DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. CDC–2011–0010]

42 CFR Part 88

RIN 0920–AA45

World Trade Center Health Program Requirements for the Addition of New WTC-Related Health Conditions

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: Title I of the James Zadroga Health and Compensation Act of 2010 amended the Public Health Service Act (PHS Act) to establish 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. The proposed rule establishes the processes by which the WTC Program Administrator may add a new condition to the list of WTC-related health conditions through rulemaking, including a process for considering petitions by interested parties to add a new condition.

DATES: HHS invites written comments from interested parties on this notice of proposed rulemaking and on the proposed information collection request sought under the Paperwork Reduction Act. Comments must be received by August 30, 2011.

ADDRESSES: You may submit comments, identified by ''RIN 0920–AA45,'' 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–AA45'' 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/NIOSHdocket0236.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, go to *http://www.regulations.gov* or *http://www.cdc.gov/niosh/docket/NIOSHdocket0236.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 request may also be submitted by e-mail to *wtcpublicinput@cdc.gov.*

SUPPLEMENTARY INFORMATION: This preamble is organized as follows:

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. Comments are invited on any topic related to this proposed rule.

II. Background

A. WTC Medical Monitoring and Treatment Program and the WTC 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 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 responder 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 Public Health Service Act (PHS Act) to add Title XXXIII [1] establishing the WTC Health Program within HHS. The WTC Health Program will assume the functions and goals of the MMTP and the 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, and to eligible survivors of the New York City attacks.

The WTC Health Program will expand the services of the MMTP to include 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. However, because no Pentagon or Shanksville, PA responders have participated in the existing MMTP, 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 authorizes 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 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 section 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 healthcare services and prescription pharmaceuticals; to certify WTC-related health conditions identified in the statute; and to establish processes for appealing adverse WTC Health Program determinations. Those statutory requirements are included in the interim final rule published elsewhere in this issue of the **Federal Register**.

Title XXXIII of the PHS Act also authorizes the WTC Program Administrator to establish a process by which health conditions, including cancer, may be considered for addition to the list of WTC-related health conditions. Those provisions are included in this NPRM.

C. Addition of New Health Conditions for Coverage in the WTC Health Program

The list of WTC-related health conditions defined in sections 3312 and 3322 of Title XXXIII of the PHS Act may be amended in the future to add other 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)).

Procedures for the addition of a new condition, which include rulemaking as required by Title XXXIII, are proposed in this notice. The addition of a new condition could be initiated either by petition from an interested party or at the discretion of the WTC Program Administrator, as specified in this proposed rule.

III. Summary of Proposed Rule

Section 88.1 Definitions

This amendment to Part 88 would add the definition of ''interested party'' to the list of definitions.

Section 88.17 Addition of Health Conditions to the List of WTC-Related Health Conditions

Pursuant to requirements specified in Title XXXIII of the PHS Act, § 88.17 would establish the process by which an interested party could petition the WTC Program Administrator to add a condition to the list of WTC-related health conditions identified in § 88.1. Under the provisions of (a)(1), the petition must include the name and contact information of the interested party; the name and description of the condition the party would like to see added to the list of WTC-related health conditions; and an explanation of the reasons for adding the condition, which must include the medical basis for the association between the September 11, 2001, terrorist attacks and the condition to be added. The provisions of (a)(2) would incorporate specifications in

[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.

Title XXXIII of the PHS Act regarding the addition of new conditions. Within 60 days of receipt of the petition, the WTC Program Administrator will either: request a recommendation of the WTC Health Program Scientific/Technical Advisory Committee; open the proposed condition to public comment by publishing an NPRM in the **Federal Register**; publish the WTC Program Administrator's determination not to publish an NPRM; or publish in the **Federal Register** a determination that not enough evidence exists to perform any of the above actions. If the WTC Program Administrator receives more than one petition to add a specific health condition, the WTC Program Administrator could consider them simultaneously under the process established by the provisions of this section.

Subsection (b) would also incorporate the statutory requirement that the WTC Program Administrator may, periodically, publish an NPRM concerning the addition of a WTC-related health condition. The Administrator would consider publishing an NPRM where the review of cancers required by Title XXXIII § 3312(a)(5)(A) of the PHS Act indicates that a type of cancer should be added, or where WTC Health Program monitoring data reveals the prevalence of a condition not previously identified by the Program. Although the WTC Administrator cannot provide a specific scientific review protocol at this time, the protocol would take into account evaluating the exposure data associated with WTC and evaluating available published and unpublished epidemiologic, toxicologic, and medical evidence relevant to evaluating the possible association between the health condition under consideration and WTC exposures. How these various relevant sources of scientific and medical information will be evaluated, separately and in relation to each other would depend on the evidence available for a given health condition under consideration. HHS notes that scientists generally look for consistency in terms of disease-mechanism theories, toxicologic and epidemiologic findings, and medical observation. The addition of any health condition requires rulemaking and the public will have the opportunity to consider and comment on the review methods applied in any actual case. HHS solicits comment on this and other approaches to reviewing evidence.

The WTC Program Administrator may extend the period described above upon finding a good cause. In the case of such an extension, the Administrator shall publish such an extension in the **Federal Register**.

IV. 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 of significant regulatory actions 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). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

This proposed rule is considered a ''significant regulatory action'' within the meaning of E.O. 12866. The rule establishes processes by which the WTC Program Administrator may consider the addition of health conditions to the current statutory list of WTC-related health conditions covered by this program. This strictly procedural rule does not itself propose the addition of any conditions and hence does not achieve any benefits nor impose any costs, other than the minor incidental administrative costs to HHS of considering possible additions. Under any circumstance, HHS would be required to conduct rulemaking to make an addition, as required by Title XXXIII of the PHS Act. Accordingly, any costs and benefits associated with adding a condition would be addressed in such future rulemaking. This rule does not adversely affect in a material way the economy, a sector of the economy, productivity, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities; it does not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; it does not materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; nor does it raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in E.O. 12866.

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 Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

This regulation has no impact on small businesses or other small entities as specified under the RFA. The rule establishes procedures by which the WTC Health Program Administrator may consider the addition of health conditions to the current statutory list of WTC-related health conditions covered by this program. These procedures do not impose any requirements or direct costs on small entities. They do not involve small entities, except that a small entity could potentially be considered an ''interested party'' under these procedures, eligible to petition the WTC Program Administrator for the addition of a health condition. Such petitioning by a small entity would be voluntary, however, and hence any costs attendant to submitting a petition would be voluntarily incurred.

The Secretary of HHS has certified to the Chief Counsel, Office of Advocacy of the Small Business Administration, that this rule does not have a significant impact on a substantial number of small entities. Accordingly, no regulatory impact analysis is required.

C. Paperwork Reduction Act

CDC has determined that this notice of proposed rulemaking contains information collection 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. 3501–1420). 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, NE., 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: Adding a Health Condition to the Statutory List of WTC-Related Health Conditions (42 CFR 88)—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description: Title I of the James Zadroga Health and Compensation Act of 2010 amended the Public Health Service Act (PHS Act) to establish 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). This proposed rule establishes the processes by which the WTC Program Administrator may add a new condition to the list of WTC-related health conditions through rulemaking, including a process for considering petitions by interested parties to add a new condition. The new provision is proposed at § 88.17 Addition of health conditions to the list of WTC-related health conditions.

§ 88.17 Addition of Health Conditions to the List of WTC-Related Health Conditions

This section describes the proposed process and data collection requirements that an interested party should follow to petition the WTC Program Administrator to add a condition to the list of WTC-related health conditions. HHS expects to receive no more than 100 petitions annually. We assume that interested parties will be enrolled WTC responders, certified-eligible survivors, or members of groups who advocate on behalf of responders or survivors. We estimate that an individual will spend an average of 40 hours gathering information to substantiate a request to add a health condition and assembling the petition. HHS requests input from the public on these estimates, which are reflected in the table below.

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Responder/Survivor/Advocate	Petition for the addition of health conditions.	100	1	40	4,000

D. Small Business Regulatory Enforcement Fairness Act

As required by Congress under the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*), HHS will report the promulgation of this rule to Congress prior to its effective date.

E. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531 *et seq.*) directs agencies to assess the effects of Federal regulatory actions on State, local, and Tribal governments, and the private sector ''other than to the extent that such regulations incorporate requirements specifically set forth in law.'' For purposes of the Unfunded Mandates Reform Act, this proposed rule would 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 proposed rule has been drafted and reviewed in accordance with Executive Order 12988, ''Civil Justice Reform,'' and will not unduly burden the Federal court system. This rule has been reviewed carefully to eliminate drafting errors and ambiguities.

G. Executive Order 13132 (Federalism)

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

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

In accordance with Executive Order 13045, 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 proposed rule on energy supply, distribution or use, and has determined that the rule will not have a significant adverse effect.

J. Plain Writing Act of 2010

Under Public Law 111–274 (October 13, 2010), executive Departments and Agencies are required to use plain language in documents that explain to the public how to comply with a requirement the Federal Government administers or enforces. 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 proposes to amend 42 CFR part 88 as follows:

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 definition of ''interested party'' to read as follows:

§ 88.1 Definitions.

* * * * *

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

* * * * *

2. Add § 88.17 to read as follows:

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

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

(1) Each petition shall be in writing and sent to the WTC Program Administrator. The petition shall include:

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

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

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

(2) Not later than 60 days after the receipt of a petition, the WTC Program Administrator shall:

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

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

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

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

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

(1) If the WTC Program Administrator requests a recommendation from the WTC Health Program Scientific/Technical Advisory Committee, the Advisory Committee shall submit its recommendation to the WTC Program Administrator no later than 60 days after the date of the transmission of the request or no later than a date specified by the Administrator (but not more than 180 days after the request).

(2) If the WTC Program Administrator decides to publish a proposed rule in the **Federal Register**, he or she shall do so no later than 60 days after the date of transmission of the Advisory Committee recommendation.

Dated: May 6, 2011.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2011–16511 Filed 6–29–11; 8:45 am]

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