

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: Final rule.

SUMMARY: Title I of the James Zadroga 9/11 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 is administered by the Director of the National Institute for Occupational Safety and Health (NIOSH), within the Centers for Disease Control and Prevention (CDC), 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, PA, and at the Pentagon, and to eligible survivors of the New York City attacks. This final 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: This final rule is effective [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. HHS invites written comments from interested parties on the proposed information collection request sought under the Paperwork Reduction Act. Comments must be received by [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit written comments on the proposed information collection request to the CDC Desk Officer at the Office of Management and Budget by email to omb@cdc.gov or by fax to (202) 395-5806.

FOR FURTHER INFORMATION CONTACT: Roy M. Fleming, Sc.D., Senior Science Advisor, World Trade Center Health Program, Office of the Director, National Institute for Occupational Safety and Health, 1600 Clifton Road, NE., MS-E74, Atlanta, GA 30329; telephone 866-

426-3673 (this is a toll-free number). Information requests may also be submitted by e-mail to wtcpublicinput@cdc.gov.

SUPPLEMENTARY INFORMATION: This preamble is organized as follows:

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II. Background

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J. Plain Writing Act of 2010

V. Final Rule

I. Public Participation

HHS received comments from six individuals and organizations on the notice of proposed rulemaking published in the Federal Register on July 1, 2011 (76 FR 38938). One anonymous commenter expressed anger about the WTC Health Program's cost to American taxpayers; another individual asked that leukemia and other blood cancers be added to the list of WTC-related health conditions; and a physician experienced with treating WTC-related health conditions requested that a mental disorder be added to the list of WTC-related health conditions. Those comments are outside the scope of this rulemaking and could not be considered. HHS received substantive comments from the New York State Laborers' Health & Safety Trust Fund, the Communication Workers of America, and the WTC Health Program Survivor Steering Committee. Those comments are described and addressed below.

II. Background

A. 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 XXXIII¹ establishing the WTC Health Program within HHS. The WTC Health Program provides medical monitoring and treatment benefits to eligible firefighters and related personnel, law enforcement officers, and rescue, recovery and cleanup workers (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 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, although the WTC Program Administrator currently lacks information that may serve as a basis for such enrollment. The WTC Program Administrator is in the process of collecting such information.

All references to the WTC Program Administrator in this notice mean the NIOSH Director or his or her designee.

Title XXXIII of the PHS Act 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 final rule.

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.

B. 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, Sec. 3312(a)(1)(A)(i)).

Procedures for the addition of a new condition are established 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 final rule.

III. Summary of Final Rule and Response to Comments

Section 88.1 Definitions

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

Comment: HHS received two comments requesting that the definition of "interested party" be expanded to reference survivor organizations.

HHS response: The definition of "interested party" was taken directly from Title I of the James Zadroga 9/11 Health and Compensation Act of 2010. Although the statutory definition of "interested party" does not explicitly mention "survivor organizations," HHS believes that the definition encompasses "survivor organizations." Therefore, HHS concurs with the comments but does not agree that amending the rule text is necessary.

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

In accordance with the requirements specified in Title XXXIII of the PHS Act, Sec. 88.17 establishes 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 Sec. 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 the WTC Program Administrator to add 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.

HHS has received some communications for which it is unclear whether the author intends to petition for the addition of a health condition or is expressing personal concerns. Since a petition results in Federal action, as specified under this rule, it is important that the intent to petition be unambiguous. Accordingly, HHS has amended the final rule text to clarify that the petition must state the petitioner's intent to petition for the addition of a health condition.

The provisions of (a)(2) incorporate specifications in 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 (STAC); open the proposed condition to public comment by publishing a notice of proposed rulemaking (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. HHS has amended the final rule text to acknowledge that a petition may request the addition of more than one health condition.

HHS has also inserted paragraph (4) into the final rule to clarify that the Administrator shall be required to reconsider a previously-considered (but not added) health condition for inclusion on the list of WTC-related health conditions in response to a petition only when the petition includes a new medical basis for the association between the terrorist attacks and the condition. A new medical basis could include a health study, whether original or updated, not previously considered by the WTC Program Administrator. A new clinical case report may not be considered a new medical basis if the occurrence of such individual cases has already been considered by the Administrator. The Administrator retains the discretion, however, to reconsider a health condition for any reason on his own initiative, with or without the receipt of a petition.

Comment: One commenter requested that all submitted petitions be shared with the STAC regardless of whether the WTC Program Administrator seeks a formal recommendation from the Committee.

HHS response: HHS appreciates this suggestion and agrees that, in the interest of keeping the STAC informed of relevant public interest, petitions received by the WTC Program Administrator will be shared with the Committee and with the public via the Program's website. HHS does not believe that amending the rule text is warranted.

Comment: A commenter also asked that a mechanism be developed to allow at least two members of the STAC to request to consider a petition and make a recommendation in the event that the WTC Program Administrator has determined not to publish an NPRM or where the Administrator determines that insufficient evidence exists to take action on a petition.

HHS response: Under Title XXXIII, the Committee's role is to review evidence and make recommendations to the WTC Program Administrator at the request of the Administrator, not to provide unsolicited reviews. Any work conducted by the STAC must be consistent with the purposes for which the Committee may be utilized as identified by the statute and the Committee charter. Therefore, this comment is not adopted.

Subsection (b) also incorporates the statutory requirement that the WTC Program Administrator may 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 Sec. 3312(a)(5)(A) of Title XXXIII of the PHS Act indicates that a type of cancer should be added, or where the review of WTC Health Program monitoring data reveals the prevalence of a condition not previously identified by the statute or Program. The protocol for such a review will take into account an evaluation of the exposure data associated with the terrorist attacks, and an evaluation of available 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, will 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.

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

Comment: HHS received several comments concerning deadlines not specified in the regulatory text. One commenter suggested that HHS did not include every deadline related to the addition of a WTC-related health condition provided by the statute. Two comments asked that we specify a time frame for the publication of an NPRM or a Federal Register notice indicating that the WTC Program Administrator has determined not to publish an NPRM; one asked that we specify the publication of an NPRM 30 days

following a STAC recommendation. Comments also requested that we specify a time frame for publication of a final rule; one asked that we require publication within 60 days after the close of an NPRM comment period.

HHS response: Each deadline specified by the PHS Act with regard to this matter has been incorporated into the regulatory text. We have specified a time frame for the publication of an NPRM following a STAC recommendation in Sec. 88.17(b)(2) according to the time frame specified in the statute. We agree with commenters who pointed out that we neglected to specify a time frame for publication of a Federal Register notice indicating a decision not to publish an NPRM following receipt of a STAC recommendation, and have amended the rule text accordingly. However, Congress did not specify a time frame for publication of a final rule. HHS is concerned that establishing such requirements by regulation could negatively impact the thorough review of scientific evidence supporting or opposing the inclusion of a specific health condition. Because of the need to ensure that a thorough review has been conducted in all cases and because of the vagaries of the rulemaking process, HHS cannot accept these comments. However, we do agree that every effort will be made to promptly review public comments and STAC recommendations, and that publication of a final rule will occur in as efficient and timely a manner as is possible.

Comment: One commenter requested that HHS develop procedures for the WTC Program Administrator to notify an individual when a new condition is added, if the individual was previously denied coverage for that condition.

HHS response: Information about newly-added WTC-related health conditions will be provided on the WTC Health Program website and shared with all Program physicians. Program physicians would be best placed to advise individuals on whether applying for certification of a newly-designated WTC-related health condition is appropriate. The WTC Health Program will consider this request further to identify other ways in which Program participants may be notified of a new WTC-related health condition.

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 final 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 it does not provide for 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 quantifiable 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

HHS has determined that this final rule contains data collection and record keeping requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1955 (44 U.S.C. 3501-3420). A description of these provisions is given below with an estimate of the annual reporting burden. Included in the estimate of the annual reporting burden is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information. CDC publishes a list of information collection requests under review by OMB in compliance with the Paperwork Reduction Act. To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639-5960 or send an e-mail to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget by email to omb@cdc.gov or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project: Adding a Health Condition to the Statutory List of WTC-Related Health Conditions (42 CFR §88.17)--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 final 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 process will be codified at 42 CFR §88.17.

Section 88.17, entitled "Addition of Health Conditions to the List of WTC-Related Health Conditions," describes the 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,

screening-eligible survivors, 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. The total burden on the public is estimated to be 4,000 hours.

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)
Responder/ Survivor/ Advocate	Petition for the addition of health conditions	100	1	40

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 final 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 2011, the inflation adjusted threshold is \$136 million.

F. Executive Order 12988 (Civil Justice)

This final 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 final 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 final 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 final rule consistent with the Federal Plain Writing Act guidelines.

V. Final Rule

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:

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.

* * * * *

3. 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 state an intent to petition and be sent to the WTC Program Administrator. The petition shall include:

- (i) Name and contact information of the interested party;
 - (ii) Name and description of the condition(s) to be added;
- and
- (iii) Reasons for adding the condition(s), including the medical basis for the association between the September 11, 2001, terrorist attacks and the condition(s) to be added.

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

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

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

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

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

(3) The WTC Program Administrator may consider more than one petition simultaneously when the petitions propose the addition of the same health condition. Scientific/Technical Advisory Committee recommendations and Federal Register notices initiated by the WTC Program Administrator pursuant to §88.17(a)(2) may respond to more than one petition.

(4) The WTC Program Administrator shall be required to consider a new petition for a health condition previously reviewed by the WTC Program Administrator and determined not to qualify for addition to the list of WTC-related health conditions only if the new petition presents a new medical basis (i.e., not previously reviewed) for the association between the September 11, 2001, terrorist attacks and the condition to be added.

(b) The WTC Program Administrator may propose to add a condition to the list of WTC-related health conditions by publishing a proposed rule in the Federal Register and providing

interested parties a period of 30 days to submit written comments. The WTC Program Administrator may extend the comment period for good cause.

(1) If the WTC Program Administrator requests a recommendation from the WTC Health Program Scientific/Technical Advisory Committee, the Advisory Committee shall submit its recommendation to the WTC Program Administrator no later than 60 days after the date of the transmission of the request or no later than a date specified by the Administrator (but not more than 180 days after the request). If the WTC Program Administrator decides to publish a proposed rule or a determination not to publish a proposed rule in the Federal Register, he or she shall do so no later than 60 days after the date of transmission of the Advisory Committee recommendation.

Dated:

Kathleen Sebelius,
Secretary, Department of Health and Human Services.