

resources available for the project, the amount of grant funds necessary for completion, and for mining grant applications, the recommendations of the Mine Health Research Advisory Committee.

(c) The Secretary may evaluate and approve two or more concurrent applications, each dealing with one or more specified aspects of the project, and make two or more concurrent grant awards for the project. This may be necessary when a project involves a number of different but related problems, activities, or disciplines which would require evaluation by different groups, or when support for a project could be more effectively administered by separate handling of various aspects of the project.

§ 87.7 For what period of time will grants be awarded?

(a) The notice of grant award specifies how long the Secretary intends to support the project without requiring the project to re compete for funds. This period, called the project period, will usually be for 3-5 years.

(b) Generally, the grant will initially be for 1 year and subsequent continuation awards will also be for 1 year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of such awards will be of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by the Secretary that continued funding is in the best interest of the Federal Government.

(c) Neither the approval of any application, nor the award of any grant commits or obligates the Federal Government in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

§ 87.8 How may a grantee use grant funds?

A grantee shall only spend funds it receives under this part according to the approved application and budget, the authorizing legislation, the terms

and conditions of the grant award, the applicable cost principles specified in subpart Q of 45 CFR part 74, and the regulations of this part.

§ 87.9 Which other HHS regulations apply?

Several other regulations apply to grants under this part. These include, but are not limited to:

- 42 CFR part 50, subpart D—Public Health Service grant appeals procedure
- 45 CFR part 16—Procedures of the Departmental Grant Appeals Board
- 45 CFR part 46—Protection of human subjects
- 45 CFR part 74—Administration of grants
- 45 CFR part 75—Informal grant appeals procedures
- 45 CFR part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services effectuation of title VI of the Civil Rights Act of 1964
- 45 CFR part 81—Practice and procedure for hearing under part 80 of this Title
- 45 CFR part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefiting from Federal financial assistance
- 45 CFR part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance

[49 FR 38117, Sept. 27, 1984]

PART 88—WORLD TRADE CENTER HEALTH PROGRAM

Sec.

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

SOURCE: 76 FR 38930, July 1, 2011, unless otherwise noted.

§ 88.1 Definitions.

Act means the 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), which created the World Trade Center (WTC) Health Program.

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

Certification means review and approval by the WTC Program Administrator of a screening-eligible survivor as eligible for monitoring and treatment, or a WTC-related health condition or a health condition medically associated with a WTC-related health condition in a particular WTC responder or certified-eligible survivor for the purpose of reimbursement of expenses for medically necessary treatment.

Certified-eligible survivor means:

(1) An individual who has been identified as eligible for medical treatment and monitoring as of January 2, 2011; or

(2) A screening-eligible WTC survivor who the WTC Program Administrator certifies to be eligible for follow-up monitoring and treatment under § 88.10(f).

Clinical Center of Excellence means a center or centers under contract with

the WTC Health Program. A Clinical Center of Excellence:

(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 WTC survivors, or certified-eligible survivors;

(2) Has experience in caring for WTC responders or screening-eligible and certified-eligible WTC survivors;

(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 WTC Program Administrator.

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

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

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

(3) Coordinate the outreach activities of the corresponding Clinical Centers of Excellence;

(4) Establish criteria for credentialing of medical providers participating in the nationwide provider network;

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

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

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

Ground Zero means a site in Lower Manhattan bounded by Vesey Street to the north, the West Side Highway to the west, Liberty Street to the south,

and Church Street to the east in which stood the former World Trade Center complex.

Health condition medically associated with a World Trade Center (WTC)-related health condition means a condition that results from treatment of a WTC-related health condition or results from progression of a WTC-related health condition.

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

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

List of WTC-related health conditions means the following disorders and conditions, including any other condition added to the list through procedures specified by the Act and under this part:

- (1) Aerodigestive disorders:
 - (i) Interstitial lung disease.
 - (ii) Chronic respiratory disorder [fumes/vapors].
 - (iii) Asthma.
 - (iv) Reactive airways dysfunction syndrome [RADS].
 - (v) WTC-exacerbated chronic obstructive pulmonary disease [COPD].
 - (vi) Chronic cough syndrome.
 - (vii) Upper airway hyperactivity.
 - (viii) Chronic rhinosinusitis.
 - (ix) Chronic nasopharyngitis.
 - (x) Chronic laryngitis.
 - (xi) Gastroesophageal reflux disorder [GERD].
 - (xii) Sleep apnea exacerbated by or related to a condition described in preceding paragraphs (1)(i) through (1)(xi) of this definition.
- (2) Mental health conditions:
 - (i) Posttraumatic stress disorder.
 - (ii) Major depressive disorder.
 - (iii) Panic disorder.

- (iv) Generalized anxiety disorder.
 - (v) Anxiety disorder [not otherwise specified].
 - (vi) Depression [not otherwise specified].
 - (vii) Acute stress disorder.
 - (viii) Dysthymic disorder.
 - (ix) Adjustment disorder.
 - (x) Substance abuse.
- (3) Musculoskeletal disorders for those WTC responders who received any treatment for a World Trade Center (WTC)-related musculoskeletal disorder (as defined in this section) on or before September 11, 2003:
- (i) Low back pain.
 - (ii) Carpal tunnel syndrome [CTS].
 - (iii) Other musculoskeletal disorders.
- (4) Cancers:
- (i) Malignant neoplasms of the lip, tongue, salivary gland, floor of mouth, gum and other mouth, tonsil, oropharynx, hypopharynx, and other oral cavity and pharynx.
 - (ii) Malignant neoplasm of the nasopharynx.
 - (iii) Malignant neoplasms of the nose, nasal cavity, middle ear, and accessory sinuses.
 - (iv) Malignant neoplasm of the larynx.
 - (v) Malignant neoplasm of the esophagus.
 - (vi) Malignant neoplasm of the stomach.
 - (vii) Malignant neoplasm of the colon and rectum.
 - (viii) Malignant neoplasm of the liver and intrahepatic bile duct.
 - (ix) Malignant neoplasms of the retroperitoneum and peritoneum, omentum, and mesentery.
 - (x) Malignant neoplasms of the trachea; bronchus and lung; heart, mediastinum and pleura; and other ill-defined sites in the respiratory system and intrathoracic organs.
 - (xi) Mesothelioma.
 - (xii) Malignant neoplasms of the peripheral nerves and autonomic nervous system, and other connective and soft tissue.
 - (xiii) Malignant neoplasms of the skin (melanoma and non-melanoma), including scrotal cancer.
 - (xiv) Malignant neoplasm of the female breast.
 - (xv) Malignant neoplasm of the ovary.

(xvi) Malignant neoplasm of the prostate.

(xvii) Malignant neoplasm of the urinary bladder.

(xviii) Malignant neoplasm of the kidney.

(xix) Malignant neoplasms of the renal pelvis, ureter and other urinary organs.

(xx) Malignant neoplasms of the eye and orbit.

(xxi) Malignant neoplasm of the thyroid.

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

(xxiii) Childhood cancers: Any type of cancer diagnosed in a person less than 20 years of age.

(xxiv) Rare cancers: any type of cancer¹ that occurs in less than 15 cases per 100,000 persons per year in the United States.

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

Medically necessary treatment means the provision of services by physicians and other health care providers, 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 and approved by the WTC Program Administrator.

Monitoring means periodic physical and mental health assessment of a WTC responder or certified-eligible survivor in relation to exposure to airborne toxins, any other hazard, or any other adverse condition resulting from the September 11, 2001, terrorist attacks and which includes a medical and

exposure history, a physical examination and additional medical testing as needed for surveillance or to evaluate symptom(s) to determine whether the individual has a WTC-related health condition.

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

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

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

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

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

Pentagon site means any area of the land (consisting of approximately 280 acres) and improvements thereon, located in Arlington, Virginia, on which the Pentagon Office Building, Federal Building Number 2, the Pentagon heating and sewage treatment plants, and other related facilities are located, including various areas designated for the parking of vehicles, vehicle access, and other areas immediately adjacent to the land or improvements previously

¹Based on 2005–2009 average annual data age-adjusted to the 2000 U.S. population. See, Copeland G, Lake A, Firth R, Wohler B, Wu XC, Stroup A, Russell C, Boyuk K, Schymura M, Hofferkamp J, Kohler B (eds) [2012]. 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.

described that were affected by the terrorist-related aircraft crash on September 11, 2001; and those areas at Fort Belvoir in Fairfax County, Virginia and at the Dover Port Mortuary at Dover Air Force Base in Delaware involved in the recovery, identification, and transportation of human remains for the incident.

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

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

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

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

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

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

Terrorist watch list means the lists maintained by the Federal government

that will be utilized to screen for known terrorists.

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-300mm-61 (codifying Title I of the James Zadroga 9/11 Health and Compensation Act of 2010 (Pub. L. 111-347)), 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) Program Administrator means 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 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 conditions, is substantially likely to be a significant factor in aggravating, contributing to, or causing the illness or health condition or a mental health condition. A WTC-related health condition includes conditions on the list of WTC-related health conditions as specified in this definition for WTC responders and certified-eligible survivors, and any other condition added to the list of WTC-related health conditions through procedures specified by the Act and under this part.

World Trade Center (WTC)-related musculoskeletal disorder means 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.

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

[76 FR 38930, July 1, 2011, as amended at 77 FR 24631, Apr. 25, 2012; 77 FR 56158, Sept. 12, 2012; 77 FR 62167, Oct. 12, 2012; 78 FR 18865, Mar. 28, 2013; 78 FR 57514, Sept. 19, 2013; 79 FR 9117, Feb. 18, 2014]

§ 88.2 General provisions.

(a) Designated representative. (1) An applicant, enrolled responder, screening-eligible survivor, or certified-eligible survivor may appoint one individual to represent his or her interests under the WTC Health Program. The appointment must be in writing.

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

(3) A properly appointed representative who is recognized by the WTC Health Program may make a request or give direction to the WTC Health Program regarding the eligibility or certification determinations 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 enrolled responder, screening-eligible survivor, or certified-eligible survivor 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 and 208).

(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) [Reserved]

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§ 88.3 Eligibility—currently identified responders.

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

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

(2) [Reserved]

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

§ 88.4 Eligibility criteria—status as a WTC responder.

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

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

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

(ii) The individual is:

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

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

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

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

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

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

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

(ii) The individual was an active or retired member of the New York City Police Department or an active or retired member of the Port Authority Police of the Port Authority of New York and New Jersey who participated onsite in rescue, recovery, debris cleanup, or related support services, for at least:

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

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

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

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

(3) Office of the Chief Medical Examiner of New York City employee. The individual was an employee of the Office of the Chief Medical Examiner of New York City involved in the examination and handling of human remains from the WTC attacks, or other morgue worker who performed similar

post-September 11 functions for such Office staff, during the period beginning on September 11, 2001, and ending on July 31, 2002.

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

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

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

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

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

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

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

(2) Performed rescue, recovery, demolition, debris cleanup, or other related services at the Shanksville, Pennsylvania site of the September 11, 2001,

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terrorist attacks, for at least 1 day beginning September 11, 2001, and ending on October 3, 2001.

(d) [Reserved]

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

[76 FR 38930, July 1, 2011, as amended at 78 FR 18865, Mar. 28, 2013]

§ 88.5 Application process—status as a WTC responder.

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

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

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

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

§ 88.6 Enrollment determination—status as a WTC responder.

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

(b) The WTC Program Administrator will determine if the applicant meets the eligibility criteria provided in § 88.4 and notify the applicant in writing (or by e-mail if an e-mail address is provided by the applicant) of any deficiencies in the application or the supporting documentation.

(c) Denial of enrollment.

(1) The WTC Program Administrator will deny enrollment if the applicant fails to meet the applicable eligibility requirements.

(2) The WTC Program Administrator may deny enrollment of a responder who is otherwise eligible and qualified

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if the WTC Program Administrator determines that 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.

(A) The WTC Program Administrator may determine, 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.

(B) [Reserved]

(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 determined to be eligible for the WTC Health Program.

(d) Notification of enrollment determination.

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

(2) If the WTC Program Administrator determines that an applicant is denied enrollment, the applicant will be notified in writing and provided an explanation, as appropriate for the determination 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.

§ 88.7 Eligibility—currently identified survivors.

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

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

(2) [Reserved]

(b) Survivors identified as certified-eligible under this section are not required to submit an application to the WTC Health Program.

§ 88.8 Eligibility criteria—status as a WTC survivor.

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

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

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

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

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

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

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

(iv) The screening applicant:

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

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

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

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

(A) At any time during the period beginning on September 11, 2001, and end-

ing on May 31, 2003, was in the New York City disaster area; and

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

(2) [Reserved]

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

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

§ 88.9 Application process—status as a WTC survivor.

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

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

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

(b) *Status as a certified-eligible survivor.* No additional application is required for status as a certified-eligible survivor. If, based upon the screening-eligible survivor's initial health evaluation (see § 88.10(e)), the WTC Program Administrator certifies the diagnosis of a WTC-related health condition, then the survivor will also obtain status as a certified-eligible survivor.

§ 88.10 Enrollment determination—status as a WTC survivor.

(a) *Screening-eligible survivor status determination.* (1) The WTC Program Administrator will determine if the applicant meets the screening-eligibility criteria pursuant to § 88.8(a), and notify the applicant in writing (or by e-mail if an e-mail address is provided by the applicant) of any deficiencies in the application or the supporting documentation.

(b) *Denial of screening-eligible status.* (1) The WTC Program Administrator may deny screening-eligible status if the applicant is ineligible under the criteria specified in § 88.8(a).

(2) The WTC Program Administrator may deny screening-eligible survivor status if the numerical limitation on certified-eligible survivors in § 88.10(f)(2) 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.

(c) *Notification of screening-eligible status determination.* (1) An individual who applies under the eligibility criteria in § 88.8(a) will be notified of his or her status as a screening-eligible survivor within 60 days of the date of transmission of the application.

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

(d) *Initial health evaluation for screening-eligible survivors.* (1) A WTC Health Program Clinical Center of Excellence

or a member of the nationwide network provider will provide the screening-eligible survivor an initial health evaluation to determine if the individual has a WTC-related health condition and is eligible for follow-up monitoring and treatment benefits under the WTC Health Program.

(2) 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.

(3) If the physician diagnoses the screening-eligible survivor with a WTC-related health condition, the physician shall promptly transmit to the WTC Program Administrator his or her determination, consistent with the requirements of § 88.12(a).

(e) *Certified-eligible survivor status determination.* (1) The WTC Program Administrator will prioritize certifications in the order in which they are received.

(2) The WTC Program Administrator will review the physician's determination, render a decision regarding certification of the individual's diagnosed WTC-related health condition, and provide written notice of the decision and the reason for the decision.

(3) If the individual's condition is certified as a WTC-related health condition, the individual will also be certified as a certified-eligible survivor.

(f) *Denial of certified-eligible survivor status.* (1) The WTC Program Administrator will deny certified-eligible status if he or she determines that the screening-eligible survivor does not have a WTC-related health condition as determined pursuant to §§ 88.12 and 88.13 of this part.

(2) The WTC Program Administrator may deny certified-eligible survivor status of an otherwise eligible and qualified screening-eligible survivor if the WTC Program Administrator determines that 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 of this part, may be determined to certified-eligible survivors at any time.

(A) The WTC Program Administrator may determine, 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.

(B) [Reserved]

(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 a certified-eligible survivor in the WTC Health Program.

(g) *Notification of certified-eligible status determination.* (1) An individual who is certified by the WTC Program Administrator as a certified-eligible survivor will be notified in writing by the WTC Program Administrator.

(2) If the WTC Program Administrator denies certification of the screening-eligible survivor's health condition, the screening-eligible survivor may appeal the WTC Program Administrator's decision to deny certification, as provided under § 88.15.

§ 88.11 Appeals regarding eligibility determinations—responders and survivors.

(a) An individual or his or her designated representative may appeal a denial of enrollment as a WTC responder or a denial of a determination of status as a screening-eligible survivor by sending a written letter to the WTC Program Administrator at the address specified in the notice of denial.

(1) The letter shall be sent within 60 days of the date of the WTC Program Administrator's notification letter, and shall state the reasons why the individual believes the denial was incorrect and may include relevant new evidence not previously considered by the WTC Program Administrator.

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

(b) The WTC Program Administrator will designate a Federal official independent of the WTC Health Program to review the appeal. The Federal official will issue a final decision after receipt and review.

(c) The WTC Program Administrator may reopen and reconsider a denial at any time.

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

(a) A physician in a Clinical Center of Excellence or a member of the nationwide provider network shall promptly transmit to the WTC Program Administrator a diagnosis and the basis for the diagnosis of a WTC-related health condition or health condition medically associated with a WTC-related health condition. The physician's diagnosis shall 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 shall 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.

§ 88.13 WTC Program Administrator's certification of health conditions.

(a) *WTC-related health condition.* (1) The WTC Program Administrator will review each physician determination, render a decision regarding certification, and notify the WTC responder, screening-eligible survivor, or certified-eligible survivor of the WTC Program Administrator's decision and the reason for the decision in writing.

(2) If certification is denied, the WTC responder, screening-eligible survivor, or certified-eligible survivor may appeal the WTC Program Administrator's decision to deny certification, as provided under § 88.15.

(b) *Health condition medically associated with a WTC-related health condition.* (1) The WTC Program Administrator will review each physician determination, render a decision regarding

certification, and notify the WTC responder or certified-eligible survivor in writing of the WTC Program Administrator's decision and the reason for the decision.

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

(ii) [Reserved]

(2) If certification is denied, the WTC responder or certified-eligible survivor may appeal the WTC Program Administrator's decision to deny certification, as provided under § 88.15.

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

§ 88.14 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 and approved by the WTC Program Administrator.

§ 88.15 Appeals regarding treatment.

(a) Individuals may appeal the following decisions made by the WTC Program Administrator: not to certify a health condition as a WTC-related condition; not to certify a health condition as medically associated with a WTC-related health condition; or not to authorize treatment due to a determination by the WTC Program Administrator about medical necessity for a certified WTC-related health condition.

(1) A WTC responder, screening-eligible survivor denied status as a certified-eligible survivor, certified-eligible survivor, or designated representative may appeal a determination by the WTC Program Administrator denying certification of the individual's health

condition for coverage under the WTC Health Program or a determination that treatment will not be authorized as medically necessary.

(2) Appeal shall be made in writing, describe the reason(s) why the individual believes the determination is incorrect, and be postmarked within 60 calendar days of the date of the WTC Program Administrator's letter notifying the individual of the WTC Program Administrator's adverse determination. No new documentation will be considered in the appeal process that was not available to the WTC Program Administrator at the time of his or her initial determination.

(b) *Review of appeal.* (1) The WTC Program Administrator will appoint a Federal official to conduct the appeal.

(2) The Federal official may convene one or more qualified experts, independent of the WTC Health Program, to review the WTC Program Administrator's initial determination. The expert reviewers shall base their review and recommendation on the documentation available to the WTC Program Administrator when the initial determination was made. The reviewers shall submit their findings to the Federal official.

(3) The Federal official shall review the expert reviewers' findings and make a final determination, which will be sent to the WTC Program Administrator and the individual who filed the appeal. No further requests for review of this final determination will be considered.

(c) At any time, the WTC Program Administrator may reopen a final determination (pursuant to paragraph (b)(2) of this section) and may affirm, vacate, or modify such final determination in any manner he or she deems appropriate.

§ 88.16 Reimbursement for medically necessary treatment, outpatient prescription pharmaceuticals, monitoring, initial health evaluations, and travel expenses.

(a) *Medically necessary treatment and outpatient prescription pharmaceuticals.*

(1) The costs of providing medically necessary treatment or services for a WTC-related health condition or a health condition medically associated with a WTC-related health condition

by a Clinical Center of Excellence or by a member of the nationwide provider network will be reimbursed according to the payment rates that apply to the provision of such treatment and services by the facility under the Federal Employees Compensation Act (5 U.S.C. 8101 *et seq.*, 20 CFR Part 20).

(i) The WTC Program Administrator will reimburse a Clinical Center of Excellence or a member of the nationwide provider network for treatment not covered under the Federal Employees Compensation Act pursuant to the applicable Medicare fee for service rate, as determined appropriate by the WTC Program Administrator.

(ii) [Reserved]

(2) 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 Program Administrator under a contract with one or more pharmaceutical providers.

(b) *Monitoring and initial health evaluations.* (1) Payment for the costs of providing monitoring and initial health evaluations to a WTC responder, screening-eligible survivor, or certified-eligible survivor by a Clinical Center of Excellence or a member of the nationwide provider network will be reimbursed according to the payment rates that would apply to the provision of such treatment and services under the Federal Employees Compensation Act (5 U.S.C. 8101 *et seq.*, 20 CFR Part 20).

(c) *Review of claims for reimbursement for medically necessary treatment.* (1) Each claim for reimbursement for treatment will be reviewed by the WTC Program Administrator.

(2) If the WTC Program Administrator determines that the treatment is not medically necessary, reimbursement will be withheld by the WTC Program Administrator.

(d) *Transportation and travel expenses.* The WTC Program Administrator may provide for necessary and reasonable transportation and expenses incident to the securing of medically necessary treatment through the nationwide provider network, involving travel of more than 250 miles.

§ 88.17 Addition of health conditions to the list of WTC-related health conditions.

(a) Any interested party may petition the WTC Program Administrator to add a condition to the list of WTC-related health conditions.

(1) Each petition shall state an intent to petition and be sent to the WTC Program Administrator. The petition shall include:

(i) Name and contact information of the interested party;

(ii) Name and description of the condition(s) to be added; and

(iii) 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 60 days after the receipt of a petition, the WTC Program Administrator shall:

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

(ii) Publish in the FEDERAL REGISTER a proposed rule to add such health condition; or

(iii) Publish in the FEDERAL REGISTER the WTC Program Administrator's determination not to publish a proposed rule and the basis for that determination; or

(iv) Publish in the FEDERAL REGISTER a determination that insufficient evidence exists to take action under paragraph (a)(2)(i) through (iii) of this section.

(3) The WTC Program 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 WTC Program Administrator pursuant to paragraph (a)(2) of this section may respond to more than one petition.

(4) The WTC Program Administrator shall be required to consider a new petition for a health condition previously reviewed by the WTC Program Administrator and determined not to qualify for addition to the list of WTC-related health conditions only if the new petition presents a new medical basis (i.e.,

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not previously reviewed) for the association between the September 11, 2001, terrorist attacks and the condition to be added.

(b) The WTC Program Administrator may propose to add a condition to the list of WTC-related health conditions by publishing a proposed rule in the FEDERAL REGISTER and providing interested parties a period of 30 days to submit written comments. The WTC Program Administrator may extend the comment period for good cause.

(1) If the WTC Program Administrator requests a recommendation from the WTC Health Program Scientific/Technical Advisory Committee, the

Advisory Committee shall submit its recommendation to the WTC Program Administrator no later than 60 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 days after the request). If the WTC Program Administrator decides to publish a proposed rule or a determination not to publish a proposed rule in the FEDERAL REGISTER, he or she shall do so no later than 60 days after the date of transmission of the Advisory Committee recommendation.

(2) [Reserved]

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