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 May 25, 2012.

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 email to wtcpublicinput@cdc.gov.

SUPPORTING INFORMATION: This preamble is organized as follows:

I. Public Participation
II. Background
A. WTC Health Program Statutory Authority
B. Addition of New Health Conditions for Coverage in the WTC Health Program
III. Summary of the Final Rule and Response to Comments
IV. Regulatory Assessment Requirements
A. Executive Order 12866 and Executive Order 13563
B. Regulatory Flexibility Act
C. Paperwork Reduction Act
D. Small Business Regulatory Enforcement Fairness Act
E. Unfunded Mandates Reform Act of 1995
F. Executive Order 12988 (Civil Justice)
G. Executive Order 13132 (Federalism)
H. Executive Order 13045 (Protection of Children From Environmental Health Risks and Safety Risks)
I. Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use)
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 suggested 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 XXXIII 1 establishing the WTC Health Program within HHS. HHS issued an interim final rule on July 1, 2011 (76 FR 38914), which codified the Program in 42 CFR Part 88. Sections 88.1 through 88.16 were included in that rulemaking; this final rule establishing § 88.17 was developed in a separate rulemaking.

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 expand 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. The WTC Program Administrator has gathered information that may serve as a basis for such enrollment, and is working to develop eligibility criteria for these responder groups.

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. This final rule establishes this process.

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 final rule. The addition of a new condition

Ill of Public Law 111–347 do not pertain to the World Trade Center Health Program and are codified elsewhere.

1Title 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
should 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 established by interim final rule on July 1, 2011 (76 FR 38914).

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 includes “survivor organizations.” HHS does not agree that amending the rule text is necessary and is therefore not amending the definition.

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, § 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 § 88.1. Under the provisions of § 88.17(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 whether the author 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 § 88.17(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 § 88.17(a)(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 on a particular health condition which compiles data from one or more patients may not necessarily be considered a new medical basis if the Administrator has previously considered one or more cases of the health condition. 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 Web site. 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: According to the requirements of Title XXXIII of the PHS Act, 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 to the list. 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 exposures associated with the September 11, 2001, terrorist attacks. 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 does not include every deadline related to the addition of a WTC-related health
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 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 an additional 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.

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. 3501–3520). 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. These data collection and record keeping requirements have been approved under OMB control number 0920–0929, exp. April 30, 2015.


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.

<table>
<thead>
<tr>
<th>Type of respondent</th>
<th>Form name</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden per response (in hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Responder/Survivor/Advocate</td>
<td>Petition for the addition of health conditions</td>
<td>100</td>
<td>1</td>
<td>40</td>
</tr>
</tbody>
</table>

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, or 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:


2. Amend §88.1 by adding the definition of “interested party” in alphabetical order 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

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

[FR Doc. 2012–9425 Filed 4–24–12; 8:45 am]

BILLING CODE 4700

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 14


Implementing the Provisions of the Communications Act of 1934, as Enacted by the Twenty-First Century Communications and Video Accessibility Act of 2010

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: In this document, the Commission announces that the Office of Management and Budget (OMB) has approved, for a period of three years, the information collection associated with the Commission’s document Implementing the Provisions of the Communications Act of 1934, as Enacted by the Twenty-First Century Communications and Video Accessibility Act of 2010, (Report and Order). This notice is consistent with the Report and Order, which stated that the Commission would publish a document in the Federal Register announcing the effective date of those rules.


FOR FURTHER INFORMATION CONTACT: Rosaline Crawford, Disability Rights Office, Consumer and Governmental Affairs Bureau, at (202) 418–0275, or email Rosaline.Crawford@fcc.gov.

SUPPLEMENTARY INFORMATION: This document announces that, on April 16, 2012, OMB approved, for a period of three years, the information collection requirements contained in the Commission’s Report and Order, FCC 11–151, published at 76 FR 82354, December 30, 2011. The OMB Control Number is 3060–1167. The Commission publishes this notice as an announcement of the effective date of the rules. If you have any comments on the burden estimates listed below, or how the Commission can improve the collections and reduce any burdens caused thereby, please contact Cathy Williams, Federal Communications Commission, Room 1–C823, 445 12th Street SW., Washington, DC 20554. Please include the OMB Control Number, 3060–1167, in your correspondence. The Commission will also accept your comments via the Internet if you send them to PRA@fcc.gov or call the Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice) or (202) 418–0432 (TTY).

Synopsis

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), the FCC is notifying the public that it received OMB approval on April 16, 2012, for the information collection requirements contained in the Commission’s rules at 47 CFR 14.5, 14.20(d), 14.31, 14.32, and 14.34 through 14.52.

Under 5 CFR 1320, an agency may not conduct or sponsor a collection of information unless it displays a current, valid OMB Control Number.

No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act that does not display a current, valid OMB Control Number. The OMB Control Number is 3060–1167.


The total annual reporting burdens and costs for the respondents are as follows:

OMB Control Number: 3060–1167.

OMB Approval Date: April 16, 2012.

OMB Expiration Date: April 30, 2015.

Title: Accessible Telecommunications and Advanced Communications Services and Equipment.

Form Number: N/A.

Type of Review: New collection.

Respondents: Individuals or households; businesses or other for-profit entities; not-for-profit institutions.

Number of Respondents and Responses: 9,454 respondents; 119,660 responses.

Estimated Time per Response: .50 to 40 hours.

Frequency of Response: Annual, one time, and on occasion reporting requirements; recordkeeping requirement; third-party disclosure requirement.

Obligation to Respond: Mandatory. Statutory authority for this information collection.