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World Trade Center Health Program Requirements for Enrollment, Appeals, Certification of Health Conditions, and Reimbursement; Interim Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. CDC-2011-0009]

42 CFR Part 88

RIN 0920-AA44

World Trade Center Health Program Requirements for Enrollment, Appeals, Certification of Health Conditions, and Reimbursement

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Interim final rule with request for comments.

SUMMARY: Title I of the James Zadroga Health and Compensation Act of 2010 amended the Public Health Service Act (PHS Act) by adding Title XXXIII, which establishes the World Trade Center (WTC) Health Program. Sections 3311, 3312, and 3321 of Title XXXIII of the PHS Act require that the WTC Program Administrator develop regulations to implement portions of the WTC Health Program established within the Department of Health and Human Services (HHS). The WTC Health Program, which will be administered in part by the Director of the National Institute for Occupational Safety and Health (NIOSH), within the Centers for Disease Control and Prevention (CDC), will provide medical monitoring and treatment 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, Shanksville, PA, and at the Pentagon, and to eligible survivors of the New York City attacks. This interim final rule establishes 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. This interim final rule also establishes a process for the certification of health conditions, and reimbursement rates for providers who provide initial health evaluations, treatment, and health monitoring.

DATES: Effective July 1, 2011. Written comments from interested parties on this interim final rule and on the information collection approval request sought under the Paperwork Reduction Act must be received by August 30, 2011.

ADDRESSES: You may submit comments, identified by "RIN 0920-AA44," by any of the following methods:

- *Internet:* Access the Federal e-rulemaking portal at <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *E-mail:* NIOSH Docket Officer, nioshdocket@cdc.gov. Include "RIN 0920-AA44" and "42 CFR 88" in the subject line of the message.

- *Mail:* NIOSH Docket Office, Robert A. Taft Laboratories, MS-C34, 4676 Columbia Parkway, Cincinnati, OH 45226.

Instructions: All submissions received must include the agency name and docket number or Regulation Identifier Number (RIN) for this rulemaking. All comments will be posted without change to <http://www.regulations.gov> and <http://www.cdc.gov/niosh/docket/NIOSHdocket0235.html>, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Public Participation" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, please go to <http://www.regulations.gov> or <http://www.cdc.gov/niosh/docket/NIOSHdocket0235.html>.

FOR FURTHER INFORMATION CONTACT: Roy M. Fleming, Sc.D., Senior Science Advisor, World Trade Center Health Program, Office of the Director, National Institute for Occupational Safety and Health, 1600 Clifton Road, NE., MS-E74, Atlanta, GA 30329; telephone 866-426-3673 (this is a toll-free number). Information requests may also be submitted by e-mail to wtpublicinput@cdc.gov.

SUPPLEMENTARY INFORMATION:

This preamble is organized as follows:

- I. Public Participation
- II. Background
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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. Public Participation

Interested persons or organizations are invited to participate in this rulemaking by submitting written views, opinions, recommendations, and data. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. HHS will consider those submissions and may revise the final rule as appropriate.

Comments are invited on any topic related to this interim final rule. In addition, HHS invites comments specifically on the following questions related to this rulemaking:

1. The PHS Act requires "1 day" of presence for a number of eligibility criteria for firefighters and related personnel (see § 88.4(a)(1) of the interim final rule text), members of the New York City Police Department (see § 88.4((a)(2)(ii)), and vehicle maintenance-workers (see § 88.4(a)(5)) to be enrolled. For the purposes of this regulation, the Department has interpreted the statutory intent of 1 day to be a full work shift, of at least 4 hours but less than 24 hours. Is there a different interpretation of 1 day that the Department should consider?

2. The medical necessity standard established in this interim final rule relies heavily on the medical protocols to be developed by the Data Centers and approved by the WTC Program Administrator, and incorporates the qualitative factors that treatment be reasonable and appropriate based on scientific evidence, professional standards of care, expert opinion, and other relevant information. Is the substantial reliance on approved medical protocols appropriate? Are the factors specified necessary and sufficient? Are there specific standards currently in use by other programs, either Federal or in private sector health care organizations that would be appropriate for use in the WTC Health Program?

3. The interim final rule implements Federal Employees Compensation Act (FECA) rates for reimbursing initial health evaluations, health monitoring, and medically necessary treatment

provided in the WTC Health Program. The use of FECA rates for treatment is specified by the PHS Act. The rule also employs applicable Medicare payment rate schedules for treatment that is not covered by FECA rates. Is there any system of rates other than Medicare that should be considered for treatment that is not covered by FECA? Note that section 3312 of the PHS Act prohibits payments for products or services made at a higher rate than the Office of Workers' Compensation Programs in the Department of Labor.

II. Background

A. WTC Medical Monitoring and Treatment Program and Environmental Health Center Community Program History

Since the tragic events of September 11, 2001, HHS, CDC, and NIOSH have facilitated health evaluations for those firefighters and related personnel, law enforcement officers, and rescue, recovery and cleanup workers who responded to the WTC disaster sites. A health screening program for responders began in 2002 under contracts awarded to the Mount Sinai School of Medicine (Mount Sinai) and the Fire Department, City of New York. Mount Sinai subcontracted with other specialty occupational health clinics in the New York metropolitan area to expand enrollment and provide a standardized and comprehensive health screening protocol.

In 2003, Congress appropriated further funding to implement longer term medical monitoring for these responders. The occupational health specialty clinics involved in the screening program were each directly funded through cooperative agreements with NIOSH to work collaboratively and provide periodic standardized medical monitoring exams. Participants in the initial screening program were enrolled beginning in 2004.

In 2006, Congress appropriated additional funds for diagnostic and treatment services to support medical care for health conditions associated with WTC-related work exposures. After receiving appropriations for treatment, the program was re-named the WTC Medical Monitoring and Treatment Program (MMTP) to reflect expanded services to eligible firefighters and related personnel, law enforcement officers, and rescue, recovery and cleanup workers. The established program providers were funded as Clinical Centers of Excellence (Clinical Centers), reflecting their multidisciplinary expertise and extensive program experience with the

WTC responder population. The MMTP made monitoring exams and treatment available to firefighters and related personnel, law enforcement officers, and rescue, recovery and cleanup workers living outside the New York metropolitan area and geographically distant from the established Clinical Centers through a network of providers. The health conditions covered under the MMTP were identified by the Clinical Centers based on assessments of the health needs of the firefighters and related personnel, law enforcement officers, and rescue, recovery and cleanup workers and with input from scientific and medical experts, and included certain upper and lower airway diseases, esophageal disorders from acid reflux, musculoskeletal injuries, and mental health problems (most notably post-traumatic stress disorder, anxiety, and depression).

In 2008, Congress appropriated additional funds for the WTC Environmental Health Center (EHC) Community Program, which provided initial health evaluations, diagnostic and treatment services for residents, students, and others in the community who were affected by the September 11, 2001, terrorist attacks in New York City.

B. WTC Health Program Statutory Authority

Title I of the James Zadroga 9/11 Health and Compensation Act of 2010, (Pub. L. 111–347), amended the PHS Act to add Title XXXIII¹ establishing the World Trade Center (WTC) Health Program within HHS. The WTC Health Program will assume the functions and goals of the MMTP and the WTC EHC Community Program to provide medical monitoring and treatment benefits to eligible firefighters and related personnel, law enforcement officers, and rescue, recovery and cleanup workers (including those who are Federal employees) who responded to the September 11, 2001, terrorist attacks, as well as those residents and other building occupants and area workers in New York City who were directly impacted and adversely affected by the attacks.

The WTC Health Program will expand to include any eligible firefighters and related personnel, law enforcement officers, and rescue, recovery and cleanup workers who responded to the September 11, 2001, terrorist attacks at the Pentagon and Shanksville, PA.

Section 3311(a)(2)(C)(ii) of Title XXXIII requires that the WTC Program Administrator develop eligibility criteria for Pentagon and Shanksville, PA emergency responders after consultation with the WTC Scientific/Technical Advisory Committee. HHS is in the process of establishing this new Federal advisory committee and the WTC Program Administrator will obtain the required consultation as soon as possible. However, because no Pentagon or Shanksville, PA responders have participated in the existing health program, the WTC Program Administrator currently lacks information that may serve as a basis for such enrollment, including information on participation in the response at these two sites and on hazard exposure circumstances at these sites relevant to currently established WTC health conditions. The WTC Program Administrator will be collecting such information.

Title XXXIII of the PHS Act directs the Secretary of HHS to designate a Department official to be the WTC Program Administrator (Title XXXIII, § 3306(14)). Certain specific activities of the WTC Program Administrator are reserved to the Secretary to delegate at her discretion; other WTC Program Administrator duties not explicitly reserved to the Secretary are assigned to the Director of NIOSH or his or her designee. This rule implements portions of the PHS Act which were both given to the Director of NIOSH and others for which the HHS Secretary has designated the Director of NIOSH to be the WTC Program Administrator. Another HHS component, Centers for Medicare & Medicaid Services, has been delegated responsibilities for disbursing payments to providers under the WTC Health Program (see Delegation of Authority, 76 FR 31337, May 31, 2011). All references to the WTC Program Administrator in this notice mean the NIOSH Director or his or her designee.

Under § 3306 of Title XXXIII of the PHS Act, the WTC Program Administrator is responsible for a program to enroll qualified firefighters and related personnel, law enforcement officers, and rescue, recovery and cleanup workers who responded to the New York City, Pentagon, and Shanksville, PA disaster sites; screen and certify qualified survivors of the New York City attacks; and to establish a nationwide system of healthcare providers to provide monitoring and treatment to those individuals found eligible. The WTC Program Administrator is also required to promulgate regulations to determine medical necessity with respect to

¹ Title XXXIII of the Public Health Service Act is codified at 42 U.S.C. 300mm to 300mm–61. Those portions of the Zadroga Act found in Titles II and III of Public Law 111–347 do not pertain to the World Trade Center Health Program and are codified elsewhere.

healthcare services and prescription pharmaceuticals; to certify WTC-related health conditions identified in the statute; and to establish processes for appealing WTC Health Program determinations. Those statutory requirements are included in this interim final rule and are described in the summary of the proposed rule below.

Title XXXIII of the PHS Act also authorizes the WTC Program Administrator to establish a process by which health conditions, including types of cancer, may be considered for addition to the list of WTC-related health conditions. Those provisions are included in a notice of proposed rulemaking published elsewhere in this issue of the **Federal Register**.

Title XXXIII of the PHS Act further authorizes the WTC Program Administrator to promulgate regulations to add eligibility criteria for Pentagon and Shanksville, PA responders after consultation with the WTC Health Program Scientific/Technical Advisory Committee. The eligibility criteria for those responders will be developed by future rulemaking.

C. Implementation of the WTC Health Program

As required by Title XXXIII of the PHS Act, this regulation establishes the process by which individuals who were firefighters and related personnel, law enforcement officers, rescue, recovery and cleanup workers who responded to the September 11, 2001, terrorist attacks in New York City or survivors associated with the September 11, 2001, terrorist attacks in New York City may be enrolled in the WTC Health Program. For firefighters and related personnel, law enforcement officers, and rescue, recovery and cleanup workers who were included in the previous MMTP program before July 1, 2011, enrollment in the newly established WTC Health Program will not require any new application, although enrollment is predicated on ensuring that the individual's name is not found to be a positive match to the terrorist watch list maintained by the Federal government. Similarly, survivors of the New York City terrorist attack who have been identified as eligible for medical treatment and follow-up monitoring services in the WTC EHC Community Program as of January 2, 2011, will not be required to file a new application to the WTC Health Program, but are also subject to watch list screening.

All firefighters and related personnel, law enforcement officers and rescue, recovery and cleanup workers who responded to the New York City attack

who will be newly seeking medical monitoring and treatment and survivors of the attack who were not covered by the WTC EHC Community Program on or before January 2, 2011, may apply to obtain coverage under the new WTC Health Program established by this rule. The application process for responders and survivors is established by this interim final rule.

An individual who believes that he or she qualifies as a WTC responder (a 'WTC responder' is defined in the interim final rule text as an individual who has been identified as eligible for monitoring and treatment as described in § 88.3 of the interim final rule, or who meets the eligibility criteria in § 88.4) must fill out an application form indicating that he or she meets certain eligibility criteria described in § 88.4. Firefighters and related personnel, law enforcement officers, and rescue, recovery and cleanup workers may submit an application to the WTC Health Program beginning on July 1, 2011. An individual who can demonstrate that he or she was firefighter or related personnel, law enforcement officer, or rescue, recovery or cleanup worker who participated at or within a certain distance of the Ground Zero site or at a specified location for the requisite amount of time may be enrolled in the WTC Health Program. If no documentation of eligibility is submitted with the application (e.g., a pay stub or personnel roster), the individual must explain how he or she attempted to find documentation and why the attempt was unsuccessful. The application must be signed by the applicant. An applicant who knowingly provides false information may be subject to a fine and/or imprisonment of not more than 5 years.

A similar application process is established for survivors who were not enrolled in the WTC EHC Community Program prior to January 2, 2011. Those survivors may submit applications to the WTC Health Program beginning on July 1, 2011. An individual who believes that he or she can qualify as a screening-eligible survivor must fill out an application form indicating that he or she meets certain eligibility criteria described in § 88.8 of the regulatory text. An individual who can demonstrate that he or she was a survivor who was present in the New York City disaster area may be found eligible to receive medical screening to determine if he or she has a health condition covered by the WTC Health Program. As with the WTC responder application, if no documentation of eligibility (e.g., a lease or utility bill) is

submitted with the application, the applicant must explain how he or she attempted to find documentation and why the attempt was unsuccessful. The application must be signed by the applicant. An applicant who knowingly provides false information may be subject to a fine and/or imprisonment of not more than 5 years. If the individual is found to have a covered health condition, he or she may be considered a certified-eligible survivor.

Once enrolled in the WTC Health Program, a WTC responder or certified-eligible survivor may receive treatment for specific physical and mental health conditions that have been certified by the WTC Health Program and that are included on the list of WTC-related health conditions. The list of these health conditions was established by Congress and is repeated in § 88.1, the definitions section of this rule. The list may be amended in the future to add other health conditions

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

The eligibility criteria and application process for individuals who responded to the September 11, 2001, terrorist attacks at the Pentagon and Shanksville, PA, will be developed as soon as possible. As discussed above, this will require additional research and consultation that could not be completed prior to this rulemaking (see Section II.B.).

III. Issuance of an Interim Final Rule With Immediate Effective Date

Rulemaking under the Administrative Procedure Act (APA) generally requires a public notice and comment period and consideration of the submitted comments prior to promulgation of a final rule having the effect of law (5 U.S.C. 553). However, the APA provides for exceptions to its notice and comment procedures when an agency finds that there is good cause for dispensing with such procedures on the basis that they are impracticable, unnecessary, or contrary to the public interest. In the case of this interim final rule, we have determined that under 5 U.S.C. 553(b)(B), good cause exists for waiving the notice and comment procedures. For similar reasons, HHS has also determined that good cause exists under 5 U.S.C. 553(d)(3) for this

interim final rule to become effective immediately.

The James Zadroga 9/11 Health and Compensation Act of 2010 was signed by the President on January 2, 2011. It amended the PHS Act to establish the WTC Health Program, administered by the WTC Program Administrator, and mandated that this program begin on July 1, 2011, just 6 months after enactment.

HHS has determined that interim regulatory provisions are necessary to implement certain provisions of Title XXXIII relating to: (1) The WTC Health Program's ability to ensure that those currently identified responders and survivors who are already receiving care under the previous program continue to receive medical monitoring and treatment benefits without interruption; (2) the WTC Health Program's ability to accept applications from responders beginning July 1, 2011 and survivors shortly thereafter; (3) the right of applicants and enrollees to appeal determinations made by the WTC Health Program; and (4) the guidelines by which WTC-related health conditions are diagnosed and certified. HHS has determined that it is not possible to complete the steps necessary for the usual notice and comment under the APA in time for the WTC Health Program to become effective by July 1, 2011.

There is a strong public interest in ensuring the continuation of monitoring and treatment benefits for those responders and survivors who were previously receiving such care. Congress has also expressed the need for ensuring the continuation of monitoring and treatment (Title XXXIII, § 3305(b)(1)(C)). In addition, there is an immediate need to initiate the process to continue to enroll those who responded to this nation's worst terrorist attacks and were harmed in the performance of their duties. These concerns are clearly reflected in the Congressional mandate to swiftly implement this program. It is especially important that currently identified responders and survivors who will be transferring to the new WTC Health Program be provided prompt guidance on how it will operate. *Coalition for Parity, Inc. v. Sebelius*, 709 F. Supp.2d 10, 15 (DC Cir. 2010) (need for prompt regulatory guidance among the factors in justifying an interim rule). HHS is working as quickly as possible to provide this guidance by issuing this interim final rule. An undue delay in enrolling and implementing certification of treatment procedures under the new program would result in real harm to those who were in the previous treatment program. With the

publication of this interim final rule, we can ensure that the necessary guidance is provided promptly to those responders and survivors currently identified and to those responders seeking to enroll, and that monitoring and treatment benefits are continued.

For similar reasons, HHS is making this interim final rule effective immediately. In making this determination, we have balanced the need for an immediately-effective rule in order to allow for continued treatment and care for responders and survivors against fairness considerations and the needs of affected parties to have time to adjust to the rule's requirements. *Omnipoint Corporation v. Federal Communications Commission*, 78 F.3d 620, 630 (DC Cir. 1996). HHS believes the need for continuation of monitoring and treatment is paramount and necessitates that this interim final rule be effective immediately.

While developing this interim rule, HHS reached out to the affected community through a public meeting (76 FR 7862, February 11, 2011), a request for comments on the implementation of Title XXXIII of the PHS Act (76 FR 12360, March 7, 2011), and other outreach efforts to interested parties. Although HHS is adopting this rule on an interim final basis, we request public comment on this rule. After full consideration of public comments, HHS will work as expeditiously as possible to publish a final rule with any necessary changes.

IV. Summary of Interim Final Rule

The section-by-section summaries provided below describe the components of the WTC Health Program for which the WTC Program Administrator has been delegated authority by the Secretary of HHS, under Title XXXIII. The components implemented here include: enrollment of WTC responders; certification of screening-eligible or certified-eligible survivors; and payment for initial health evaluation, monitoring, and treatment of covered individuals. Certain paragraphs are reserved for provisions that will be promulgated by notice-and-comment rulemaking at such time as is determined by the WTC Program Administrator.

Section 88.1 Definitions

This section of the regulation includes definitions for the principal terms used in part 88. It includes terms specifically defined in Title XXXIII.

The "WTC Program Administrator" is defined, for purposes of this regulation, as the Director of the National Institute

for Occupational Safety and Health or his or her designee.

"WTC responder," "screening-eligible survivor," and "certified-eligible survivor," refer to individuals who are found to be eligible to participate in certain aspects of the WTC Health Program. "WTC responder" is a term defined in Title XXXIII. It is used to refer not only to people who worked or volunteered in rescue, recovery, and clean-up at the site of the terrorist attacks in New York City but also to those individuals who participated in those activities at the sites in Shanksville, PA and the Pentagon. "Screening-eligible survivors" are individuals who meet the initial eligibility requirements found in § 88.8 and are thus approved to have an initial health evaluation. "Certified-eligible survivors" are individuals who have at least one WTC-related health condition for which he or she qualified for treatment benefits and follow-up monitoring services.

The terms "list of WTC-related health conditions," and "WTC-related health condition" refer to those conditions specifically designated in Title XXXIII and to any future conditions that may be added to that list by the WTC Program Administrator in subsequent rulemakings. A "health condition medically associated with a WTC-related health condition" is a condition that results from the treatment of a condition on the list of WTC-related health conditions or from the natural progression of one of those conditions.

"Clinical Centers of Excellence" and the "nationwide provider network" are the medical providers meeting specified statutory requirements and are affiliated with the WTC Health Program by contract.

"Terrorist watch list" is included to incorporate the statutory requirement that no individual who is determined to be a positive match to the watch list maintained by the Federal government shall qualify to become a WTC responder or screening-eligible or certified-eligible survivor. The PHS Act inadvertently identifies the watch list as being maintained by the Department of Homeland Security; the watch list is in fact maintained by the Terrorist Screening Center of the Federal Bureau of Investigation, Department of Justice.

Section 88.2 General Provisions

Paragraph (a) of this section establishes that an enrolled WTC responder, a screening-eligible survivor, or a certified-eligible survivor may designate one person to represent their interests related to applying to or seeking treatment from the WTC Health

Program. The provisions of this section specify that a WTC responder or eligible survivor can have only one individual represent him or her at a time; identifies those individuals for whom a Federal employee may act as a designated representative; and specifies that a parent or guardian may act on behalf of a minor seeking monitoring or treatment under the WTC Health Program. HHS believes it is important and necessary to provide a means for an enrollee who is a minor child or who is otherwise unable to represent himself or herself to be able to designate the person who will represent the enrollee in the Program.

Section 88.3 Eligibility—Currently Identified Responders

This section restates the eligibility criteria, as outlined in Title XXXIII, § 3311 of the PHS Act, for WTC responders who have received medical monitoring and treatment benefits from the MMTP program. Under § 88.3(a), responders who have been identified as eligible for program benefits prior to July 1, 2011, by the MMTP will be automatically enrolled in the WTC Health Program. These individuals are not required to submit an application for enrollment. As required by statute, an individual who meets the eligibility criteria under (a) of this section is not qualified to enroll in the WTC Health Program if the individual is determined to be a positive match to the terrorist watch list.

Section 88.4 Eligibility Criteria—Status as a WTC Responder

The eligibility criteria in § 88.4 apply to those firefighters, law enforcement officers, certain employees of the Office of the Chief Medical Examiner of New York City, Port Authority Trans-Hudson Corporation Tunnel Workers, vehicle-maintenance workers, and other rescue, recovery, and cleanup workers not previously identified as eligible under the MMTP. New applicants will be considered for enrollment according to the criteria provided in paragraph(a), which describes individuals who conducted rescue, recovery, and cleanup at the World Trade Center sites (including Ground Zero, the Staten Island Landfill, or the New York City Chief Medical Examiner's Office), for specific lengths of time during the dates specified.

Paragraphs (b) and (c) are reserved for eligibility criteria for responders to the September 11, 2001, terrorist attack sites in Shanksville, PA and at the Pentagon. Paragraph (d) is reserved for any modified eligibility criteria that may be developed in the future.

Paragraph (e) states that the WTC Program Administrator will keep a list of enrolled WTC responders.

Section 88.5 Application Process—Status as a WTC Responder

This section informs applicants who believe they meet the eligibility criteria for a WTC responder how to apply for enrollment in the WTC Health Program. The provisions of this section require that the individual submit an application and provide evidence of eligibility under the provisions of § 88.4. The applicant must provide documentary evidence of his or her employment and type of work activity during the rescue, recovery, and debris cleanup periods after the terrorist attacks. The WTC Health Program will accept a pay stub, official personnel roster, site credentials or other similar documents to establish that the applicant meets the eligibility criteria. If no documentation is submitted with the application, the applicant must explain how he or she attempted to find documentation and why he or she was unsuccessful. The application must be signed by the applicant, under penalty of perjury. An applicant who knowingly provides false information may be subject to fines and criminal penalties under 18 U.S.C. 1001 and 18 U.S.C. 1621.

Section 88.6 Enrollment Determination—Status as a WTC Responder

This section explains how and when the WTC Program Administrator will promptly notify the applicant of the enrollment decision. The WTC Program Administrator will evaluate applications on a first-come, first-served basis; applicants will be promptly notified if there are any deficiencies in the application or supporting materials.

An applicant will be denied enrollment in the Program if he or she does not meet the eligibility criteria in § 88.4; if the numerical limitations established by Congress are met, or the WTC Program Administrator determines that funds are insufficient to continue accepting new enrollees into the Program; or if the individual is determined to be a positive match to the terrorist watch list maintained by the Federal government. Individuals denied enrollment because of the numerical limitation will be placed on a waitlist, and notified promptly when they are removed from the waitlist and enrolled in the Program.

Title XXXIII expressly states that the total number of newly-enrolled WTC responders “shall not exceed 25,000 at any time,” and similarly limits the total

number of new certified-eligible survivors to 25,000 (§ 3311(a)(4), § 3321(a)(3)). The WTC Program Administrator is authorized to limit enrollment to a number of WTC responders and certified-eligible survivors that is less than the limit set by Congress. That determination must be based on the best available information and on the amount available funding necessary to provide treatment and monitoring benefits to all individuals who are enrolled in the program.

The qualified applicant will be notified in writing no later than 60 days after the application date. An applicant who is found ineligible for enrollment will be provided an explanation, as appropriate for that determination, and given the opportunity to appeal.

Section 88.7 Eligibility—Currently Identified Survivors

This section establishes that survivors who have been identified as eligible for medical treatment and monitoring benefits by the WTC EHC Community Program as of January 2, 2011, will be automatically enrolled in the WTC Health Program. These individuals are not required to submit an application for enrollment. As required by Title XXXIII of the PHS Act, an individual who meets the eligibility criteria under (a) of this section is not qualified to enroll in the WTC Health Program if the individual is determined to be a positive match to the terrorist watch list.

Section 88.8 Eligibility Criteria—Status as a WTC Survivor

This section restates the eligibility criteria for screening-eligible survivors established in Title XXXIII of the PHS Act. Individuals who wish to apply for benefits under the WTC Health Program may do so beginning on July 1, 2011.

New applicants to the WTC Health Program will be considered for status as a screening-eligible survivor according to the criteria provided in (a), which describes an individual who is not a WTC responder, who claims symptoms of a WTC-related health condition, and who is not an individual identified in § 88.7. Individuals who would be eligible for an initial health evaluation were, during the dates and durations specified, either present in the dust cloud; worked, lived, or attended school or daycare in the New York City disaster area; performed cleanup or maintenance work in the New York City disaster area; received a grant from the Lower Manhattan Development Corporation Residential Grant Program for a residence he or she leased or owned and lived in; or was employed in the

disaster area and received a grant from the Lower Manhattan Development Corporation or other government incentive program to revitalize the area economy.

Paragraph (b) explains that screening-eligible survivors can become certified-eligible survivors by obtaining an initial health evaluation, provided by the WTC Health Program. If the exam results in a physician's diagnosis of a WTC-related health condition, the WTC Program Administrator may certify that condition. In that case, the survivor will be considered certified-eligible.

Section 88.9 Application Process—Status as a WTC Survivor

This section informs applicants who believe they meet the eligibility criteria for a WTC survivor how to apply for screening-eligible status in the WTC Health Program. The provisions of this section require that the individual submit an application and provide documentation of his or her presence, residence, or employment in the New York City disaster area. The WTC Health Program will accept various forms of proof of presence, residence, or work activity including a written statement, under penalty of perjury, from the applicant or the applicant's employer. An applicant who is unable to submit any required documentation must instead offer a written explanation of what the individual did to try to find proof of presence, residence, or work activity and why he or she was unsuccessful. The application will be signed under penalty of perjury. Any applicant who knowingly supplies false information may be subject to fines and criminal prosecution under 18 U.S.C. 1001 and 18 U.S.C. 1621. As required by Title XXXIII, § 3321(a)(1)(A)(ii), the applicant would also be required to claim symptoms of a WTC-related health condition. A WTC-related health condition is defined as a health condition associated with exposure to adverse conditions resulting from the September 11, 2001, terrorist attacks, and identified in Title XXXIII of the PHS Act and in § 88.1. Paragraph (b) explains that an individual is not required to submit an additional application to become certified-eligible.

Section 88.10 Enrollment Determination—Status as a WTC Survivor

This section explains how and when the WTC Program Administrator will notify the applicant of the decision to enroll the individual as a screening-eligible or certified-eligible survivor. The WTC Program Administrator will evaluate applications for screening-

eligible status on a first-come, first-served basis; applicants will be promptly notified if there are any deficiencies in the application or supporting materials.

An applicant will be denied enrollment in the Program if he or she does not meet the eligibility criteria for screening-eligible survivors in § 88.8; if the numerical limitations established by Congress are met, or the WTC Program Administrator determines that funds are insufficient to continue accepting new screening-eligible or certified-eligible survivors into the Program; or if the individual is determined to be a positive match to the terrorist watch list maintained by the Federal government. Individuals denied screening-eligible status because of the numerical limitation on certified-eligible survivors will be placed on a waitlist and notified promptly when they are removed from the waitlist and deemed screening-eligible.

The qualified screening-eligible status applicant will be notified in writing no later than 60 days after the application date. An applicant who is found ineligible for enrollment will be provided an explanation, as appropriate for that determination, and given the opportunity to appeal.

Paragraph (d) explains that a screening-eligible survivor will receive an initial health evaluation from a WTC Health Program Clinical Center of Excellence or a member of the nationwide provider network to determine if the individual has a WTC-related health condition. While the WTC Health Program will offer only one initial health evaluation, nothing in this rule will prohibit the screening-eligible survivor from requesting and paying for additional health evaluations.

This section also establishes that the screening-eligible survivor may be denied certified-eligible status if the individual does not have a diagnosed WTC-related health condition or if the WTC Program Administrator does not find that the physician's determination sufficiently establishes the relationship between the individual's exposure to the conditions resulting from the September 11, 2001, terrorist attacks and the health condition being claimed. The screening-eligible survivor may also be denied certified-eligible status if the numerical limitations established by Congress are met, or the WTC Program Administrator determines that funds are insufficient to continue accepting new certified-eligible survivors into the Program; or if the individual is determined to be a positive match to the terrorist watch list maintained by the Federal government. Individuals denied

enrollment because of the numerical limitation will be placed on a waitlist and notified promptly when they are removed from the waitlist and deemed certified-eligible.

The newly certified-eligible survivor will be notified in writing. A screening-eligible survivor who is found ineligible for certified-eligible status will be provided an explanation, as appropriate for that determination, and given the opportunity to appeal.

Section 88.11 Appeals Regarding Eligibility Determinations—Responders and Survivors

This section establishes procedures for the appeal of a WTC Program Administrator's decision not to enroll an individual who believes he or she meets the eligibility criteria for enrollment as a WTC responder or screening-eligible survivor. The individual or his or her designated representative may appeal the decision in writing within 60 days of the decision. The appeal must contain the reasons the individual believes the decision is incorrect, and may also include relevant information that was not previously considered by the WTC Program Administrator. If the individual is denied because his or her name is determined to be a positive match to the terrorist watch list, the appeal will be forwarded to the appropriate Federal agency. Upon receipt and review of the appeal, the WTC Program Administrator will designate the NIOSH Associate Director for Science, a Federal official who is independent of the Program, to review the appeal and make a final decision on the matter. Status as a certified-eligible survivor is predicated on certification of a WTC-related health condition; appeal of a WTC Program Administrator denial of status as a certified-eligible survivor will be available only through the appeal process outlined in § 88.15.

Section 88.12 Physician's Determination of WTC-Related Health Conditions

This section establishes the basis for a determination that an enrolled WTC responder or survivor has a health condition that can be certified and covered by the WTC Health Program. Paragraph (a) requires that a WTC Health Program physician promptly send his or her diagnosis to the WTC Program Administrator. The physician's diagnosis must include information establishing that the September 11, 2001, terrorist attacks were substantially likely to be a significant factor in aggravating, contributing to or causing the condition being claimed for

certification. Paragraph (b) establishes that the physician must provide documentation that a health condition medically associated with a WTC-related health condition is determined to be a result of treatment or progression of a previously-certified WTC-related health condition.

Section 88.13 WTC Program Administrator's Certification of Health Conditions

This section establishes that the WTC Program Administrator will promptly assess the diagnosis submitted by the physician pursuant to § 88.12. If the WTC Program Administrator determines that a diagnosed condition is a WTC-related health condition (paragraph (a)) or a health condition medically associated with a WTC-related health condition (paragraph (b)), the condition will be certified as eligible for coverage under the WTC Health Program. If the WTC Program Administrator determines that the condition is neither a WTC-related health condition nor a health condition medically associated with a WTC-related health condition, the applicant will be notified in writing. The WTC responder or the screening-eligible or certified-eligible survivor may appeal the decision pursuant to the process in § 88.15. Paragraph (c) establishes that prior authorization for treatment must be received from the WTC Program Administrator while certification of a WTC-related health condition or a health condition medically associated with a WTC-related health condition is pending, unless treatment is necessary for a medical emergency. As established by § 88.16(a)(1), the provider will be reimbursed only for treatment of a certified WTC-related health condition or a health condition medically associated with a WTC-related health condition.

Section 88.14 Standard for Determining Medical Necessity

This section establishes the standard for determining whether the treatment for a WTC-related health condition or a health condition medically associated with a WTC-related health condition is medically necessary. Medically necessary treatment is reasonable and appropriate, and is based on scientific evidence, professional standards of care, expert opinion, or other relevant information, and is in accordance with medical treatment protocols developed by the Data Centers and approved by the WTC Program Administrator. Treatment protocols developed using current medical information from previously established guidelines from both

national professional standards of care and program-specific expertise will be used until the Data Centers are operational and are able to create a Program-wide, unified operations manual.

Section 88.15 Appeals Regarding Treatment

This section explains that a WTC responder, a screening-eligible survivor denied status as certified-eligible, a certified-eligible survivor, or a designated representative may appeal the WTC Program Administrator's decision not to certify the health condition or not to authorize treatment for a certified WTC-related health condition or health condition medically associated with a WTC-related health condition.

The individual or his or her designated representative may appeal the decision in writing within 60 calendar days of the decision. The appeal must be in writing and describe why the individual believes the WTC Program Administrator's initial determination not to certify the condition or authorize treatment was in error. Pursuant to paragraph (b)(1), the WTC Program Administrator will appoint the NIOSH Associate Director for Science, a Federal official independent of the WTC Health Program, who may convene one or more qualified experts to review the WTC Program Administrator's initial determination. The expert(s) will conduct a review of the documentation available at the time of the initial determination and submit the findings to the Federal official. The Federal official will review the expert findings and make a final determination which will not be further considered upon request of the WTC responder, screening-eligible or certified-eligible survivor, or designated representative.

Section 88.16 Reimbursement for Medically Necessary Treatment, Outpatient Prescription Pharmaceuticals, Monitoring, Initial Health Evaluations, and Travel Expenses

This section establishes that the Clinical Center of Excellence or member of the nationwide provider network will be reimbursed by the WTC Health Program for the cost of medical treatment and outpatient prescription pharmaceuticals, and that a WTC responder or certified-eligible survivor may be reimbursed for certain transportation expenses. Under section 3331 of the PHS Act, subject to certain limitations pertinent only to workers' compensation programs and other plans

under which New York City is obligated to pay, the WTC Program Administrator may reduce or recoup payment for treatment of a WTC-related health condition if it is determined that the individual's condition is work related, and the individual is covered by a workers' compensation or similar work-related injury or illness plan. For an individual who has a WTC-related health condition that is not work-related and who has coverage under a public or private health insurance plan, the WTC Program Administrator may also take this insurance coverage into account in determining payment for treatment under Title XXXIII of the PHS Act.

Paragraph (a)(1) establishes that payment for medical treatment will be based on the rates set by the Office of Workers' Compensation Programs to administer the Federal Employees Compensation Act (FECA, 5 U.S.C. 8101 *et seq.*, 20 CFR Part 20).² Services or treatment not covered by the FECA rate structure will be reimbursed pursuant to the applicable Medicare fee for service rate, as determined appropriate by the WTC Program Administrator. Paragraph (a)(2) states that the cost of medically necessary outpatient prescription pharmaceuticals will be reimbursed according to rates established by contract between the WTC Health Program and one or more pharmaceutical providers through a competitive bidding process. Paragraph (b)(1) establishes that costs associated with monitoring and initial health evaluations will be reimbursed according to rates established by FECA. Paragraphs (c)(1) and (2) state that the WTC Program Administrator will review all claims for reimbursement and that reimbursement will be denied if the treatment is not medically necessary. Finally, paragraph (d) establishes that the WTC Program Administrator may provide reimbursement for necessary and reasonable transportation and other expenses that are related to securing medically necessary treatment through the nationwide provider network, involving travel of more than 250 miles. The WTC Health Program will administer this provision consistently with the procedures of the Office of Workers' Compensation Programs of the Department of Labor, as specified in the statute.

² U.S. Department of Labor, Office of Workers' Compensation Programs Medical Fee Schedule, <http://www.dol.gov/owcp/regs/feeschedule/fee.htm>. Accessed June 3, 2011.

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, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs

and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

This rulemaking has been determined to be an “economically significant” regulatory action within the meaning of E.O. 12866. Providing medical monitoring and treatment through the WTC Health Program administered pursuant to this regulatory action will have an annual effect on the economy of \$100 million or more.

Federal Cost Estimates

Based on the factors and assumptions set forth below, HHS estimates the

aggregate cost of medical monitoring and treatment to be provided and administrative expenses of this regulatory action, which partially implements Title XXXIII, in millions of dollars as presented in Table 1, below. The table represents estimates, and is subject to change based on actual expenditures and future data analyses. These costs represent high and low estimates; actual costs and future estimates may be significantly below or above the estimated ranges.

TABLE 1—HEALTHCARE AND ADMINISTRATIVE COSTS OF THE WTC HEALTH PROGRAM

[\$ millions; undiscounted]

	FY 2011 (fourth quarter only)	FY 2012	FY 2013	FY 2014	FY 2015
Administrative Costs:					
Low Estimate	\$1.8	\$15	\$15	\$15	\$15
High Estimate	1.8	22.5	22.2	22.2	22.2
Medical Monitoring and Treatment Costs:					
Low Estimate	33.7	91.8	91.8	91.8	91.8
High Estimate	45.1	107.1	114.3	121.6	128.8
Total Costs:					
Low Estimate	35.5	106.8	106.8	106.8	106.8
High Estimate	46.9	129.6	136.5	143.8	151.0

HHS’s estimate of the costs of medical monitoring and treatment to be provided pursuant to the PHS Act and of the administrative costs of providing this monitoring and treatment is based on data from the WTC programs in operation to date. The current NIOSH WTC Medical Monitoring and Treatment Program and Environmental Health Center Program, referred to below as “current NIOSH WTC programs,” have operated over the past 10 years. As a result, the current NIOSH WTC programs now approximate the starting point of the scope of the WTC Health Program’s activities to be established by the PHS Act and implemented by this rule. The data from operational experience to date is the basis by which HHS has estimated costs for administrative activities, medical monitoring and treatment, and estimated related rates of enrollment and certification (respectively) of additional responders and survivors not currently participating in the current NIOSH WTC programs. Since the current NIOSH WTC grants are set to expire in FY 2011, the analyses of WTC Health Program costs (and health benefits) that follow use a low estimate reflecting actual costs associated with maintaining the existing program plus additional administrative activities, and a higher level that assumes a significant

increase in enrollment and increase in both administrative costs and other health care costs.

The WTC Health Program expects to enroll the approximately 58,000 New York City responders and survivors who are enrolled in the current NIOSH WTC programs on July 1, 2011. In the high estimates, HHS assumes that up to 1,064 new responders and survivors in the final quarter of FY 2011 will be enrolled, resulting in a total of up to 59,064 enrollees in the WTC Health Program for FY 2011. Over the first full year (FY 2012) of the WTC Health Program within the high estimate, HHS expects up to 4,255 new enrollees associated with the New York City terrorist attack, (3,018 responders and 1,237 survivors). The upper bound of this estimated range is based on the highest annual rates of enrollment over the past three years for responders and survivors, respectively. The lower bound assumes no new enrollment as the majority of responders affected by the WTC attacks have insurance and may not want to change healthcare providers. The actual enrollment is likely to fall within these bounds but is highly uncertain. HHS has not estimated enrollment for the Pentagon or Shanksville, PA populations as this is outside the scope of the rulemaking.

• Administrative Costs

HHS estimates administrative costs ranging between \$15,000,000 and \$22,500,000 annually (higher start-up costs are projected for 2012), covering program management, enrollment of responders and survivors, certification of WTC-related health conditions in enrolled responders and certified eligible survivors, authorization of medical care, payment services, administration of appeals processes, education and outreach, and administration of the advisory and steering committee specified in the PHS Act. The range of the costs estimated reflects uncertainty associated with levels of activity for enrollment, appeals, the establishment and maintenance of new quality management and administrative data systems, and competitively established costs for contractual administrative services.

• Costs of Medical Monitoring and Treatment

Initial health evaluations are estimated to cost between \$0 and \$59,000 in the final quarter of FY 2011 and between \$0 and \$2,360,000 over the first full year (FY 2012) of the WTC Health Program, depending on the levels of actual enrollment and average

costs per patient. It is unclear how many new people may enroll in the new program within the first quarter. The high range of costs per patient are projected to be between \$517 and \$555 per individual, based on the average costs for patients having received these evaluations through the current NIOSH WTC programs and accounting for uncertainty in medical care inflation (3.4 percent in 2010) and the range of uncertainty in clinical infrastructure costs (discussed below).

Annual medical monitoring for responders and survivors is estimated to cost between \$8,380,000 and \$8,990,000 in the final quarter of FY 2011 for 10,875 responders and survivors and between \$33,54,000 and \$36,630,000 in FY 2012, the first full year of the WTC Health Program for between 43,500 and 44,298 responders and survivors and to increase with enrollment. This is based on an average cost of between \$771 and \$827 per patient for a medical monitoring exam. The range of average per patient costs is based on the average costs for patients having received a medical monitoring exam through the current NIOSH WTC programs and accounting for uncertainty in medical care inflation (3.4 percent in 2010) and the range of uncertainty in clinical infrastructure costs (discussed below). Based on participation in the current

program, these projections assume 75 percent of responders and survivors will obtain annual monitoring examinations. These examinations are provided in the years following the initial health evaluation, which is why there is a 1-year lag with respect to program enrollment numbers in the number of patients projected to receive these exams each fiscal year.

Medical treatment is estimated to cost between \$14,550,000 and \$15,890,000 in the final quarter of FY 2011 for between 4,205 and 4,282 responders and survivors and between \$58,210,000 and \$68,130,000 in the first full year (FY 2012) of the WTC Health Program for between 16,820 and 18,363 responders and survivors and to increase with enrollment. This estimate is based on an average cost in the current NIOSH WTC programs for these services of between \$3,461 and \$3,710 per patient under treatment and an estimated 29 percent of enrolled participants in current NIOSH WTC programs receiving treatment annually. However, there are current grantees that provide treatment services per patient significantly below this average cost. The range of average per patient costs is based on the average costs for patients having received treatment through the current NIOSH WTC programs and accounting for uncertainty in medical care inflation

(3.4 percent in 2010) and the range of uncertainty in clinical infrastructure costs (discussed below).

The initial health evaluation, medical monitoring and treatment cost estimates include infrastructure costs for the Clinical Centers of Excellence, which will provide the medical services. The infrastructure costs are those that the Clinical Centers would need to operate the WTC Health Program that are not covered by FECA, such as the costs for retention of participants, case management, medical review and appeals, benefits counseling, quality management, data transfer, interpreter services, and the development of treatment protocols. Beginning in FY 2012, HHS projects annual infrastructure costs ranging from \$15,400,000 to \$28,220,000, depending on competitively established contractual costs for operating clinical centers of excellence to carry out the functions described above. These infrastructure costs will be obligated through contracts with the Clinical Centers annually. These costs are included within the initial health evaluation, medical monitoring, and treatment cost estimates but are shown as a non-additive total in Table 2 for the fiscal years 2012–2015, without adjustment for inflation.

TABLE 2—SUMMARY OF MEDICAL MONITORING AND TREATMENT AND CLINICAL CENTERS OF EXCELLENCE INFRASTRUCTURE COST CALCULATIONS
[In \$ millions]

	FY 2011 (4th qtr)	FY 2012	FY 2013	FY 2014	FY 2015
Total Number of WTC Health Program Enrollees (Low & High Estimates)	58,000 59,064	58,000 63,319	58,000 67,574	58,000 71,829	58,000 76,084
Initial Health Evaluation					
New Enrollees	0 1,064	0 4,255	0 4,255	0 4,255	0 4,255
Total Undiscounted Cost of Initial Health Evaluation:					
Low Estimate = \$517 per person	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
High Estimate = \$555 per person	\$0.59	\$2.36	\$2.36	\$2.36	\$2.36
Annual Medical Monitoring					
75% of All Enrollees, (1-year lag)	10,875 10,875	43,500 44,298	43,500 47,489	43,500 50,681	43,500 53,872
Total Undiscounted Cost of Medical Monitoring:					
Low Estimate = \$771 per person	\$8.38	\$33.54	\$33.54	\$33.54	\$33.54
High Estimate = \$827 per person	\$8.99	\$36.63	\$39.27	\$41.91	\$44.55
Medical Treatment					
29% of All Enrollees	4,205 4,282	16,820 18,363	16,820 19,596	16,820 20,830	16,820 22,064
Total Undiscounted Cost of Medical Treatment:					
Low Estimate = \$3,461 per person	\$14.55	\$58.21	\$58.21	\$58.21	\$58.21
High Estimate = \$3,710 per person	\$15.89	\$68.13	\$72.70	\$77.28	\$81.86

TABLE 2—SUMMARY OF MEDICAL MONITORING AND TREATMENT AND CLINICAL CENTERS OF EXCELLENCE
INFRASTRUCTURE COST CALCULATIONS—Continued
[In \$ millions]

	FY 2011 (4th qtr)	FY 2012	FY 2013	FY 2014	FY 2015
Medical Treatment Total					
Low Estimate	\$33.73	\$91.75	\$91.75	\$91.75	\$91.75
High Estimate	\$45.14	\$107.12	\$114.33	\$121.55	\$128.77
Clinical Centers Fixed Infrastructure Costs (non-add)					
Low Estimate	\$10.80 (obligated) ..	\$15.40	\$15.40	\$15.40	\$15.40
+ \$3.60 (non-add) ..					
High Estimate	\$19.67 (obligated) ..	\$28.22	\$28.22	\$28.22	\$28.22
+ \$6.56 (non-add) ..					

• Congressional Budget Office Estimates Comparison

HHS has compared the cost estimates it has derived above, based on the actual expenditures of the current NIOSH WTC programs, with estimates prepared by the Congressional Budget Office (CBO) during the legislative process that led to the enactment of Title XXXIII of the PHS Act (Congressional Budget Office, June 25, 2010). CBO used different methods and assumptions to produce its estimates. The purpose of the comparison was to consider further the baselines, assumptions and results of the HHS cost estimates. Excluding costs under Title XXXIII extraneous to this rulemaking, the CBO estimates for the first 5 years are somewhat higher than those of HHS for each full year, but well within a factor of two.

Although many of the details of CBO's methodology are not presented in its report, it appears to HHS that this difference is likely to be driven by the difference in the estimation of the prevalence of WTC-related health conditions among responders and survivors and medical costs for their treatment. CBO based its health care cost estimates on national data summarizing medical expenditures for the health conditions covered by the WTC Health Program, whereas these estimates by HHS are based on actual expenditures in the current NIOSH WTC programs for these conditions. While it is unclear what prevalence of

each individual health condition CBO applied to calculate its health care costs, the current actual prevalence of these conditions, to the extent they are receiving monitoring and treatment, is integrated in the HHS estimate.

Enrollment estimates projected by CBO fall within the range of estimates provided in the RIA for this interim final rule. CBO estimated a WTC Health Program enrollment of New York City responders and survivors of 3,750 annually. HHS estimated enrollment of up to 4,255 New York City responders and survivors in FY 2012 as the high range, the first full year, and each year following.

CBO estimated a higher overall prevalence of WTC conditions among responders and survivors than HHS. CBO projected 40 percent of enrollees in the WTC Health Program would develop a WTC-related health condition; HHS cost estimates are based on 29 percent of enrollees in current NIOSH WTC programs currently receiving treatment for one or more WTC-related health conditions in the last 12 months.

Examination of Benefits (Potential Health Impacts)

The purpose of this examination is to describe generally with illustrative detail the benefits that may be expected to result from this rule in terms of improved health of patients treated through the WTC Health Program.

An assessment of the health benefits for patients treated through the WTC

Health Program begins with identifying and estimating the prevalence of health conditions for which participants would be treated under this rule and the numbers of participants to be treated for these health conditions. NIOSH has information on the numbers and proportion of responders and survivors receiving medical treatment in the current NIOSH WTC programs and has projected enrollment rates in the WTC Health Program, as specified in the cost discussion above. This information, and projections of increase associated with new enrollments of responders and survivors in the WTC Health Program, is summarized in Table 3, below, which presents the upper bound annual projections of the total expected population of patients who will be treated under the WTC Health Program. These figures assume that the prevalence of each health condition will be and remain the same across all subgroups among responders and survivors in the WTC Health Program as exists presently for the participants in current NIOSH WTC programs. If Table 3 were also to present the lower bound projections of the expected population of patients who will be treated under the program, assuming there would be no increase in the enrolled population from 2010, the figures for FY 2012–2015 would be approximately seven percent lower than the figures presented for FY 2012.

TABLE 3—ESTIMATED PREVALENCE OF WTC-RELATED HEALTH CONDITIONS AMONG ENROLLED/CERTIFIED WTC HEALTH PROGRAM RESPONDERS AND SURVIVORS
[High range only]

	2011	2012	2013	2014	2015
Total Patients	4,282	18,363	19,596	20,830	22,064
Patients with any Physical Health Condition	3,775	16,190	17,277	18,365	19,453
Upper Airway	3,175	13,616	14,530	15,445	16,360
Chronic rhinosinusitis	2,858	12,254	13,077	13,900	14,724
Chronic nasopharyngitis	64	272	291	309	327
Chronic laryngitis	222	953	1,017	1,081	1,145

TABLE 3—ESTIMATED PREVALENCE OF WTC-RELATED HEALTH CONDITIONS AMONG ENROLLED/CERTIFIED WTC HEALTH PROGRAM RESPONDERS AND SURVIVORS—Continued
[High range only]

	2011	2012	2013	2014	2015
Upper airway hyperreactivity	0	0	0	0	0
Cough	413	1,770	1,889	2,008	2,127
Sleep apnea	953	4,085	4,359	4,633	4,908
Lower Airway	1,952	8,372	8,934	9,496	10,059
Asthma	1,113	4,772	5,092	5,413	5,734
Reactive airway dysfunction syndrome	683	2,930	3,127	3,324	3,521
Chronic obstructive pulmonary disease (COPD)	390	1,674	1,787	1,899	2,012
Other chronic respiratory disorder due to fumes and vapors	78	335	357	380	402
Interstitial lung diseases	98	419	447	475	503
Gastrointestinal	2,316	9,931	10,597	11,265	11,932
Gastroesophageal reflux	2,304	9,881	10,545	11,209	11,873
Musculoskeletal	505	2,166	2,312	2,457	2,603
Low back pain	197	845	902	958	1,015
Carpal tunnel syndrome	30	130	139	147	156
Other musculoskeletal conditions	424	1,820	1,942	2,064	2,186
<i>Patients with any Mental Health Condition</i>	1,416	6,072	6,479	6,887	7,296
Post traumatic stress disorder (PTSD)	750	3,218	3,434	3,650	3,867
Depression	878	3,764	4,017	4,270	4,523
Panic disorder with agoraphobia	85	364	389	413	438
Generalized anxiety disorder	184	789	842	895	948
Anxiety disorder NOS	524	2,247	2,397	2,548	2,699
Acute stress disorder	42	182	194	207	219
Dysthymic disorder	99	425	454	482	511
Adjustment disorder	71	304	324	344	365
Substance abuse	*nda	nda	nda	nda	nda
All Patients with both Physical and Mental Conditions	1,170	5,017	5,354	5,691	6,028

* No data available.

Based on this prevalence information, HHS has examined the health and quality of life improvements associated with medical treatment of several of the most common conditions in the covered population. The expected health benefits of the WTC Health Program are compared with those expected if there was no program after June 30, 2011. Where HHS has estimated such improvements quantitatively, it has assumed that the condition would continue to be represented among new participants in the WTC Health Program with the same prevalence with which it is occurring in current NIOSH WTC programs, as noted above. Notwithstanding these and other uncertainties discussed in more detail in the limitations section below, HHS finds the following information indicative of the nature and scope of health benefits expected to result from implementation of this rule.

Using the expected number of patients for FY 2011–2015 from Table 3, above, and published information on treatment effectiveness, when possible, a rough estimate of patient increased quality of life attributable to the WTC Health Program is presented for several WTC-related health conditions. HHS used quality of life as a common metric of expected treatment effectiveness for all the conditions assessed. The

assessment is based on a series of assumptions and relies on very limited information. As a starting point, HHS assumed that participants in the WTC Health Program will receive medical treatment that follows the New York City Department of Health and Mental Hygiene's "Clinical Guidelines for Adults Exposed to the World Trade Center Disaster" (Guidelines) when possible, along with published information about the effectiveness of specific medical treatment. The Guidelines recommend a coordinated approach to assessing and treating mental and physical health conditions but, as noted above, HHS lacks information identifying the occurrence of specific single or multiple health conditions among the patients of current NIOSH WTC programs. Therefore, HHS assessed the medical treatment of each condition expected to be prevalent in WTC Health Program participants individually. HHS also assumes that patients treated through the WTC Health Program will receive the best care available, based on the assumption that WTC Health Program healthcare providers would be experts in treating WTC-related health conditions, both individually and as syndromes. Given the many unaddressed uncertainties of this assessment, HHS deliberately used methods that would underestimate

potential benefits. One general method used for all the health conditions addressed was to assume that all responders and survivors will receive some but not optimal treatment for their conditions in the absence of the WTC Health Program. So the benefits estimated represent the incremental improvement in health patients in the WTC Health Program can expect from receiving the optimal treatment provided by the WTC Centers of Clinical Excellence versus standard treatments that are commonly received outside of this program.

Limitations in deriving health benefits estimates include the following. There is considerable uncertainty involved in the findings described below due to the lack of specificity of the condition information (NIOSH does not have access to condition information in current NIOSH WTC programs by specific International Classification of Diseases codes), the availability of multiple medical treatments for each condition, and limitations of published studies on the effectiveness of the medical treatments available. There are other sources of uncertainty as well. For example, some new participants in the WTC Health Program, if they have not obtained treatment previously, may present in worse health and may benefit less from medical treatment than

participants who received timely treatment through current NIOSH WTC programs. Also, HHS has not given consideration in these analyses to the fact that some WTC Health Program participants have or will have multiple illnesses concurrently, which can impact the effectiveness of medical treatment for any given condition. HHS has also not estimated what the likely impact of expanded coverage and more affordable health care would be through health reform.

- Asthma

The recommended treatment for asthma in the Guidelines is a combination of a daily inhaled corticosteroid (ICS) and a short-acting inhaled bronchodilator. HHS assumes that all patients in the WTC Health Program would be treated accordingly, compared to a hypothetical scenario according to which patients would be treated with a bronchodilator only, and compared the quality of life of these two groups. An alternative would have been to compare the presumed quality of life of WTC Health Program patients to that of untreated patients suffering from asthma. HHS chose the former approach because HHS lacks good quality empirical evidence of the effectiveness of treatment inside or outside WTC Health Program, and because this approach likely results in an underestimate of the true health benefits for these patients. Paltiel *et al.* studied adult asthma patients and projected their health-related quality of life outcomes for 10 years into the future, with and without ICS treatment.³ Without ICS, the quality-adjusted life years (QALYs) of each such patient for a 10-year-long period were estimated to be 8.65, while with ICS they were estimated to be 8.94 QALYs (without discounting). The difference in QALYs between treatment outcomes for the period was 0.29 QALYs for each patient, which divided by 10 years results in 0.029 QALYs annually. Multiplying the WTC Health Program's asthma patient population for each year during FY 2011–2015 by 0.029 results in 642 total or 151 annualized undiscounted QALYs gained from treating asthma patients in the Program with ICS versus no ICS (without adjusting for deaths based on life expectancy tables, which would mostly be attributed to non-asthma related causes). As discussed above, this estimate has a high degree of

uncertainty. To illustrate this uncertainty, HHS assumes a lower or higher degree of treatment effectiveness by halving or doubling the estimated improvement in quality of life, which results in a low estimate of 321 total or 76 annualized undiscounted QALYs to a high estimate of 1,284 total or 302 annualized undiscounted QALYs. HHS also applies a standard low and high discount rate of 3 percent and 7 percent, respectively, to estimate the present value of health benefits occurring in the future. Under the assumption of 0.029 QALYs gained per year per patient under treatment, this results in 581 total or 150 annualized QALYs when discounting future health benefits at 3 percent and 510 total or 146 annualized QALYs when discounting at 7 percent, respectively.

- Reactive Airways Dysfunction Syndrome (RADS)

According to the Guidelines, medical treatment similar to that for asthma can be provided for patients suffering from RADS. Using the assumptions described above, HHS estimates this would result in 394 total or 93 annualized undiscounted QALYs gained from treatment of RADS. HHS estimates of positive health impact range from a low of 197 total or 47 annualized undiscounted QALYs to a high of 788 total or 186 annualized undiscounted QALYs, when assuming that half or double the effectiveness of treatment in improving quality of life. Assuming that treating one patient results in 0.029 QALYs gained and discounting future health benefits at 3 and 7 percent, results in 67 total or 92 annualized QALYs and 313 total or 90 annualized QALYs, respectively.

- Chronic Obstructive Pulmonary Disease (COPD)

The Guidelines do not address COPD treatment in detail. HHS used information from Briggs *et al.*, who compared treatments of adult COPD patients in several countries, including the United States.⁴ Comparison treatments included placebo, salmeterol only, fluticasone propionate only, and a combination salmeterol/fluticasone propionate. The authors found the combination treatment was the most effective. HHS used the difference in QALYs between the combination treatment and salmeterol (0.067), which

yields less health improvement than the combination compared to a placebo (0.077). Multiplying the WTC Health Program's COPD population for each year during FY 2011–2015 by 0.077 results in 598 total or 141 annualized undiscounted QALYs gained. Assuming half and double the improvement in quality of life results in 299 total or 71 annualized undiscounted QALYs gained and 1,196 total or 282 annualized undiscounted QALYs gained, respectively. Assuming that treatment of one patient results in 0.077 QALYs gained and discounting future health benefits at 3 and 7 percent results in 541 total or 140 annualized QALYs gained and 475 total or 137 annualized QALYs gained, respectively.

- Chronic Rhinosinusitis (CRS)

The literature provides some evidence that medical treatment of CRS, similar to what is recommended in the Guidelines, would be as effective as surgery for many levels of severity of CRS.⁵ HHS did not find any published studies on CRS that included health-related quality of life related information. Ko and Coons report on mean quality of life for several chronic conditions in U.S. adults, that include asthma (0.924) and sinusitis (0.933).⁶ However, in general CRS is probably associated with a lower quality of life than sinusitis. Assuming that the improvement in CRS-related quality of life with effective treatment is only half that of asthma (*i.e.*, 0.0145, see above), treating CRS patients through the WTC Health Program would result in 824 total or 194 annualized undiscounted QALYs gained. Assuming half and double the improvement in quality of life results in 52 total or 97 annualized undiscounted QALYs gained and 1,648 total or 388 annualized undiscounted QALYs gained, respectively. Assuming that annual treatment of one patient results in 0.0145 QALYs gained and discounting future health benefits at 3 and 7 percent results in 746 total or 192 annualized QALYs gained and 655 total or 188 annualized QALYs gained, respectively.

- Gastroesophageal Reflux (GERD)

The Guidelines recommend the use of proton pump inhibitors (PPIs) for 4–8 weeks, followed by maintenance PPI (PPI on demand) to treat GERD. Gerson

³ Paltiel AD, Fuhlbrigge AL, Kitch BT, Lijas B, Weiss ST, Neumann PJ, Kuntz KM. 2001. Cost effectiveness of inhaled corticosteroids in adults with mild to moderate asthma: results from the Asthma Policy Model. *J Allergy Clin Immunol* 108(1):39–46.

⁴ Briggs AH, Glick HA, Lozano-Ortega G, Spencer M, Caverley PMA, Jones PW, Vestbo J on behalf of the Towards a Revolution in COPD Health (TORCH) investigators. 2010. Is treatment with ICS and LABA cost-effective for COPD? Multinational economic analysis of the TORCH study. *European Respiratory Journal* 35(3):532–539.

⁵ Ragab SM, Lund VJ, Scadding G. 2004. Evaluation of the medical and surgical treatment of chronic rhinosinusitis: a prospective, randomized, controlled trial. *Laryngoscope* 114:923–930.

⁶ Ko Y, Coons SJ. Self-reported chronic conditions and EQ-5D index scores in the US adult population. 2006. *Current Medical Research and Opinions* 22(10):2065–2071.

et al. compared PPI on demand to several other treatments.⁷ The authors report 0.012 QALYs gained when comparing PPI on demand to the next most effective treatment they examined (continuous PPI). Multiplying the WTC Health Program's GERD population for each year during FY 2011–2015 by 0.012 results in 550 total or 129 annualized undiscounted QALYs gained. Assuming half and double the improvement in quality of life results in 275 total or 65 annualized undiscounted QALYs gained and 1,100 total or 258 annualized undiscounted QALYs gained, respectively. Assuming that annual treatment of one patient results in 0.012 QALYs gained and discounting future health benefits at 3 and 7 percent results in 498 total or 128 annualized QALYs gained and 437 total or 125 annualized QALYs gained, respectively.

- PTSD and Depression

One of the treatments for PTSD addressed in the Guidelines is exposure therapy (in combination with medication or other treatment as

needed). Nacash *et al.* found a significant reduction of over 50 percent of PTSD and depression symptoms measured by the PSS–I (PTSD Symptom Scale-Interview Version) between “treatment as usual” and prolonged exposure therapy.⁸ PSS–I is roughly equivalent to CAPS, another longer diagnostic tool for PTSD, according to Foa and Tolin;⁹ CAPS has been studied in relation to quality of life by Mancino *et al.*¹⁰ HHS assumed that the exposure therapy treatment would result in an increase in quality of life that is approximately half that reported by Mancino as the difference between moderately severe and moderate PTSD, or 0.013 QALYs. This result means that WTC Health Program patients suffering from PTSD and depression would gain 421 total or 99 annualized undiscounted QALYs. Assuming half and double the improvement in quality of life results in 211 total or 47 annualized undiscounted QALYs gained and 842 total or 198 annualized undiscounted QALYs gained, respectively. Assuming that annual treatment of one patient results

in 0.013 QALYs gained and discounting future health benefits at 3 and 7 percent results in 381 total or 98 annualized QALYs gained and 334 total or 96 annualized QALYs gained, respectively.

In summary, available information indicates the WTC Health Program is likely to provide substantial improvements in health to responders and survivors. The discounted QALY estimates discussed above and summarized in Table 4 below are illustrative of these benefits. Annualized mid-range estimates for these six health conditions, as well as annualized cost estimates, are provided in Table 5 concluding these analyses of costs and benefits. Table 5 presents the benefits in terms of a range from no effect or benefit to the midrange estimated values of benefit to account for uncertainty regarding the number of WTC health program responders and survivors who might receive the same medical treatments for these conditions using other sources of health insurance coverage.

TABLE 4—POTENTIAL QALYs GAINED FROM THE WTC HEALTH PROGRAM TREATMENT OF SELECT WTC-RELATED HEALTH CONDITIONS: FY 2011–2015 SUMMARY

Health condition	Total undiscounted QALYs gained by treatment (mid-range estimates)	Present value of QALYs gained by treatment discounted at 3%	Present Value of QALYs gained by treatment discounted at 7%
Asthma	642	581	510
RADS	394	357	313
COPD	598	541	475
CRS	824	746	655
GERD	550	498	437
PTSD & Depression	421	381	335

TABLE 5—ACCOUNTING STATEMENT: ANNUALIZED COSTS AND SELECT HEALTH BENEFITS OF THE WTC HEALTH PROGRAM

	Estimate range (low/high)	Year dollar	Discount rate (%)	Period covered
Benefits (Quantified, unmonetized)				
Annualized (QALYs gained/year)				
Asthma	0–146	7	5
	0–150	3	5
RADS	0–90	7	5
	0–92	3	5
COPD	0–137	7	5
	140	3	5
CRS	0–88	7	5
	92	3	5
GERD	0–125	7	5

⁷ Gerson LB, Robbins AS, Garber A, Hornberger J, Triadafilopoulos G. 2000 A cost-effectiveness analysis of prescribing strategies in the management of gastroesophageal reflux disease. *The American Journal of Gastroenterology* 95(2): 395–407.

⁸ Nacasch N, Foa EB, Huppert JD, Tzur D, Fostick L, Dinstein Y, Polliack M, Zohar J. 2010. Prolonged

exposure therapy for combat- and terror-related posttraumatic stress disorder: a randomized control comparison with treatment as usual. *J Clin Psychiatry* (published online ahead of print): doi:10.4088/JCP.09m05682blu.

⁹ Foa EB, Tolin DF. 2000. Comparison of the PTSD Symptom Scale-Interview Version and the

Clinician-Administered PTSD Scale. *Journal of Traumatic Stress* 13(2):181–191.

¹⁰ Mancino MJ, Pyne JM, Tripathi S, Constans J, Roca V, Freeman T. 2006. Quality-adjusted health status in veterans with posttraumatic stress disorder. *J Nerv Ment Dis* 194:877–879.

TABLE 5—ACCOUNTING STATEMENT: ANNUALIZED COSTS AND SELECT HEALTH BENEFITS OF THE WTC HEALTH PROGRAM—Continued

	Estimate range (low/high)	Year dollar	Discount rate (%)	Period covered
PTSD & Depression	0–128 0–96 0–98	3 7 3	5 5 5
Transfers (Federal Government to centers under contract with the WTC Health Program)				
Annualized monetized (\$ million/year)	\$104–\$136.08 \$106.70–\$139.93	2011	7 3	5 5

Regulatory Options

Under E.O. 13563, HHS is required to “identify and assess available alternatives to direct regulation.” The provisions of this rule are either specifically mandated by the PHS Act to be established by regulation or they establish substantive rights for members of the public, which are issued through notice and comment rulemaking and codified as Federal regulations.

E.O. 13563 also requires HHS to “tailor its regulations to impose the least burden on society,” consistent with the regulatory objectives, and to choose among “alternative regulatory approaches those that maximize net benefits.” However, the PHS Act provides only minor discretion or no discretion to HHS for the most significant provisions of the rule. Title XXXIII of the PHS Act specifies without ambiguity the following major elements: eligibility criteria for responders and certain survivors of the New York City attacks and procedures for their enrollment or certification; an initial list of WTC-related health conditions that may be covered by the Program and criteria and certain procedures for determining whether one or more of these conditions shall be covered for a given responder or survivor; criteria and procedures for determining whether a condition medically associated with a WTC-related health condition shall also be covered for a given responder or survivor; procedures for determining the medical necessity and hence the coverage of specific treatments for covered conditions; the opportunity for responders and survivors to appeal adverse decisions determined by the program regarding their enrollment, coverage for specific health conditions, or coverage of specific medical treatments; and the use of Federal Employee Compensation Act (FECA) reimbursement rates for treatments provided, when applicable. As a result, the very limited discretion granted to HHS by the PHS Act does not provide substantial opportunities for policy

choices that would have any significant impact on burdens on society. Similarly, the options for alternative regulatory approaches are minor and can have little or no bearing on maximizing net benefits. However, in accordance with this latter requirement, HHS examined several alternative approaches to specific provisions in this rule for which the PHS Act provides discretion in determining the policy to be established. A summary of the three more substantive of these alternatives follows:

Verifying Applicant Qualifications: The PHS Act does not specify the procedure or requirements by which the WTC Program Administrator is to verify the qualifications of a responder applicant in relation to the eligibility criteria specified by the PHS Act. The rule could require written documentation from the applicant’s employer or other entity that might verify an individual’s presence, residence, or employment, as proof of their eligibility. The rule prioritizes such documentation but requires applicants to attest to their eligibility as an alternative, together with explanation of the lack of documentation and their efforts to obtain such. Attestations made in lieu of documentation would be verified as described below. False attestations would be subject to penalty as noticed and specified on the application forms.

HHS decided not to exclusively rely on documentation because experience in the current NIOSH WTC programs has demonstrated that many responders do not have access to such documentation; this includes many of the unpaid volunteers who were involved in the response effort as well as day laborers and other contingent workers common to the construction industry involved in the site remediation activities. The current NIOSH WTC programs have verified the eligibility of applicants despite this documentary limitation by comparing the specific information provided by an

applicant during the application process with the applicant’s exposure history obtained during the initial health evaluation. The WTC Health Program will continue to verify the responses provided by individuals on the application form by checking them against the responses given during the exposure assessment. Doing so will allow Program staff to evaluate the veracity of information provided by the individual and thereby assess eligibility. HHS has rejected the specification of a more restrictive documentary requirement for verifying the eligibility of responders, which would exclude responders who meet the statutory criteria for enrollment and is unnecessary for effectively assessing eligibility. HHS invites public comment on the appropriateness of this verification process.

Medical Necessity Standard: The PHS Act authorizes the WTC Program Administrator to establish a medical necessity standard, which governs the approval of specific medical treatments, together with the use of treatment protocols to be approved by the Administrator. Public and private health plans all have such standards, which typically require a determination that procedures are reasonable and appropriate on the basis of professional standards of care and scientific evidence. They vary substantially regarding their level of detail and particular features, such as considerations of cost-effectiveness or exclusions of experimental procedures. HHS could have adopted a medical necessity standard from another public or private health care plan or program. However, HHS did not identify useful distinctions among these standards aside from the salient features of relying on professional standards of care and scientific evidence. HHS does recognize that the very particular exposure history of the population under care would require some latitude for considering expert opinion when the current state of

science or professional standards of care might be deficient.

Accordingly, in the medical necessity standard included in this rule, HHS coupled the two salient features of other standards, relying on professional standards of care and scientific evidence, as well as the option of relying on expert opinion, with the requirement that treatments adhere to treatment protocols approved by the WTC Program Administrator, as specified in Title XXXIII of the PHS Act. HHS believes that this standard will adequately support the WTC Program Administrator to effectively and efficiently manage determinations of medical necessity in this Program and ensure that responders and survivors receive necessary medical treatments. HHS invites public comment on the appropriateness of this standard and whether any additional elements or criteria should be considered.

Treatment Payment Rates: Title XXXIII of the PHS Act requires the WTC Program Administrator to reimburse costs using the FECA payment rate for medically necessary treatment that is covered by the FECA rates. For any treatment that is not covered by FECA rates, the WTC Program Administrator is authorized to establish payment rates, within the limitation that payment rates for such treatment not exceed the rates paid for these products and services by the Department of Labor's Office of Workers' Compensation. HHS is not aware of any treatment to be provided that is not currently covered by FECA rates. However, NIOSH is not fully expert in FECA coding and such a deficiency is possible. To address this need, HHS considered establishing rates uniquely for this program. HHS could have promulgated the basis for rate setting in this rule and then would have published rate schedules periodically to account for the additions of treatments, health care inflation, and local health care market changes. HHS decided against this approach because it would be highly inefficient, as such rate setting is already conducted by the Centers for Medicare & Medicaid Services for the far larger populations of patients served by its programs. Moreover, most, if not all, of the treatments required in this Program are covered by FECA rates, so the extent of the rate-setting that might be needed for this Program would be minor. Finally, although this Program covers a small population, its scope is national, as responders and survivors are covered wherever they might live, and over time one can expect this population to continually disperse for employment, retirement, and other reasons.

Accordingly, HHS has decided it would adopt Medicare payment rates, which are updated periodically and cover all U.S. localities nationally. HHS believes this is optimal for several reasons: (1) The rates are promulgated on the basis of extensive expert analysis, which ensures competence in the rate setting; (2) the rates are already widely applied in every locality throughout the nation and hence, their application for this relatively minor use is unlikely to significantly impact any health care organization involved in this program; and (3) the rates meet the statutory requirement under the PHS Act of not exceeding rates paid by the Department of Labor's Office of Workers' Compensation Programs. HHS invites public comment on the appropriateness of this approach and whether any additional possibilities should be considered.

C. Paperwork Reduction Act

CDC has determined that this interim final rule contains information collection and record keeping requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3420). A description of these provisions is given below with an estimate of the annual reporting burden. Included in the estimate of the annual reporting burden is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information. In compliance with the requirement of § 3506(c)(2)(A) of the PRA for opportunity for public comment on proposed data collection projects, CDC will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–5960 and send comments to Daniel Holcomb, CDC Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to omb@cdc.gov.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information shall have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents. Written comments

should be received within 60 days of this notice.

Proposed Project: World Trade Center Health Program (42 CFR 88) (OMB Control Number 0920–0891, expiration date 12/31/2011)—New—National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

Background and Brief Description: Title XXXIII of the Public Health Service Act as amended establishes the WTC Health Program within HHS. The Program will provide medical monitoring and treatment benefits to responders to the September 11, 2001, terrorist attacks in New York City, at the Pentagon, and at Shanksville, PA, and survivors of the terrorist attacks in New York City. Title XXXIII of the PHS Act requires that various program provisions be established by regulation, and also requires that the Program begin providing benefits on July 1, 2011.

This interim final rule contains the data collection requirements that have been approved by OMB through their emergency clearance process under OMB Control Number 0920–0891, with an expiration date of December 31, 2011. The provisions in the interim final rule that contain data collection requirements are:

Section 88.3 Eligibility—currently identified responders; Section 88.7 Eligibility—currently identified survivors. These sections restate the eligibility criteria, as outlined in Title XXXIII, § 3311 and § 3321 of the PHS Act, for WTC responders and survivors who have received medical monitoring and treatment benefits from the NIOSH WTC program. HHS estimates that approximately .5 percent of currently identified responders and survivors, or 290, will be asked to provide the Program with additional information to ensure that the individual meets all eligibility criteria. We expect that responding to this inquiry will take no more than 10 minutes.

Section 88.5 Application process—status as a WTC responder. This section informs applicants who believe they meet the eligibility criteria for a WTC responder how to apply for enrollment in the WTC Health Program, and describes the types of documentation the WTC Program Administrator will accept as proof of eligibility.

Two distinct but equivalent application forms will be available, one appropriate to members of the Fire Department, City of New York (FDNY) (and their eligible family members), and a second appropriate to members of specified law enforcement organizations and certain other rescue, recovery, and cleanup workers.

Section 88.9 Application process—status as a WTC survivor. This section informs applicants who believe they meet the eligibility criteria for a WTC survivor how to apply for screening-eligible status in the WTC Health Program, and describes the types of documentation the WTC Program Administrator will accept as proof of eligibility.

Section 88.11 Appeals regarding eligibility determination—responders and survivors. This section establishes the process for appeals regarding eligibility determinations. The burden table reflects the annualized total burden (14,184/3 = 4,728), broken into the three separate applicant groups (Fire Department of New York responders (189), general responders (2,979), and survivors (1,560)). Of those applications, we expect that 10 percent will fail due to ineligibility. We further assume that 10 percent of those individuals (47 respondents) will appeal the decision.

Section 88.12 Physician's Determination of WTC-Related Health Conditions. This section requires the collection and reporting of information related to the diagnosis of a WTC-related health condition or health condition medically associated with a WTC-related health condition in a WTC responder or certified-eligible survivor.

Data collection activities in § 88.12, "Physician's Determination of WTC-Related Health Conditions," do not fall under the PRA because they are within one of the ten categories of inquiry generally not deemed to constitute information (5 CFR 1320.3(h)(1)–(10)). Medical diagnosis and treatment, which falls under § 88.12 and § 88.14 of this part, includes an initial and follow-up clinical examinations designed to detect health disorders, as well as direct treatment of clinical disorders to improve or prevent progression of the disorders. Results of clinical examinations and treatment will be used in connection with research to understand the disease processes and to develop better prophylactic procedures

for healthcare of the served population. Burden associated with epidemiologic and other research regarding certain health conditions related to the September 11, 2001, terrorist attacks is not contemplated as part of this rulemaking.

Data reporting from physicians to the WTC Program Administrator under § 88.12 is subject to the PRA. Physicians will report this data electronically and on paper. HHS expects that 2,300 program physicians will spend approximately 30 minutes extracting the required elements from the patient records and transmitting them to NIOSH, and that approximately 32,361 diagnoses, or 14 per provider, will be reported to the WTC Health Program each year.

Section 88.15 Appeals regarding treatment. This section establishes the timeline and process to appeal decisions regarding treatment decisions. HHS estimates that program participants will request certification for 32,361 health conditions each year. Of those 32,361, we expect that .001 percent (32) will be denied certification by the WTC Program Administrator. We further expect that such a denial will be appealed 95 percent of the time. Of the projected 19,596 enrollees who will receive medical care, it is estimated that 3 percent (588) will appeal decisions of unnecessary treatment. We estimate that the appeals letter will take no more than 30 minutes.

Section 88.16 Reimbursement for medically necessary treatment, outpatient prescription pharmaceuticals, monitoring, initial health evaluations, and travel expenses. This section establishes the process by which a Clinical Center of Excellence or member of the nationwide provider network will be reimbursed by the WTC Health Program for the cost of medical treatment and outpatient prescription pharmaceuticals, and a WTC responder or certified-eligible survivor may be reimbursed for certain transportation expenses.

Standard U.S. Treasury form SF 3881 (OMB No. 1510–0056) will be used to gather necessary information from Program healthcare providers so that they can be reimbursed directly from the Treasury Department. HHS expects that approximately 200 providers and provider groups will submit SF 3881, which is estimated to take 15 minutes to complete. Providers will submit only one SF 3881.

Pharmacies will electronically transmit reimbursement claims to the WTC Health Program. HHS estimates that 150 pharmacies will submit reimbursement claims for 39,192 prescriptions per year, or 261 per pharmacy; we estimate that each submission will take 1 minute.

WTC responders or certified eligible survivors who travel more than 250 miles to a nationwide network provider for medically necessary treatment may be provided necessary and reasonable transportation and other expenses. These individuals may submit a travel refund request form, which should take respondents 10 minutes. HHS expects no more than 10 claims per year.

The reporting and record keeping requirements contained in these regulations are used by NIOSH to carry out its responsibilities related to the implementation of the WTC Health Program as required by law. The burdens imposed have been reduced to the absolute minimum considered necessary to permit NIOSH to carry out the purpose of the legislation, *i.e.*, to implement the WTC Health Program. This emergency data collection is warranted because it is essential that individuals who wish to be enrolled, apply to the WTC Health Program, appeal a determination made by the WTC Program Administrator, or submit a claim for reimbursement have the opportunity to do so as soon as the Program begins.

This new information collection request is for 19,111 burden hours.

Section	Title	Number of respondents	Responses per respondent	Average burden per response	Total burden (in hours)
88.3	Eligibility—currently identified responders;	290	1	10/60	48
88.7	Eligibility—currently identified survivors.				
88.5	Application process—status as a WTC responder (FDNY)	189	1	30/60	95
88.5	Application process—status as a WTC responder (general)	2,979	1	30/60	1,490
88.9	Application process—status as a WTC survivor	1,560	1	15/60	390
88.11	Appeals regarding eligibility determinations—responders and survivors.	47	1	30/60	24
88.12	Physician's determination of health conditions in WTC responders and certified-eligible survivors [physician reporting].	2,300	14	30/60	16,100
88.15	Appeals regarding treatment	588	1	30/60	294
88.15	Appeals regarding certification of health conditions	30	1	30/60	15
88.16	Reimbursement for medically necessary treatment, monitoring, initial health evaluations.	200	1	15/60	50

Section	Title	Number of respondents	Responses per respondent	Average burden per response	Total burden (in hours)
	Outpatient prescription pharmaceuticals	150	261	1/60	653
	Travel expenses	10	1	10/60	2
Total	* 19,111

* The physician reimbursement claim under § 88.16 is subtracted from the total because it is captured elsewhere.

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.*), the Department 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 rule does not include any Federal mandate that may result in increased annual expenditures in excess of \$100 million by State, local or Tribal governments in the aggregate, or by the private sector.

F. Executive Order 12988 (Civil Justice)

This 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 Department has reviewed this 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, HHS has evaluated the environmental health and safety effects of this rule on children. HHS 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, HHS has evaluated the effects of this 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. HHS has attempted to use plain language in promulgating this rule consistent with the Federal Plain Writing Act guidelines.

List of Subjects in 42 CFR Part 88

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

Text of the Rule

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

PART 88—WORLD TRADE CENTER HEALTH PROGRAM

- Sec.
- 88.1 Definitions.
- 88.2 General provisions.
- 88.3 Eligibility—currently-identified responders.
- 88.4 Eligibility criteria—status as a WTC responder.
- 88.5 Application process—status as a WTC responder.
- 88.6 Enrollment determination—status as a WTC responder.
- 88.7 Eligibility—currently-identified survivors.
- 88.8 Eligibility criteria—status as a WTC survivor.
- 88.9 Application process—status as a WTC survivor.
- 88.10 Enrollment determination—status as a WTC survivor.

- 88.11 Appeals regarding eligibility determinations—responders and survivors.
- 88.12 Physician’s determination of WTC-related health conditions.
- 88.13 WTC Program Administrator’s certification of health conditions.
- 88.14 Standard for determining medical necessity.
- 88.15 Appeals regarding treatment.
- 88.16 Reimbursement for medically necessary treatment, outpatient prescription pharmaceuticals, monitoring, and initial health evaluations, and travel expenses.

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

§ 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.

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:

- (i) Aerodigestive disorders:
- (ii) Interstitial lung disease.
- (iii) Chronic respiratory disorder [fumes/vapors].
- (iv) Asthma.
- (v) Reactive airways dysfunction syndrome [RADS].
- (vi) WTC-exacerbated chronic obstructive pulmonary disease [COPD].
- (vii) Chronic cough syndrome.
- (viii) Upper airway hyperactivity.
- (ix) Chronic rhinosinusitis.
- (x) Chronic nasopharyngitis.
- (xi) Chronic laryngitis.
- (xii) Gastroesophageal reflux disorder [GERD].

(1)(i) 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.

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.

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.

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.

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.

§ 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]

§ 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

(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) [Reserved]

(c) [Reserved]

(d) [Reserved]

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

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

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

(2) [Reserved]

(b) *Criteria for status as a certified-eligible survivor.* Survivors who have been determined to have screening-eligible status under § 88.10(a), may seek status as a certified-eligible survivor. Status as a certified-eligible survivor is based on a certification by the WTC 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.

Dated: May 6, 2011.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

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