Paragraph (a)(1)(iii) would be amended to indicate that a petitioner may include either the name “and/or” a description of the petitioned health condition.

Paragraph (a)(2) would be amended to state that the Administrator will take one of the available actions within 90 calendar days after receipt of a valid petition, including requesting a recommendation from the WTC Health Program Scientific/Technical Advisory Committee (STAC) or publishing a notice in the **Federal Register**. The window for administrative action following receipt of a petition was extended from 60 to 90 days in the recent amendments to the PHS Act.<sup>17</sup> Each petition and corresponding **Federal Register** notice is published on the WTC Health Program Web site.

Existing paragraph (a)(3) would be redesignated (a)(4), and new text in paragraph (a)(3) would allow the 90-day deadline to be tolled while the Administrator seeks more information from the interested party regarding an unclear submission.

Because of the preceding change, existing paragraph (a)(4) is redesignated (a)(5), and proposed amendments would clarify the handling of a submission that requests the addition of a health condition previously evaluated for addition to the List by the WTC Health Program. In such a case, if the submission does not include a new medical basis for an association between the health condition and 9/11 exposures and is received after the publication of a response to an earlier petition in the **Federal Register**, then the submission would not be considered a valid petition and would not be answered in the **Federal Register**. The submitter would

be provided an explanation of the Program’s decision in writing.

The Administrator proposes to amend paragraph (b) to identify the proposed new location of the List of WTC-Related Health Conditions as a separate section in Part 88. Other amendments to paragraph (b) would incorporate additional PHS Act amendments extending the respective deadlines for the submission of the STAC’s recommendation, when requested, and the subsequent publication of the Administrator’s decision from 60 to 90 calendar days.<sup>18</sup> Paragraph (b)(1) would be amended to update those deadlines and clarify that all deadlines will be calculated in terms of calendar days. A new paragraph (b)(2) would reflect the recent amendments to the PHS Act requiring the Administrator to provide for an independent peer review of the scientific and technical evidence that would be the basis for adding a health condition to the List.<sup>19</sup>

#### *Section 88.17 Physician’s Determination of WTC-Related Health Conditions*

A new § 88.17 would comprise language formerly found in § 88.12. This section establishes the basis for a CCE or NPN-affiliated physician’s determination that a WTC Health Program member has a health condition that can be certified and covered by the WTC Health Program.

The Administrator finds it important to clarify the statutory standard for a physician’s determination that a health condition is WTC-related or medically associated with a WTC-related health condition. The language of this existing section requires simply that a physician communicate the “basis for the diagnosis” to the WTC Health Program; the Program then decides whether to certify the health condition for treatment. The Administrator proposes to amend this section to incorporate statutory language requiring that the basis for a physician’s determination be a finding that 9/11 exposure is “substantially likely” to be a “significant factor in aggravating, contributing to, or causing the illness or health condition.” Although the WTC Health Program has not documented any problems with interpretation of the existing rule text, the Administrator thinks that inclusion of the statutory standard would clarify for stakeholders what the physician is required to establish before requesting certification of a health condition or medically associated health condition. This

<sup>15</sup> This interim final rule amended the List of WTC-Related Health Conditions to reverse the policy of considering cancers of the brain and the pancreas ineligible for Program coverage, clarified the definition of “childhood cancers,” and revised the definition of “rare cancers” (79 FR 9100). As a result of the IFR, cancer of the brain, the pancreas, the testes, and invasive cervical cancer are considered eligible for coverage in the Program.

<sup>16</sup> See John Howard, Administrator of the WTC Health Program, *Rare Cancers*, May 5, 2014, [http://www.cdc.gov/wtc/pdfs/WTCHP\\_PP\\_RareCancers05052014.pdf](http://www.cdc.gov/wtc/pdfs/WTCHP_PP_RareCancers05052014.pdf).

<sup>17</sup> See Public Law 111–347, as amended by Public Law 114–113, PHS Act, sec. 3312(a)(6)(B)–(C).

<sup>18</sup> PHS Act, sec. 3312(a)(6)(C).

<sup>19</sup> PHS Act, sec. 3312(a)(6)(F).

amendment would have no impact on the Program or its members.

Because of proposed amendments to earlier sections, the original number of this section, § 88.12, would be changed to § 88.17. “Shall” would be replaced with “must.”

Public comments submitted to the July 2011 IFR docket on this section<sup>20</sup> included a request to specify that a physician’s determination must be transmitted to the Administrator “promptly, but in no case longer than 30 days from the initial clinical visit.” The Administrator declines to establish such a deadline because doing so may unduly burden the physician. No amendments to this section are proposed in response to comments. Physician determinations and certification requests are typically submitted to the WTC Health Program within 60 days of the completion of the member’s examination and/or record review.

#### *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. The Administrator has identified the need to amend this section to make necessary clarifications and respond to public comment.

The Administrator proposes to change the number of this existing section from § 88.13 to § 88.18, and to change the title from “WTC Program Administrator’s certification of health conditions” to “Certification.”

The section would also be amended to include the statutory 60-day deadline for the Program’s decision on whether to certify a health condition as medically associated with a WTC-related health condition,<sup>21</sup> as requested by commenters. Specifically, the proposed amendment to paragraph (b) would specify that the Program will notify the WTC Health Program member in writing of the certification decision within 60 calendar days of the date the physician’s determination is received.

The language in existing paragraph (c) concerning authorization of treatment pending certification would be removed to a new § 88.20. Language in existing paragraphs (a)(2) and (b)(2) concerning

the right to appeal a denial of certification would be consolidated in paragraph (c).

Public comments submitted to the July 2011 IFR docket on this section<sup>22</sup> included concerns about the use of physician panels for the review of health conditions medically associated with WTC-related health conditions, as authorized in the PHS Act and included in paragraph (b). Commenters asserted that the use of the physician panel identified in the rule text is mandatory, that the empaneled physicians should be board certified, and that the Administrator should publicize the qualification criteria for such a panel as well as the names and credentials of empaneled physicians. Finally, commenters asserted that input on panel selection should be sought from the “community,” including recommendations from the CCEs, Data Centers, and Steering Committees.

The Administrator interprets the statutory language in section 3312(b)(2)(B) of the PHS Act to require the establishment of procedures governing the use of such a panel. The Administrator finds that in many cases, certification of a medically associated health condition is clearly supported, making panel review unnecessary. The addition of unnecessary administrative layers may delay a decision; therefore, the Administrator declines to make panel review mandatory. Any physician panel members would be chosen for their medical or scientific expertise at the sole discretion of the Administrator.

Commenters also suggested a deadline for certification decisions and recommended that decisions be made within 30 days of the Administrator’s receipt of the physicians’ determination and request for certification. Although the Administrator declines to set a 30-day deadline for WTC Health Program certification decisions, he is committed to rendering this decision in a timely manner. WTC Health Program members are typically notified of Program decisions within approximately a month of receipt of a physician’s determination.

One commenter expressed concern that on-going treatment for a certified condition should not require re-certification each time treatment is necessary. The Administrator agrees. WTC Health Program physicians are not required to request re-certification for on-going treatment of a certified WTC-related health condition.

Finally, one commenter requested that notification regarding a certification decision by the Administrator should be

made by certified mail, return receipt requested, and by email where such contact information is available. Although the Administrator generally agrees that notification of any certification decisions made pursuant to this section should be sent by certified mail, he declines to specify in the rule text the mode of transmission, finding the detail potentially detrimental to Program flexibility. He also declines to send notifications by email because receiving more than one notification may be confusing and email notifications do not ensure the protection of private health information.

#### *Section 88.19 Decertification*

Similar to the issue of disenrollment, the Administrator has also identified a need for the WTC Health Program to clarify the process for decertification of a WTC-related health condition or health condition medically associated with a WTC-related health condition. Circumstances that would lead to decertification would be limited to those where the condition was certified in error, such as where the WTC Health Program member’s 9/11 exposure is later found to be insufficient; the Program decides that the physician erroneously found that the member’s 9/11 exposures were substantially likely to be a significant factor in aggravating, contributing to, or causing the health condition; or the Program decides the health condition was erroneously certified as medically associated with a WTC-related health condition. Such concerns may be discovered during routine audit of enrollment decisions. Allowing a health condition to remain certified in error may result in WTC Health Program members receiving treatment for conditions that were not associated with their 9/11-related exposures, leading to inappropriate use of Program services and dollars. The WTC Health Program member would be notified of the decision to decertify the health condition and given an opportunity to appeal the Program’s decertification decision.

#### *Section 88.20 Authorization of Treatment*

Amendments to the existing section titled “Standard for determining medical necessity” would clarify the WTC Health Program’s treatment authorization process. A new paragraph (a) would describe the provision of medically necessary treatment in accordance with applicable Program protocols and policies and procedures.

Paragraph (b) would incorporate the existing standard for determining whether the treatment for a WTC-related

<sup>20</sup> NIOSH Docket 235, CDC–2011–0009.

<sup>21</sup> See PHS Act, sec. 3312(b)(2)(B)(ii).

<sup>22</sup> NIOSH Docket 235, CDC–2011–0009.

health condition or a health condition medically associated with a WTC-related health condition is medically necessary. The Administrator finds it important to clarify that the medical treatment protocols<sup>23</sup> are developed by the Data Centers, with input from the CCEs.

The Administrator proposes to amend the original number of this section, § 88.14, to § 88.20, and change the title to "Authorization of treatment." The Administrator further proposes to replace "WTC Program Administrator" with "Administrator of the WTC Health Program."

Public comments submitted to the July 2011 IFR docket on this section<sup>24</sup> included a request that the Administrator create a mechanism by which additional treatment modalities, including alternative therapies not presently part of the existing treatment protocols, would be considered for addition to those existing protocols deemed medically necessary. The Program routinely considers and discusses proposals for new treatment modalities with the CCEs and NPN and reviews available scientific evidence from authoritative bodies to support the inclusion of the proposed treatment modalities.

A new paragraph (c) would incorporate existing language in § 88.13(c) regarding treatment pending certification.

#### *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. Based on Program administrative experience and in response to public comments on the July 2011 IFR,<sup>25</sup> the Administrator has found a need to revise the existing health condition certification and treatment appeals section. Providing more clarity regarding the appeal

process will benefit WTC Health Program members and help address concerns raised by commenters asking that the appeal process be more member-friendly. In particular, stakeholders requested that a member be allowed to submit new evidence in support of his or her appeal and interact with the Federal Official reviewing the case.

The Administrator proposes to change the number of this existing section from § 88.15 to § 88.21 and change the section name from "Appeals regarding treatment" to "Appeal of certification, decertification, or treatment authorization decision."

The Administrator proposes to include in paragraph (a)(3) a right of appeal for a WTC Health Program member for whom the Program has decided to decertify a WTC-related health condition or health condition medically associated with a WTC-related health condition, pursuant to proposed language in § 88.19. Members would still be allowed the right to appeal WTC Health Program decisions not to certify a health condition as WTC-related; not to certify a health condition as medically associated with a WTC-related health condition; or to deny treatment authorization for a certified WTC-related health condition or medically associated condition because the treatment is not deemed medically necessary.

Public comments on the July 2011 IFR<sup>26</sup> asked that the Administrator allow the member to appeal a decision made by a CCE or NPN-affiliated physician not to request certification of the member's health condition. Section 3312(b)(1)(A) of the PHS Act requires that a CCE [or NPN-affiliated] physician make a determination regarding the health condition before the WTC Health Program can decide whether to certify the health condition as WTC-related. In accordance with WTC Health Program policies and procedures, a Program member may request a secondary review of the physician's decision not to seek certification of a condition as a WTC-related or medically associated health condition.<sup>27</sup>

Commenters also asked the Administrator to allow the member's physician or CCE medical director to represent the responder or survivor in

the appeal, or give the physician the right to appeal the Administrator's certification denial directly. The Administrator declines to allow a CCE or NPN medical director, provider, or staff to represent a member in an appeal because doing so may create a conflict of interest for the medical director, provider, or staff. The Administrator also declines to allow the physician to appeal the certification denial directly; if the physician believes that the Administrator has denied a certification in error, the physician may re-submit the request for certification and provide additional explanation or evidence supporting the physician's determination that the health condition is WTC-related.

The Administrator proposes to amend paragraph (b)(1) to clarify that the appeal process begins when the member or member's designated representative sends a signed letter, either submitted in hard copy or scanned and submitted electronically, to the Administrator requesting the appeal. In response to public comment, the Administrator also proposes to extend the amount of time for filing an appeal from 60 to 90 calendar days from the date of the letter to the member notifying them of the WTC Health Program's adverse decision.

As in the current rule, the appeal request letter must describe the reasons the WTC Health Program's decision is incorrect and should be reversed. For example, the member could argue for reversal on the grounds that factual errors were contained in the scientific or medical information submitted to the Program by the CCE or NPN physician; the Program failed to correctly follow or apply relevant Program policies or procedures; or the Program's decision was unreasonable as applied to the facts of the case. Any basis provided in the appeal request must be sufficiently detailed and supported by information to permit review of the appeal. The Administrator agrees with commenters that the member may have additional relevant information that was not available to the member, the determining physician, or the Program at the time of the decision not to certify the health condition, decertify the condition, or not to authorize treatment. Accordingly, the Administrator now proposes to allow the member or designated representative to submit new information with the appeal request or at a later date, if requested by the Program.

The Administrator proposes to amend portions of the section to clarify the appeal review process and incorporate procedures the WTC Health Program

<sup>23</sup> See *Policy and Procedure Manual for the WTC Health Program*, Jan. 1, 2015, Chapter 4: Medical Benefits, Section 4: Covered Medical Services, Part B: Medically Necessary Treatment, <http://www.cdc.gov/wtc/ppm.html#4d>. Program communications sometimes also refer to medical treatment protocols as "medical guidelines."

<sup>24</sup> NIOSH Docket 235, CDC-2011-0009.

<sup>25</sup> NIOSH Docket 235, CDC-2011-0009.

<sup>26</sup> NIOSH Docket 235, CDC-2011-0009.

<sup>27</sup> See *Policy and Procedure Manual for the WTC Health Program*, Jan. 1, 2015, Chapter 3: Certification of Health Conditions, Section 5: CCE/NPN Physician Determination and Request for Certification of Health Conditions, Part B: Secondary Review of Negative Physician Determination, <http://www.cdc.gov/wtc/ppm.html#3e>.

has outlined elsewhere.<sup>28</sup> As requested by commenters, the Administrator proposes new paragraph (b)(3) to codify the WTC Health Program's current process allowing the Program member or the member's designated representative the opportunity to make a 15-minute oral statement by telephone.<sup>29</sup> A transcript of the oral statement is included in the record and provided to the Program member and/or the member's designated representative. The Administrator finds that more formal hearings would be administratively burdensome, divert Program resources away from patient care, and be of little benefit to the member.

Finally, the Administrator proposes to amend paragraph (c) to clarify that after receipt of the appeal request, the Administrator assigns an independent Federal Official to review the case and the WTC Health Program's decision not to certify the health condition or medically associated condition, to decertify, or not to authorize treatment. The Federal Official decides whether to recommend granting the appeal by considering whether the WTC Health Program substantially complied with all relevant Program policies and procedures; whether the information supporting the Program's decision was factually accurate; and whether the Program's decision was reasonable as applied to the facts of the case.

Proposed paragraph (c)(1) would clarify that 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 any additional relevant new information submitted with the appeal request or provided at the request of the WTC Health Program. As established in paragraph (b)(2) of the current rule, proposed paragraph (c)(2) would state that the Federal Official may consult one or more qualified experts; amendments to this paragraph would permit any experts consulted to review the WTC Health Program's adverse decision and the Program member's records as well as any new information provided by the member during the appeal. As described in proposed paragraph (c)(3), the Federal Official

will submit his or her recommendation to the Administrator. The recommendation would include the Federal Official's recommendation and findings regarding the disposition of the appeal and any relevant supporting materials, including the transcript of any oral statement and the findings of any experts. One commenter asserted that some of the experts must be unaffiliated with the Federal government to prevent bias and that community input should be obtained for the selection of experts, including from the WTC Health Program survivor and responder steering committees and CCEs. The Administrator declines to adopt this suggestion and notes that relevant expertise is likely to be related to exposure assessments and medical findings. Further, the Federal Official may consult one or more expert reviewers when deemed necessary; the use of expert reviewers may not always be beneficial and could result in administrative burden and delay.

The Administrator proposes to further revise the section by adding paragraph (d), which would recharacterize the outcome of the Federal Official's review of the appeal as a recommendation to be provided to the Administrator. In the final step of the appeal process, the Administrator would review the Federal Official's recommendation and supporting materials and make a final decision regarding the certification, decertification, or treatment authorization decision being appealed. The Administrator would notify the member and/or the member's designated representative of the Federal Official's findings and recommendation, the Administrator's final decision, and provide an explanation of the decision and any administrative actions taken by the WTC Health Program in response to the final decision. The Administrator declines to adopt a deadline for notification of a final appeal decision, as requested by public comment on the July 2011 IFR.<sup>30</sup> Given the potentially complex nature of appeals decisions, the Administrator is concerned that limiting the amount of time available to the Federal Official and/or the Administrator to review the Program member's file (including any new information submitted) could result in undue burden and prevent a thorough review of the appeal.

Finally, for administrative clarity, the Administrator proposes striking existing paragraph (c), which allows the Administrator to reopen final decisions, and moving the text from this section to a new section § 88.25.

#### *Section 88.22 Reimbursement for Medical Treatment and Services*

A new § 88.22 would comprise language formerly found in § 88.16. This section establishes how the WTC Health Program will reimburse or pay for the cost of monitoring, initial health evaluations, medical treatment, and outpatient prescription pharmaceuticals.

The Administrator proposes to change the number of this existing section from § 88.16 to § 88.22, and to move provisions regarding travel expenses, unchanged, out of this section and into § 88.2, General provisions (*see above*). The existing language would be rearranged slightly. Existing paragraph (c)(1) would be redesignated as paragraph (a) to clarify that each reimbursement or payment claim is reviewed by the WTC Health Program and that claims that cannot be validated will be further assessed by the Administrator. Paragraph (b)(1) would consolidate existing language about reimbursement for costs associated with initial health evaluations, medical monitoring, and medically necessary treatment, and also correct the reference to regulations implementing the Federal Employees Compensation Act (FECA), 20 CFR part 10. New text in paragraph (b)(1)(ii) would clarify that treatment for which rates have not been established under either FECA or Medicare fee for service rate schedules, such as dental services, is reimbursed at rates set by the Administrator.<sup>31</sup> Language would be added to paragraph (b)(2) to clarify that the Administrator may withhold reimbursement if the treatment is inconsistent with WTC Health Program protocols, pursuant to language in section 3312(c)(3) of the PHS Act.

Paragraph (c) would include language from existing paragraph (a)(2). The term "pharmaceutical providers" would be replaced with "pharmaceutical benefit management services."

#### *Section 88.23 Appeal of Reimbursement Denial*

The Administrator has determined that the right of a CCE or NPN medical director or affiliated provider to appeal a WTC Health Program decision not to authorize reimbursement or payment for treatment should be included in Part 88 for clarity and completeness. This appeal right is established in section 3312(b)(3)(B) of the PHS Act, which calls on the Administrator to establish a

<sup>28</sup> See WTC Health Program: Appeals Process, Overview of the Appeal Process For Denial of Health Condition Certification, [http://www.cdc.gov/wtc/appeals\\_condition.html](http://www.cdc.gov/wtc/appeals_condition.html). The 15-minute oral statement allows the member to present his or her case to the Federal Official assigned to review the case; however, the member is not permitted to present witnesses and the Federal Official does not issue a ruling at the conclusion of the oral statement.

<sup>29</sup> See *id.*

<sup>30</sup> NIOSH Docket 235, CDC-2011-0009.

<sup>31</sup> Rates for dental services are available in the *Policy and Procedure Manual for the WTC Health Program*, Jan. 1, 2015, Chapter 4: Medical Benefits, Section 28: Medically Necessary Dental Care, <http://www.cdc.gov/wtc/ppm.html>.

process for appeal of a determination under section 3312(c)(3). Section 3312(c)(3) authorizes the WTC Health Program to withhold reimbursement or payment for treatment provided when it determines the treatment is not medically necessary or is not in accordance with medical treatment protocols.

Accordingly, the Administrator proposes to establish an appeal process in § 88.23 to allow the CCE or NPN medical director or affiliated provider to appeal such decisions where all contractual or procedural remedies have been exhausted. Appeals of WTC Health Program decisions to not authorize reimbursement or payment for treatment would be made in accordance with Program policies and procedures published on the Program Web site.

#### *Section 88.24 Coordination of Benefits and Recoupment*

The Administrator proposes to add a new section to address the matter of coordination of benefits, including recoupment from workers' compensation settlements. Pursuant to section 3331 of the PHS Act, this section would explain that the WTC Health Program attempts to recover the costs associated with treatment, including pharmacy benefits, for a member's certified WTC-related health condition or medically associated health condition in certain situations. As directed by the Act, the WTC Health Program coordinates benefits with any workers' compensation insurance available<sup>32</sup> for members' work-related<sup>33</sup> conditions, and with any public or private health insurance available for members' non-work-related conditions.

Proposed paragraph (a) would describe circumstances in which the WTC Health Program member is eligible

<sup>32</sup>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.

<sup>33</sup>The term "work-related" is defined in sec. 3331(e) of the PHS Act to mean: "(1) the condition is diagnosed in an enrolled WTC responder, or in an individual who qualifies as a certified-eligible WTC survivor on the basis of being a rescue, recovery, or cleanup worker; or (2) with respect to the condition the individual has filed and had [sic] established a claim under a workers' compensation law or plan of the United States or a State, or other work-related injury or illness benefit plan of the employer of such individual."

for workers' compensation or another illness or injury benefit plan to which New York City is obligated to pay.

Proposed paragraph (b) would describe circumstances in which the WTC Health Program member has filed a workers' compensation claim but the claim is still pending acceptance by the workers' compensation board.

Proposed paragraph (c) would describe circumstances in which the WTC Health Program member has filed a workers' compensation claim but a final decision is issued denying coverage for medical treatment of the condition.

Proposed paragraph (d) would describe circumstances in which the WTC Health Program member has filed a successful claim for a certified WTC-related health condition or medically associated health condition with a workers' compensation plan to which New York City is not obligated to pay. In this case, the WTC Health Program recoups costs for treatment from the workers' compensation insurer. As described in proposed paragraph (d)(1), if the WTC Health Program member settles the workers' compensation claim by entering into a settlement agreement that releases the employer or insurance carrier from paying for future medical care, the agreement must protect the WTC Health Program's interests regarding future medical expenses that might otherwise have been paid for by the workers' compensation insurance.<sup>34</sup> If the WTC Health Program member has accepted a lump sum or other payment award for future medical care, the WTC Health Program may require the member to reimburse the Program for treatment services provided after receipt of the award. Proposed paragraph (d)(2) would also clarify that the WTC Health Program pays providers for treatment in accordance with the rates recognized under § 88.22(b) of this part, but recoups at the worker's compensation rate, if lower than the WTC Health Program rates.

Proposed paragraph (e) would describe circumstances in which the WTC Health Program member's certified health condition is not work-related and the member's public or private health insurance plan is the primary payer. In such cases, the WTC Health Program pays costs not reimbursed by the public or private health insurance plan due to the application of deductibles, co-payments, co-insurance, other cost

<sup>34</sup>*Policy and Procedures for Recoupment: Lump-Sum Workers' Compensation Settlements*, addressing the adequacy of settlement agreements to protect the WTC Health Program's interests, is found on the Program's Policies and Procedures Web page, at <http://www.cdc.gov/wtc/policies.html>.

sharing arrangements, or payment caps up to and in accordance with the rates described in § 88.22(b) of this part.<sup>35</sup>

Finally, proposed paragraph (f) would describe how the WTC Health Program handles situations that are not specifically covered by proposed paragraphs (a)–(e) described above and refers interested parties to the Program policies and procedures<sup>36</sup> for further guidance.

#### *Section 88.25 Reopening of WTC Health Program Final Decisions*

As discussed above, the Administrator proposes the creation of a new section to clarify the Administrator's authority to reopen any final decisions made by the WTC Health Program, including those concerning enrollment, health condition certification, and appeals. At any time, and without regard to whether new evidence or information is provided or obtained, the Administrator may reopen a final decision and may affirm, vacate, or modify such decision, or take any other action he or she deems appropriate. Such reopenings may be necessary to address administrative errors or to incorporate or address changes in Program eligibility criteria, regulations, or policies and procedures. This authority is currently described in the two existing appeals sections, at §§ 88.11(c) and 88.15(c); for clarity and to aid administrative decision-making, the Administrator intends to consolidate the authority into one section.

### **V. Regulatory Assessment Requirements**

#### *A. Executive Order 12866 and Executive Order 13563*

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, 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 proposed rule has been determined not to be a "significant regulatory action" under section 3(f) of Executive Order 12866. With this action, the Administrator is proposing

<sup>35</sup>PHS Act, sec. 3331(c)(1).

<sup>36</sup>Policies and procedures describing recoupment and coordination of benefits are found on the WTC Health Program's Web site at <http://www.cdc.gov/wtc/policies.html>.

amendments to certain sections in 42 CFR part 88. Non-substantive amendments would include a reorganization of provisions from the existing § 88.10 into new §§ 88.11 and 88.12 and the addition of a new § 88.15, List of WTC-Related Health Conditions. Reorganization of this part would necessitate the renumbering of existing Part 88 sections, which would be done throughout the regulatory text. The Administrator would also clarify throughout Part 88 that deadlines are calculated in terms of calendar days. An amendment to the existing section regarding the physician's determination of WTC-related health conditions would clarify that the determination must be predicated upon the statutory requirements for a WTC-related health condition. Various other minor clarifications of WTC Health Program practice would be made throughout Part 88.

New, substantive regulatory text would be added to Part 88 to define the term "WTC Health Program member," codify an existing statutory appeal right for CCEs and NPN-affiliated providers, and codify existing WTC Health Program policies regarding the disenrollment of WTC Health Program members, decertification of certified WTC-related health conditions, and coordination of benefits.

Amendments to the existing provision regarding the addition of health conditions to the List of WTC-Related Health Conditions would include the following: A valid petition must include the petitioner's signature; the statutory deadline for a response to a petition is extended from 60 to 90 calendar days and may be tolled while the Administrator seeks clarification from the interested party regarding the submission, if necessary; and the Administrator would not consider a submission to be a valid petition if it does not provide a new medical basis for the addition of the health condition and is received after the publication of a response in the **Federal Register** to a petition requesting the addition of the same health condition.

Lastly, amendments to the existing certification and treatment authorization appeals section would codify existing WTC Health Program policy and also allow for an appeal of a Program decision to decertify a WTC-related health condition.

This proposed rule does not result in substantial costs to the WTC Health Program, Program members, or stakeholders, nor does it raise any novel legal or policy issues. The Administrator finds that amendments to § 88.14 and § 88.21 (enrollment and

medical appeals) and § 88.16 (addition of health conditions) will result in necessary changes to several existing WTC Health Program policies; the proposed 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. Accordingly, this rulemaking is expected to cost the WTC Health Program approximately \$42,742.

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. 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 non-substantive changes may be needed to the information collection request already approved by OMB and that these revisions would not result in any change in respondent burden.

#### D. Small Business Regulatory Enforcement Fairness Act

As required by Congress under the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 801 *et seq.*, HHS will report the promulgation

of this rule to Congress prior to its effective date.

#### E. Unfunded Mandates Reform Act of 1995

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

#### F. Executive Order 12988 (Civil Justice)

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

#### G. Executive Order 13132 (Federalism)

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

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

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

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

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

J. Plain Writing Act of 2010

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

Proposed Rule

For the reasons discussed in the preamble, the Administrator proposes to amend 42 CFR part 88 as follows:

PART 88—WORLD TRADE CENTER HEALTH PROGRAM

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

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.

■ 2. In § 88.1, revise the definitions “Act”, “Certification”, “Certified-eligible survivor”, “Clinical Center of Excellence”, “List of World Trade Center (WTC)-related health conditions”, “Medically necessary treatment”, “Nationwide provider network”, “World Trade Center (WTC) Health Program”, “World Trade Center (WTC) Program Administrator”, “World Trade Center (WTC)-related health condition”, and “World Trade Center (WTC)-related musculoskeletal disorder”, and add “World Trade Center (WTC) Health Program member” and “World Trade Center (WTC)-related acute traumatic injury” to read as follows:

§ 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.

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.

\* \* \* \* \*

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.

\* \* \* \* \*

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 Clinical Centers of Excellence, and approved by the Administrator of the WTC Health Program.

\* \* \* \* \*

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.

\* \* \* \* \*

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.

World Trade Center (WTC) Health Program member means any responder, screening-eligible survivor, or certified-eligible survivor enrolled in the WTC Health Program.

World Trade Center (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.

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

World Trade Center (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.

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

\* \* \* \* \*

■ 3. Revise § 88.2 to read as follows:

**§ 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 a screening-eligible or certified-eligible survivor is a minor, a parent or guardian may act on his or her behalf.

(b) *Transportation and travel expenses.* The Administrator of 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.

■ 4. Amend § 88.4 to revise the section heading to read as follows:

**§ 88.4 Eligibility criteria—WTC responders.**

■ 5. Amend § 88.5 to revise the section heading to read as follows:

**§ 88.5 Application process—WTC responders.**

■ 6. Revise § 88.6 to read as follows:

**§ 88.6 Enrollment decision—WTC responders.**

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

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

(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) Applicants who meet the current eligibility criteria for WTC responders in § 88.4 and are qualified will be notified in writing by the WTC Health Program of the enrollment decision within 60 calendar days of the date of receipt of the application.

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

■ 7. Amend § 88.8 to revise the section heading to read as follows:

**§ 88.8 Eligibility criteria—WTC survivors.**

■ 8. Amend § 88.9 to revise the section heading to read as follows:

**§ 88.9 Application process—WTC survivors.**

■ 9. Revise §§ 88.10 through 88.18 to read as follows:

**§ 88.10 Enrollment decision—screening-eligible survivors.**

(a) The WTC Health Program will decide if the applicant meets the screening-eligibility criteria pursuant to § 88.8(a) and notify the applicant of the decision in writing within 60 calendar days of the date of receipt of the application. The applicant will be notified of any deficiencies in the application or the supporting documentation. 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 applicant will be notified in writing and provided an explanation for the decision to deny enrollment. The notification will 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 NPN 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) 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 90 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 90 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 (1)–(11).

- (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 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 neoplasm of the colon and rectum.
    - (8) Malignant neoplasm 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<sup>37</sup> 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 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.

<sup>37</sup> 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.

(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 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.

■ 10. Add § 88.19 to read as follows:

**§ 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.

■ 11. Add § 88.20 to read as follows:

**§ 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 Administrator of the WTC Health Program before treatment is provided, except for the provision of treatment for a medical emergency.

■ 12. Add § 88.21 to read as follows:

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

(a) 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 90 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 90 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.

■ 13. Add § 88.22 to read as follows:

**§ 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.

■ 14. Add § 88.23 to read as follows:

**§ 88.23 Appeal of reimbursement denial.**

*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

■ 14. Add § 88.23 to read as follows:

**§ 88.23 Appeal of reimbursement denial.**

*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.

■ 15. Add § 88.24 to read as follows:

**§ 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<sup>38</sup> for members' work-related health conditions, and with any public or private health insurance available<sup>39</sup> 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

<sup>38</sup> 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.

<sup>39</sup> As described in PHS Act, sec. 3331(c).

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 treatments

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.

■ 16. Add § 88.25 to read as follows:

**§ 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: July 27, 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: July 27, 2016.

**Sylvia M. Burwell,**

*Secretary, Department of Health and Human Services.*

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