• Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

• Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

• Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and

• Does not provide EPA with the discretionary authority to address disproportionate human health or environmental effects with practical, appropriate, and legally permissible methods under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the State, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by May 28, 2013. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the Proposed Rules section of today's **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Volatile organic compounds.

Dated: January 25, 2013.

Jared Blumenfeld,

Regional Administrator, Region IX.

Part 52, Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for Part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraph (c)(411)(i)(F) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(411) * * *

(i) * * *

(F) South Coast Air Quality Management District.

(*1*) Rule 463, ''Organic Liquid Storage,'' amended on November 4, 2011.

* * * * *

[FR Doc. 2013–06423 Filed 3–27–13; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 88

[Docket No. CDC–2013–0002; NIOSH–261]

RIN 0920–AA48

World Trade Center Health Program Eligibility Requirements for Shanksville, Pennsylvania and Pentagon Responders

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Interim final rule with request for comments.

SUMMARY: Title I of the James Zadroga 9/11 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. The WTC Health Program is administered by the Director of the National Institute for Occupational Safety and Health (NIOSH), within the Centers for Disease Control and Prevention (CDC), in the Department of Health and Human Services (HHS), and provides 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, Pennsylvania, and at the Pentagon, and to eligible survivors of the New York City attacks. Section 3311(a)(2)(C) of the PHS Act requires the WTC Program Administrator (Administrator) to develop eligibility criteria for enrollment of Shanksville, Pennsylvania and Pentagon responders. This interim final rule establishes those eligibility criteria.

DATES: This interim final rule will be effective May 1, 2013. HHS invites written comments from interested parties on this interim final rule and on the information collection approval request sought under the Paperwork Reduction Act. Comments must be received by April 30, 2013.

ADDRESSES: You may submit comments, identified by ''RIN 0920–AA48,'' by either of the following methods:

• *Internet:* Access the Federal e-rulemaking portal at *http://www.regulations.gov.* Follow the instructions for submitting comments to Docket No. CDC–2013–0002.

• *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 relevant comments will be posted without change to *http://www.regulations.gov* and *http://www.cdc.gov/niosh/docket/review/docket261/default.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/review/docket261/default.html.

FOR FURTHER INFORMATION CONTACT: Frank J. Hearl, PE, Chief of Staff, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Patriots Plaza, Suite 9200, 395 E St. SW., Washington, DC 20201. Telephone: (202) 245–0625 (this is not a toll-free number). Email: *WTCpublicinput@cdc.gov.*

SUPPLEMENTARY INFORMATION: This notice is organized as follows:

I. Executive Summary

A. Purpose of Regulatory Action

The WTC Health Program does not currently offer monitoring or treatment services to individuals who responded to the September 11, 2001, terrorist attacks at the Pentagon or in Shanksville. The statute clearly defines eligibility criteria for New York responders, whereas the Administrator is required to develop criteria for the enrollment of Pentagon and Shanksville responders. This rule establishes those eligibility criteria. Upon the effective date of this rule, individuals who believe they may be eligible for enrollment in the WTC Health Program may submit an application and supporting documentation.

B. Summary of Major Provisions

This interim final rule will establish eligibility criteria for the enrollment of responders to the September 11, 2001, terrorist attacks at the Pentagon and in Shanksville, Pennsylvania. The PHS Act does not allow for enrollment of survivors from either of the two sites. Therefore, survivors of the terrorist attacks at those sites who did not engage in rescue, recovery, cleanup or other related activities will not be eligible for enrollment.

The eligibility criteria in § 88.4(b) and (c) apply to those individuals who were a member of a fire or police department (whether fire or emergency personnel, active or retired), worked for a recovery or cleanup contractor, or were volunteers; and performed rescue, recovery, demolition, debris cleanup, or other related services at either site.

This interim final rule adds the definition of ''police department'' to the list of definitions in 42 CFR 88.1. It also adds definitions for ''Pentagon site'' and ''Shanksville, Pennsylvania site.''

In order to establish that the individual is eligible for membership in the WTC Health Program, he or she must have participated in activities at either site for a minimum amount of time. Pentagon responders must have participated at the site for at least 1 day beginning September 11, 2001, and ending on November 19, 2001. Shanksville, Pennsylvania responders must have participated at that site for at least 1 day beginning September 11, 2001, and ending on October 3, 2001.

C. Costs and Benefits

The total cost, transfers, and benefits resulting from this regulatory action are due to the expansion of the population of responders eligible to enroll in the WTC Health Program. For the purpose of this analysis, HHS assumes that between 540 and 1,467 Pentagon and Shanksville responders will enroll in the Program in 2013. We estimate the total cost of initial medical examinations, annual monitoring, and treatment for Pentagon and Shanksville responders to be at least $988,300 and no more than $3,203,400 annually through 2016.

II. Public Participation

Interested persons or organizations are invited to participate in this rulemaking by submitting written views, opinions, recommendations, and/or data. Comments are invited on any topic related to this interim final rule. In addition, HHS invites comments specifically on the following questions related to this rulemaking:

1. The terms ''Pentagon site'' and ''Shanksville, Pennsylvania site'' are not defined in the PHS Act. The Administrator believes it is necessary to define the geographic boundaries of the respective sites, in order to better identify eligible responders and has defined the terms in this interim final rule. The Administrator seeks input on whether the definitions are clearly understood and contain the locations that are relevant to the response activities. After reviewing published reports and anecdotal accounts of the events at both sites, the Administrator is unable to ascertain whether there may have been perimeter boundaries broader than our proposed definitions, and whether the proposed definitions may unintentionally exclude some response personnel who worked at the sites. We have identified a number of specific locations around the Pentagon where response activities occurred: the heliport, triage areas established on the lawn near S. Washington Road and Jefferson Davis Highway and in the Pentagon Center Court, and in the North Parking lot debris sifting area. We have also identified Fort Belvoir in Virginia and Dover Air Force Base in Delaware as locations where responders may have worked closely with victims' remains. Similarly, for the Shanksville site, we are aware that responders transported remains to the Pennsylvania National Guard armory in Friedens. We welcome input from responder organizations who participated in Pentagon and Shanksville response activities regarding these definitions.

2. The Administrator is establishing dates for the end of clean-up activities at each site. Based on the best available evidence, the rule establishes end-dates of November 19, 2001, for the Pentagon site and October 3, 2001, for the Shanksville, Pennsylvania site. The Administrator welcomes additional public input on these dates.

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 the comments submitted and may revise the final rule as appropriate.

III. Background

A. WTC Health Program History

After the terrorist attacks of September 11, 2001, HHS, CDC, and NIOSH facilitated medical monitoring for those firefighters and related personnel, law enforcement officers, and rescue, recovery, and cleanup workers who responded to the terrorist attacks in New York City. A health screening program for responders that

began in 2002 was expanded through a series of congressional appropriations, and in 2006 the program was re-named the WTC Medical Monitoring and Treatment Program (MMTP) to reflect expanded services available for responders. A separate NIOSH health program for residents, students, and others in the community who were affected by the September 11, 2001, terrorist attacks in New York City (survivors) was funded in 2008.

Responders, including members of fire and police departments and others who conducted rescue, recovery, and cleanup at the September 11, 2001, terrorist attack sites in Shanksville, Pennsylvania and at the Pentagon were not provided services under the MMTP because congressional appropriations language did not specify inclusion of those groups.

The WTC Health Program was established by law on January 2, 2011, and went into effect July 1, 2011. Regulations established in 42 CFR Part 88 describe 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 New York City attacks may be enrolled in the WTC Health Program. Part 88 also sets out the processes by which the Administrator makes enrollment determinations, certifies WTC-related health conditions for monitoring and treatment, reimburses providers for medically necessary treatment, and adds conditions to the List of WTC-Related Health Conditions.

The WTC Health Program does not currently offer monitoring or treatment services to individuals who responded to the September 11, 2001, terrorist attacks at the Pentagon or in Shanksville. The statute clearly defines eligibility criteria for New York responders, whereas the Administrator is required to develop criteria for the enrollment of Pentagon and Shanksville responders. This rule establishes those eligibility criteria. Upon the effective date of this rule, individuals who believe they may be eligible for enrollment in the WTC Health Program may submit an application and supporting documentation. Information about applying to the WTC Health Program is available at *http://www.cdc.gov/wtc.*

B. 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 XXXIII,[1] establishing the WTC Health Program within HHS. Under Title XXXIII of the PHS Act, the Administrator is responsible for the WTC Health Program. All references to the Administrator in this notice mean the NIOSH Director or his or her designee.

Section 3311(a)(2)(C) of the PHS Act identifies a responder to the September 11, 2001, terrorist attacks at the Pentagon and Shanksville, Pennsylvania as an individual who ''was a member of a fire or police department (whether fire or emergency personnel, active or retired), worked for a recovery or cleanup contractor, or was a volunteer; and performed rescue, recovery, demolition, debris cleanup, or other related services.'' The Act requires that the Administrator establish the dates on which cleanup was concluded at the Pentagon and Shanksville sites, respectively. The Administrator is also required under § 3311(a)(2)(C)(ii) to develop eligibility criteria for determining whether an individual applicant is at an increased risk of developing a WTC-related health condition as a result of exposure to airborne toxins, other hazards, or adverse conditions resulting from the September 11, 2001, terrorist attacks, at each site. The Administrator is required to consult with the WTC Health Program Scientific/Technical Advisory Committee (STAC) on the development of eligibility criteria related to such exposures. The PHS Act does not allow for enrollment of survivors from either of the two sites.

C. Summary of WTC Health Program Findings: Evidence Concerning Eligibility Criteria for Pentagon and Shanksville, Pennsylvania Responders

The Administrator reviewed relevant data to determine whether further eligibility criteria, beyond those criteria described in the Act for Pentagon and Shanksville responders (see Section III.B., above), was warranted. A report to the Administrator produced by NIOSH at the Administrator's request reviewed published literature and other authoritative sources and consultations with participating responders from both sites, and served as the basis for the Administrator's consideration.[2] The Administrator assessed the reported results of environmental sampling at the respective sites as well as the estimated length of time that each of the various responder groups participated in rescue, recovery, demolition, debris cleanup, and other related response activities. The Administrator's review of the evidence identified important response and cleanup events after the terrorist attacks and provided information on the exposures potentially experienced by the responders. The review also identified the sequence of events related to clean-up at the sites and identified the likely dates of termination of clean-up activities.

Based on the evidence summarized below and after consultation with the STAC, the Administrator is revising the eligibility criterion to require that a Pentagon or Shanksville responder worked on-site for at least 1 day (the length of a standard work shift, or at least 4 hours but less than 24 hours) during the prescribed periods of time at either site. The Administrator is establishing dates for the end of clean-up activities at each site based on the best available evidence; they are November 19, 2001, for the Pentagon site and October 3, 2001, for the Shanksville, Pennsylvania site and seeks input on whether these dates are accurate.

Pentagon Site

According to the report to the Administrator, an estimated 60 Federal, State, and local agencies, including military personnel, responded to the Pentagon within the first 8 hours of the terrorist-related plane crash. Response activities included rescue efforts, site security, traffic control, and evidence collection. American Red Cross and Salvation Army personnel provided food and water, and civilian and military groups collaborated to address mental health issues. Emotional well-being support was provided by mental health professionals, clergy, physiotherapists, chiropractors, and therapy dogs and their handlers. Response activities occurred in many areas of the Pentagon Reservation, including but not limited to: the heliport; triage areas established on the Pentagon lawn near S. Washington Road and Jefferson Davis Highway and in the Pentagon Center Court; and the North Parking lot debris sifting area. Human remains were removed from the area of the crash site and driven to Fort Belvoir in Fairfax County, Virginia, where they were retrieved by Army helicopters and

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

[2] McCleery RE [2012]. Summary of Evidence for Establishing Dates on which Cleanup of the Pentagon and Shanksville, Pennsylvania Sites of the Terrorist-Related Aircraft Crashes of September 11, 2001 Concluded. Prepared for the Administrator, WTC Health Program. Released February 8, 2012. This document is available in the docket for this rulemaking.

flown to Dover Air Force Base in Delaware.[3]

The Administrator found that the firefighter groups were on-site from September 11 to September 21, 2001, at which time control of the site was turned over to the Federal Bureau of Investigation (FBI). One fire company, a technical rescue team, paramedics, and some police departments were on-site until the Department of Defense assumed control from the FBI, which occurred no later than September 28, 2001. Demolition and cleanup began on October 18 and concluded on November 19, 2001. It is unclear what period of time fire and police department personnel were on-site during the period from the end of September until the end of cleanup activities on November 19, 2001, based on the available information. Recovery or cleanup contractors were on-site until November 19, 2001, which is when the demolition activities concluded.[4] Finally, available evidence suggests that volunteers were likely on-site through September 28, 2001.[5]

Environmental sampling at the Pentagon site was conducted by U.S. Army, Navy, and Air Force personnel, as well as personnel from the former Walter Reed Army Medical Center, Department of Defense, the Uniformed Services University of the Health Sciences, and a civilian contractor. The Administrator's review of the available literature found that contamination from the jet fuel, jet fuel combustion products, combustion products from aircraft and building materials, building debris, and human remains was concentrated at the incident site and most of the environmental samples collected were below occupational health and environmental exposure standards.[6]

After reviewing the length of time the various responder groups spent working at the Pentagon site, the Administrator has determined that, for the purposes of establishing eligibility criteria for Pentagon responders in 42 CFR 88.4(b), all rescue, recovery, demolition, debris cleanup, and other related response activities at the site concluded on November 19, 2001, which is when the demolition activities concluded.

Shanksville, Pennsylvania Site

The report to the Administrator determined that fire and police departments responded immediately to the plane crash at the Shanksville, Pennsylvania site and extinguished localized hot spots and brush fires. Because of the nature of the incident, there was only a limited fire response phase and no rescue response phase; responders proceeded to a recovery and investigatory response phase. Pennsylvania State Troopers provided security in and around the site, and the FBI assumed control over the site shortly after arriving on September 11. Personnel from the Somerset County (Pennsylvania) Coroner's office, the Pennsylvania Region 13 Counter-Terrorism Task Force, the State Funeral Directors Association, and other volunteers also joined the search for airplane parts and human remains. During the response, the American Red Cross and Salvation Army provided food and mental health services to responders. Response activities occurred on the property in Stonycreek Township, Somerset County, Pennsylvania, which is bounded by Route 30 (Lincoln Highway), State Route 1019 (Buckstown Road), and State Route 1007 (Lambertsville Road). Human remains were removed from the area of the crash site and taken to the Pennsylvania National Guard Armory in Friedens, Pennsylvania for identification.[7]

FBI controlled the crash site in Shanksville beginning on September 11 and ending on September 24, 2001. At that time, control was relinquished to the Somerset County Coroner. The effort to search the area for remaining aircraft parts and human remains was conducted on September 29–30, 2001.

After the response to the crash, Environmental Resources Management, Inc. (ERM) was contracted by United Airlines to document soil and water quality at the site. ERM compared the sampling results obtained to standards established by the Pennsylvania Department of Environmental Protection (PADEP) and the Pennsylvania Land Recycling and Environmental Remediation Standards Act. Although ERM concluded that no surface or subsurface soil samples exceeded any Pennsylvania standards and the site did not require any remediation, the Administrator has concluded that it is likely that responders to the Shanksville site were exposed to contamination from the jet fuel, jet fuel combustion products, combustion products from aircraft materials, and human remains.[8] ERM's reclamation activities took place between October 1 and October 3, 2001. It is not clear from available literature whether fire personnel or volunteers were on-site during these reclamation activities. Law enforcement personnel provided security on-site for a number of years following the events of September 11, 2001.

After reviewing the length of time the various responder groups spent working at the Shanksville, Pennsylvania site, the Administrator has determined that, for the purposes of establishing eligibility criteria for Shanksville responders in 42 CFR 88.4(c), all rescue, recovery, demolition, debris cleanup, and other related response activities at the site concluded on October 3, 2001.

STAC Review of Proposed Eligibility Criteria

The report to the Administrator and the Administrator's findings, including the response end-dates, were presented to the STAC during a public meeting held February 15–16, 2012. The STAC considered the proposed eligibility criteria and agreed that they are reasonable.[9]

IV. Issuance of an Interim Final Rule with Delayed Effective Date

In most circumstances, the APA 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. 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 (IFR), HHS has determined that under 5 U.S.C. 553(b)(B), good cause

[3] Goldberg A, Papadopoulos S, Putney D, Berlage N, Welch R [2007]. Pentagon 9/11. Washington, DC: Historical Office, Office of the Secretary of Defense. *http://osdhistory.defense.gov/history.html.*

[4] Goldberg A, Papadopoulos S, Putney D, Berlage N, Welch R [2007]. Pentagon 9/11. Washington, DC: Historical Office, Office of the Secretary of Defense. *http://osdhistory.defense.gov/history.html.* Accessed March 4, 2013.

[5] A Pentagon employee would not qualify as a responder unless he or she actively participated in rescue, recovery, demolition, debris cleanup, or other related response activities at the Pentagon site.

[6] Our review of the response reports indicated that all environmental samples collected on floors 1–5 of the Pentagon were below relevant health standards, except for lead (<10%) and asbestos (<5%) wipes. The majority of lead and asbestos wipes that exceeded the limit were collected on the fourth and fifth floors before cleanup activities.

[7] Lash C [2001]. Flight 93 victim identification long, arduous. Pittsburg Post-Gazette, September 25. *http://www.post-gazette.com/headlines/20010925sledzik0925p3.asp.* Accessed January 2012.

[8] ERM [2002]. Final Closure Report Flight 93, Shanksville, Pennsylvania. Environmental Resources Management. Prepared for United Airlines.

[9] Transcript; Meeting Two of the World Trade Center Scientific/Technical Advisory Committee (STAC), Vol. I, Day One, February 15, 2012. The transcript is available in the STAC docket available at *http://www.cdc.gov/niosh/docket/archive/docket248.html.*

exists for waiving the notice and comment procedures, and that the use of such procedures would be contrary to the public interest. This IFR amends 42 CFR 88.4 to establish eligibility criteria for the enrollment of responders who responded to the September 11, 2001, terrorist attacks at the Pentagon and in Shanksville, Pennsylvania. HHS has determined that it is contrary to the public interest to delay any longer than necessary those individuals' eligibility for treatment for WTC-related health conditions that are found to be related to the time they spent conducting rescue, recovery, demolition, debris cleanup, or other related services at either the Pentagon or Shanksville sites. Postponement in the implementation of eligibility criteria for Pentagon and Shanksville responders could result in real harm to those individuals who are currently coping with one or more health conditions found on the List of WTC-Related Health Conditions in 42 CFR 88.1, or who are at risk for developing such a condition. Thus, HHS is waiving the prior notice and comment procedures in the interest of protecting the health of the Pentagon and Shanksville, Pennsylvania responders and allowing them to apply for enrollment in the WTC Health Program as soon as possible.

Members of the affected communities have been given opportunities to meet with WTC Health Program staff to learn about the WTC Health Program and share thoughts and concerns. To date, WTC Health Program staff have traveled to both Arlington, Virginia and Shanksville, Pennsylvania to meet with responder representatives, including the Arlington, Virginia and Shanksville, Pennsylvania fire chiefs, and have also met with FBI responders. WTC Health Program staff have interviewed responders at both sites to collect exposure data and timelines of events. In addition, interested parties were given the opportunity to provide comment to the STAC on the proposed eligibility criteria for the Pentagon and Shanksville responders during the February 15–16, 2012, meeting of the STAC (no comments were received).

The effective date of this interim final rule will be 31 days after publication in order to allow for any substantive feedback on the rule text. While amendments to § 88.4 will be effective 31 days after the date of publication of this IFR, they are interim and will be finalized following the receipt of any substantive public comments. (*See* Section II. Public Participation, above.)

V. Summary of Interim Final Rule

This interim final rule will establish eligibility criteria for the enrollment of responders to the September 11, 2001, terrorist attacks at the Pentagon and in Shanksville, Pennsylvania.

The eligibility criteria in § 88.4(b) and (c) apply to those individuals who were a member of a fire or police department (whether fire or emergency personnel, active or retired), worked for a recovery or cleanup contractor, or were volunteers; and performed rescue, recovery, demolition, debris cleanup, or other related services at either site.

This interim final rule adds the definition of ''police department'' to the list of definitions in 42 CFR 88.1. Section 3311(a)(2)(C) of the PHS Act identifies eligible individuals who were a ''member of a * * * police department.'' The definition of ''police department'' promulgated in this interim final rule includes members of Federal, State, and local police departments and law enforcement agencies who were present on-site at the Pentagon or in Shanksville, Pennsylvania.

This rule also adds definitions of ''Pentagon site'' and ''Shanksville, Pennsylvania site'' to § 88.1. Based on the review of available evidence discussed above in section III.C., the definition ''Pentagon site'' includes the statutory definition of Pentagon Reservation found in 10 U.S.C. 2674(f)(1): any area of the land (consisting of approximately 280 acres) and improvements thereon, located in Arlington, Virginia, on which the Pentagon Office Building, Federal Building Number 2, the Pentagon heating and sewage treatment plants, and other related facilities are located, including various areas designated for the parking of vehicles, affected by the terrorist-related aircraft crash on September 11, 2001. The Administrator believes that the specific locations where response activities occurred near the Pentagon were contained within the Pentagon Reservation, although the Administrator is seeking comment on boundaries of the Pentagon Reservation and the specific locations where response activities occurred. The Administrator has determined that the definition should also include those areas at Fort Belvoir in Virginia and at the Dover Port Mortuary at Dover Air Force Base in Delaware involved in the recovery, identification, and transportation of human remains from the terrorist attacks. The mortuary at Dover and areas of Fort Belvoir are included in the definition of ''Pentagon site'' in order to parallel the provision in the eligibility criteria for New York responders identifying responders (including morgue workers) who were involved in the examination and handling of human remains from the World Trade Center.

After review of the evidence of events at the Shanksville, Pennsylvania site, the Administrator has defined ''Shanksville, Pennsylvania site'' as the property in Stonycreek Township, Somerset County, Pennsylvania, which is bounded by Route 30 (Lincoln Highway), State Route 1019 (Buckstown Road), and State Route 1007 (Lambertsville Road); the site also includes the Pennsylvania National Guard Armory in Friedens, Pennsylvania. Similar to the Pentagon site definition described above, the armory in Friedens is identified in order to establish parity with the eligibility criteria for the New York responders involved in the examination and handling of human remains.

In order to establish that the individual is eligible for membership in the WTC Health Program, he or she must have participated in activities at either site for a minimum amount of time. Pentagon responders must have participated at the site for at least 1 day beginning September 11, 2001, and ending on November 19, 2001. Shanksville, Pennsylvania responders must have participated at that site for at least 1 day beginning September 11, 2001, and ending on October 3, 2001. ''One day'' is defined in 42 CFR 88.1 as ''the length of a standard work shift, or at least 4 hours but less than 24 hours.'' The Administrator determined that presence at either site for at least 4 hours is in keeping with the corresponding minimum amount of time required to establish eligibility for responders in the New York City area. (*See,* New York City responders eligibility criteria, 42 CFR 88.4(a).) The report to the Administrator (discussed in Section III.C., above) found that while area sampling was conducted at both sites in the aftermath of the terrorist attacks, personal exposure data is not available. The Administrator recognizes the potential for responders at the two sites to have been exposed to chemical, biological, and physical hazards, similar to some of the exposures experienced as a result of the September 11, 2001, terrorist attacks on the former World Trade Center site in New York City.

VI. Applying for Coverage under this Interim Final Rule

Upon promulgation of this interim final rule, individuals who were a member of a fire or police department (whether fire or emergency personnel,

active or retired), worked for a recovery or cleanup contractor, or who were volunteers; and performed rescue, recovery, demolition, debris cleanup, or other related services at either the Pentagon or Shanksville sites may apply to obtain coverage under the WTC Health Program. The application process for responders can be found in 42 CFR 88.5.

Beginning with the effective date of this rulemaking, an individual who believes that he or she meets the eligibility criteria established in this interim final rule and qualifies as a 'WTC responder (a 'WTC responder' is defined in § 88.1 as an individual who meets the specified eligibility criteria),[10] must fill out and submit an application form to the WTC Health Program indicating that he or she meets certain eligibility criteria described in § 88.4.[11] An individual who can demonstrate that he or she meets the eligibility criteria may be enrolled in the WTC Health Program. Supporting documentation is required to be submitted along with the application and if no documentation is included (*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 or a designated representative. An applicant who knowingly provides false information may be subject to a fine and/or imprisonment of not more than 5 years.

Once enrolled in the WTC Health Program, a WTC responder may receive treatment for specific physical and mental health conditions that have been certified by the WTC Health Program and are included on the List of WTC-Related Health Conditions.[12] The List of WTC-Related Health Conditions was established by Congress and may be expanded by the Administrator through rulemaking; the List is included in § 88.1, the definitions section of this rule. In order for an individual enrolled as a WTC responder to obtain coverage for treatment of any health condition on the List of WTC-Related Health Conditions, a two-step process must be satisfied. First, a physician at a Clinical Center of Excellence or in the nationwide provider network must make a determination that the particular health condition for which the responder seeks treatment coverage is both on the List of WTC-Related Health Conditions and that exposure to airborne toxins, other hazards, or adverse conditions resulting from the September 11, 2001, terrorist attacks is substantially likely to be a significant factor in aggravating, contributing to, or causing the health condition for which the responder seeks treatment coverage.[13] Pursuant to 42 CFR 88.12(a), the physician's determination must be based on the following: (1) an assessment of the individual's exposure to airborne toxins, any other hazard, or any other adverse condition resulting from the September 11, 2001, attacks; and (2) the type of symptoms reported and the temporal sequence of those symptoms. As a second statutory requirement, all physician determinations are reviewed by the Administrator. The Administrator will certify the determination unless he or she determines that the responder's condition is not on the List of WTC-Related Health Conditions or that exposure to airborne toxins, other hazards, or adverse conditions resulting from the September 11, 2001, terrorist attacks, is not substantially likely to be a significant factor in aggravating, contributing to, or causing the condition.

VII. 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 interim final rule has been determined to be a ''significant'' action, as defined in section 3(f)(1) of E.O. 12866. Providing medical monitoring and treatment for Pentagon and Shanksville, Pennsylvania responders through the WTC Health Program will have an annual effect on the economy of less than $100 million.

Summary

The total cost, transfers, and benefits resulting from this regulatory action result from the expansion of the population of responders eligible to enroll in the WTC Health Program. In July, 2011, HHS published an interim final rule establishing the WTC Health Program regulations at 42 CFR Part 88 (76 FR 38914, 38921, July 1, 2011). HHS estimated the costs and benefits associated with the development of the WTC Health Program and the subsequent enrollment, treatment, and monitoring of responders and survivors of the September 11, 2001, terrorist attacks on New York City. For the purpose of this analysis and as discussed below, HHS assumes that a percentage of enrolled responders will not have health insurance. Program costs associated with these uninsured responders are characterized as new ''societal costs'' since these responders would not otherwise receive the health care available from the WTC Health Program. HHS further assumes that all of these previously uninsured responders will have access to health insurance after implementation of relevant provisions of the Patient Protection and Affordable Care Act (Affordable Care Act) (Pub. L. 111–148) in 2014. Accordingly, for the years 2014–2016, all program costs, including program costs for these previously uninsured responders, are characterized as ''transfers,'' since all responders will have access to some type of health insurance under the Affordable Care Act beginning in 2014 and the impact of this regulation is only to ''transfer'' the cost from other such payers to the WTC Health Program. The costs and transfers identified in the July 2011 interim final rule include administrative expenses for enrollment and claims processing, the costs of medical monitoring, and medical treatment costs. To estimate the costs associated with enrollment and medical care of the Pentagon and Shanksville responders, HHS assumes that the program and administrative costs will be analogous to those costs for the New York City responders. HHS estimates the annual cost of medical monitoring and treatment to be provided and administrative expenses of this regulatory action in millions of dollars as presented in Table 1, below. The WTC Health Program has recently conducted rulemaking to add certain types of cancer to the List of WTC-Related Health Conditions in 42 CFR 88.1 (77 FR 56138, September 12, 2012). The cost of treating and monitoring

[10] Please note that Section 3311(a)(5) of the PHS Act states that no individual who is determined to be a positive match to the terrorist watch list maintained by the Federal government shall qualify to become a WTC responder or screening-eligible or certified-eligible survivor.

[11] WTC Health Program application for Pentagon and Shanksville responders will be available on the Program's Web site at *http://www.cdc.gov/wtc/apply.html.*

[12] The List of WTC-Related Health Conditions can be found on the Program Web site at *http://www.cdc.gov/wtc/faq.html.*

[13] See § 3312(a)(1) of the PHS Act; 42 U.S.C. 300mm–22(a)(1).

cancers that may be certified for Pentagon and Shanksville responders is included in the analysis conducted in that rulemaking.

TABLE 1—ANNUAL HEALTHCARE AND ADMINISTRATIVE COSTS AND TRANSFERS $MILLIONS (2011$)

	Societal Costs		Transfers	
	Discounted 7 percent *	Discounted 3 percent	Discounted 7 percent	Discounted 3 percent
Administrative				
Low Estimate	$0.33	.....	.....	.....
High Estimate	.....	$0.90	.....	.....
Medical Monitoring and Treatment				
Low Estimate	$0.27	.....	$0.73	.....
High Estimate	.....	$0.80	.....	$1.62
Total				
Low Estimate	$0.60	.....	$0.73	.....
High Estimate	.....	$1.70	.....	$1.62

* Discount rates are used to estimate the present value of health benefits occurring in the future. (See OMB Circulars A–4 and A–94 Revised.)

Population Covered

According to published studies, up to 8,000 individuals responded to the terrorist attack at the Pentagon and approximately 1,000 responded in Shanksville, Pennsylvania.[14] For the purposes of this economic analysis, HHS estimates the total population of potential new enrollees in the WTC Health Program from the Pentagon and Shanksville sites to be 9,000 responders. In order to estimate the number and rate of Pentagon and Shanksville responders who may apply for enrollment in the WTC Health Program, HHS assumed two enrollment scenarios based on the share of uninsured responders. First, HHS assumed that of the 9,000 eligible responders, 1,467 (16.3 percent, the current National average rate of uninsured persons)[15] will be uninsured and therefore will likely apply for enrollment as soon as eligibility criteria are promulgated. Alternatively, HHS assumed that of the 9,000 responders, 540 (6 percent) will be uninsured. The 6 percent uninsured rate is derived from a study by the Urban Institute, which indicates that 97 percent of workers in public administration are insured.[16] For the purposes of this analysis, HHS further assumed that most public agencies (Federal, state, and local) involved in these responses similarly offer health insurance to employees, that retention rates for public sector employment tend to be high, and that disability insurance and health insurance among retired public employees are also likely to be high. To account for uncertainty regarding the impact on insurance rates of retention, disability, and retirements among public employee responders involved in these responses, as well as uncertainty regarding the quotient of volunteer responders who were not public employees, we doubled the uninsured rate of 3 percent documented in the Urban Institute study to 6 percent. HHS further assumed that 1.3 percent of the remaining unenrolled population will enroll on an annual basis thereafter. This percentage is based on the current rate at which individuals who responded to or survived the terrorist attacks in New York City are enrolling in the WTC Health Program.

Cost Estimates

Using data from the Program's operational experience to date (since July 1, 2011), HHS has estimated costs for administrative activities and medical monitoring and treatment, and has estimated related rates of enrollment and certification of individuals who responded at the Pentagon or in Shanksville. The analyses of WTC Health Program costs use a low estimate reflecting actual costs associated with maintaining the existing program plus additional administrative activities, and a higher estimate level that assumes increases in both administrative costs and other health care costs.

As discussed above, the WTC Health Program expects to initially enroll a minimum of 540 and a maximum of 1,467 Pentagon and Shanksville, Pennsylvania responders in 2013 and between 97 and 110 additional new enrollees over the course of the first year. HHS assumes that there will be between 97 and 109 new enrollees in 2014, between 95 and 107 in 2015, and between 94 and 106 in 2016.

- Administrative Costs

HHS estimates administrative costs ranging between $326,519 and $900,565 annually, covering program management, enrollment of Pentagon and Shanksville responders, certification of WTC-related health conditions, authorization of medical care, payment services, administration of appeals processes, and education and outreach. The range of the costs estimated reflects uncertainty associated with levels of activity for enrollment, appeals, and competitively established costs for contractual administrative services. All administrative costs are counted as societal costs.

- Costs of Medical Monitoring

New enrollees are eligible for an initial medical examination. The costs per patient are estimated between $650 and $1,032 per individual. The low estimate is based on the average costs

[14] Goldberg A, Papadopoulos S, Putney D, Berlage N, Welch R [2007]. Pentagon 9/11. Washington, DC: Historical Office, Office of the Secretary of Defense. *http://osdhistory.defense.gov/history.html.* Accessed January 2012.

The George Washington University, Institute for Crisis, Disaster, and Risk Management. The University of Pittsburgh. Observing and Documenting the Inter-Organizational Response to the September 11th Attack on the Pentagon: Activities and Findings. Research Supported by National Science Foundation Grant CMS–013909.

Grant NK, Hoover DH, Scarisbrick-Hauser AM, Muffet SL [2003]. The Crash of United Flight 93 in Shanksville, Pennsylvania. In Natural Hazards Research and Applications Information Center, Public Entity Risk Institute, and Institute for Civil Infrastructure Systems, Beyond September 11th: An Account of Post-Disaster Research. Special Publication No. 39. Boulder, Colorado: Natural Hazards Research and Applications Information Center, University of Colorado.

[15] U.S. Census Bureau [2011]. Current Population Survey. *http://www.census.gov/hhes/www/cpstables/032011/health/h05_000.xls.* Accessed July 10, 2012.

[16] The Urban Institute. Garrett B, Nichols L, and Greenman E [2001]. Workers Without Health Insurance: Who Are they and How Can Policy Reach Them? A Series of Community Voices Publications.

for patients currently enrolled in the WTC Health Program serviced by the nationwide provider network.[17] The high estimate is based on the services if all tests were conducted and billed at the Federal Employees Compensation Act (FECA) rates for Washington, DC.[18]

These projections assume 35 percent of enrolled responders will obtain annual monitoring examinations, which is the average participation rate for WTC responders in the current Program. The monitoring exams are provided only in the years following the initial medical exam. All monitoring costs incurred in 2013 are counted as societal costs because the population basis assumed that the initial influx of new enrollees will be uninsured, and that an additional 97 to 110 new responders will be added over the course of the year. All medical costs incurred in 2014 through 2016 are counted as transfers.

- Costs of Medical Treatment

The estimated costs for medical treatment are based on an average cost in the WTC Health Program. HHS estimates the cost of treatment to be $3,500 per patient. The estimate is based on the average costs for patients currently enrolled in the WTC Health Program serviced by the nationwide provider network. HHS has no quantitative basis to estimate a different rate of medical treatment utilization for this population as compared to the New York City WTC responders. Therefore, as was done in the July 2011 economic analysis, HHS assumes that 29 percent of future enrolled WTC responders will receive treatment annually. The range of average per patient costs is based on the average costs for patients having received treatment through the WTC Health Program. HHS assumes that in 2013 the initial influx of Pentagon and Shanksville enrollees who receive medical treatment in the WTC Health Program will not have medical insurance provided by employer, private sources, Medicare, or Medicaid; thereafter, HHS assumes that an additional 97 to 110 responders would enroll throughout the year. HHS assumes that all of the enrollees who receive medical treatment will have access to medical insurance in 2014 and beyond when the provisions of the Affordable Care Act are implemented. Therefore, all treatment costs occurring in 2014 and beyond are counted as transfers.

A summary of annual WTC Health Program costs associated with this rulemaking is presented in Table 2 below.

TABLE 2—SUMMARY OF MEDICAL MONITORING AND TREATMENT (IN $2011)

Pentagon & Shanksville Responders	2013	2014	2015	2016
Total Number of WTC Health Program Enrollees				
Low	650	759	866	971
High	1,565	1,662	1,757	1,851
Initial Medical Examination				
New Enrollees				
Low	650	109	107	106
High	1,565	97	95	94
Total Undiscounted Cost of Initial Health Evaluation				
Low Estimate=$650 per person	$422,500	$70,600	$69,600	$68,700
High Estimate = $1,032 per person	1,615,000	99,700	98,500	97,200
Annual Medical Monitoring				
35% of All Enrollees, (1-year lag)				
Low	.....	227	265	303
High	.....	548	582	615
Total Undiscounted Cost of Annual Evaluation				
Low Estimate = $650 per person	.....	147,900	172,600	196,900
High Estimate = $1,032 per person	.....	565,300	600,200	634,600
Medical Treatment				
29% of All Enrollees				
Low	188	220	251	282
High	454	482	510	537
Total Undiscounted Cost of Medical Treatment				
Low Estimate	659,700	769,900	878,700	986,000
High Estimate	1,588,400	1,686,500	1,783,300	1,878,900
Initial Medical Examination, Monitoring, and Treatment Total				
Low Estimate	1,082,200	988,300	1,120,900	1,251,700
High Estimate	3,203,400	2,351,500	2,482,000	2,610,700

[17] The nationwide provider network is the system of healthcare providers that provides medical monitoring and treatment to WTC Health Program responders and survivors who live outside of the New York City area. Although a Pentagon responder enrolled in the WTC Health Program may be evaluated, diagnosed, and/or treated at a Clinical Center of Excellence (New York-based, WTC Health Program providers), this analysis presumes that all enrollees will visit local providers in the nationwide network.

[18] Section 3312(c)(1)(A) of the PHS Act requires the Administrator to base treatment costs on the relevant Federal Employees Compensation Act rates. See 5 U.S.C. 8101 *et seq.,* 20 CFR part 20.

Benefits

Although we cannot quantify the benefits associated with the WTC Health Program, enrollees with a WTC-related health condition are expected to experience a higher quality of care than they would in the absence of the Program. Mortality and morbidity improvements for patients expected to enroll in the WTC Health Program are anticipated because barriers may exist to access and delivery of quality health care services in the absence of the services provided by the WTC Health Program. HHS anticipates benefits to patients treated through the WTC Health Program, who may otherwise not have access to health care services, to accrue in 2013. Starting in 2014, continued implementation of the Affordable Care Act will result in increased access to health insurance and improved health care services for the general responder and survivor population that currently is uninsured.

B. Regulatory Flexibility Act

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

Because no small businesses are impacted by this rulemaking, HHS certifies that this rule will not have a significant economic impact on a substantial number of small entities within the meaning of the RFA. Therefore, a regulatory flexibility analysis as provided for under RFA is not required.

C. Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), a Federal agency shall not conduct or sponsor a collection of information from 10 or more persons other than Federal employees unless the Director of the Office of Management and Budget (OMB) has approved the proposed collection of information. A person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

HHS has determined that this interim final rule contains information collection and record keeping requirements that are subject to review by OMB. This interim final rule will result in additional responses and burden hours associated with an existing information collection (World Trade Center Health Program Enrollment, Appeals & Reimbursement, OMB Control Number 0920–0891, current expiration date 12/31/2014). In order to account for those increases in responses and burden without delay, HHS is requesting emergency review and clearance for a new information collection specifically for Pentagon and Shanksville responders. A description of the relevant regulatory 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 section 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, you may call 404–639–5960; send comments to Kimberly S. Lane, 1600 Clifton Road, MS–D74, Atlanta, GA 30333; or send an email to *omb@cdc.gov.*

Comments are invited on the following: (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 30 days of the publication of this notice.

Proposed Project: World Trade Center Health Program Enrollment, Appeals & Reimbursement for Pentagon and Shanksville Responders—New—National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

Background and Brief Description: Title XXXIII of the PHS Act as amended establishes the WTC Health Program within HHS. The Program provides medical monitoring and treatment benefits to responders to the September 11, 2001, terrorist attacks in New York City, at the Pentagon, and in Shanksville, Pennsylvania, and to survivors of the terrorist attacks in New York City. Title XXXIII requires that various Program provisions be established by regulation, including eligibility criteria for responders at the Pentagon and in Shanksville, Pennsylvania.

This interim final rule revises the data collection requirements that have been approved by OMB under OMB Control Number 0920–0891, with an expiration date of 12/31/2014. The addition of eligible respondents resulting from this interim final rule will increase the number of respondents and burden associated with the following provisions of 42 CFR part 88:

Section 88.5 Application process—status as a WTC responder. This section informs applicants (1,605 respondents) 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. We estimate that the application process will take an average of 30 minutes.

Section 88.11 Appeals regarding eligibility determination—responders and survivors. This section establishes the process for appeals regarding eligibility determinations. Of those Pentagon and Shanksville responders expected to apply for enrollment in the Program (1,605), HHS expects that 2.5 percent (40) will fail due to ineligibility. HHS further assumes that 10 percent of those individuals (4 respondents) will appeal the decision. We estimate that the appeals letter will take no more than 30 minutes.

Section 88.15 Appeals regarding treatment. This section establishes the timeline and process to appeal the Administrator's determinations regarding treatment decisions. HHS estimates that Program participants will request certification for 874 health conditions each year. Of those 874, we expect that 1 percent (<1) 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 454 enrollees who will receive medical care, based on current Program data it is estimated that 3 percent (14) 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 member of the Clinical Centers of Excellence or 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 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 5 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 4 pharmacies will submit reimbursement claims for 1,058 prescriptions per year, or 265 per pharmacy; we estimate that each submission will take 1 minute.

WTC responders 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 to complete. HHS expects no more than 1 claim 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 eligibility criteria are established upon the effective date of this interim final rule.

This new information collection request is for 832.5 annual burden hours.

Section	Title	Number of respondents	Responses per respondent	Average burden per response (min)	Total burden (hr)
88.5	Application process—status as a WTC responder (Pentagon and Shanksville).	1,605	1	30/60	803
88.11	Appeals regarding eligibility determinations	4	1	30/60	2
88.15	Appeals regarding treatment	14	1	30/60	7
88.15	Appeals regarding certification of health conditions	1	1	30/60	.5
88.16	Reimbursement for:	5	1	15/60	*1.5
	Medically necessary treatment, monitoring, initial health evaluations.				
	Outpatient prescription pharmaceuticals	4	265	1/60	18
	Travel expenses	1	1	10/60	*.5
Total					832.5

*These values are rounded up to the nearest half-hour.

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. For 2012, the inflation adjusted threshold is $139 million.

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 the proposed 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 amends 42 CFR part 88 as follows:

PART 88—WORLD TRADE CENTER HEALTH PROGRAM

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

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

■ 2. Amend § 88.1 by adding the definitions of ''Pentagon site,'' ''police department,'' and ''Shanksville, Pennsylvania site,'' in alphabetical order, to read as follows:

§ 88.1 Definitions.

* * * * *

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

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

* * * * *

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

■ 3. Amend § 88.4 by adding paragraphs (b) and (c) to read as follows:

§ 88.4 Eligibility criteria—status as a WTC responder.

* * * * *

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

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

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

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

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

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

* * * * *

Dated: October 2, 2012.

John Howard,

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

[FR Doc. 2013–07146 Filed 3–27–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 215 and 252

RIN 0750–AH47

Defense Federal Acquisition Regulation Supplement: Proposal Adequacy Checklist (DFARS Case 2011–D042)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to incorporate a proposal adequacy checklist for proposals in response to solicitations that require submission of certified cost or pricing data.

DATES: *Effective Date:* March 28, 2013

FOR FURTHER INFORMATION CONTACT: Mr. Dustin Pitsch, telephone 571–372–6090.

SUPPLEMENTARY INFORMATION:

I. Background

DoD published a proposed rule in the **Federal Register** at 76 FR 75512 on December 2, 2011, to incorporate the requirement for a proposal adequacy checklist into DFARS 215.408, and an associated solicitation provision at 252.215–7009, to ensure offerors take responsibility for submitting thorough, accurate, and complete proposals. Fifteen respondents submitted public comments in response to the proposed rule.

II. Discussion and Analysis of the Public Comments

DoD reviewed the public comments in the development of the final rule. A discussion of the comments and the changes made to the rule as a result of those comments is provided, as follows:

A. Summary of significant changes from the proposed rule.

• The sentence ''Completion of this checklist in no way reduces the responsibility to fully comply with all of the requirements of 41 U.S.C. chapter 35, Truthful Cost or Pricing Data, and any other special requirements of the solicitation.'' is removed from the checklist instructions at DFARS 252.215–7009.

• The sentence ''In preparation of the offeror's checklist, offerors may elect to have their prospective subcontractors use the same or similar checklist as appropriate.'' was added to the end of