Board (NRB). However, the NRB's functions are purely regulatory, advisory, and policy-making. Under *Wis. Stats.* 15.05, the administrative powers and duties of the WDNR, including issuance of permits and enforcement orders, are vested in the secretary. Under the statutes that govern its operations, the NRB does not and cannot approve permits or enforcement orders. Therefore, Wisconsin has no further obligations under section 128(a)(1) of the CAA.

Under section 128(a)(2) of the CAA, the head of the executive agency with the power to approve permits or enforcement orders must adequately disclose any potential conflicts of interest. In Wisconsin, this power is vested in the Secretary of the WDNR. *Wis. Stats.* 19.45(2) prevents financial gain of any public official, which addresses the issue of deriving any significant portion of income from persons subject to permits and enforcement orders. Additionally, *Wis. Stats.* 19.46 prevents a public official from taking actions where there is a conflict of interest. As a public official under *Wis. Stats.* 19, the Secretary of the WDNR is subject to these ethical obligations. As requested in WDNR's submission, EPA is proposing to incorporate *Wis. Stats.* 15.05, 19.45(2), and 19.46 into Wisconsin's SIP. EPA proposes that these statutes satisfy all requirements under section 128 of the CAA.

B. Section 110(a)(2)(E)(ii)

Section 110(a)(2)(E)(ii) of the CAA also requires each SIP to contain provisions that comply with the state board requirements of section 128 of the CAA.

In its submittal dated July 2, 2015, WDNR requested that *Wis. Stats.* 15.05, 19.45(2), and 19.46 be applied not only to obligations under section 128 of the CAA, but also to infrastructure SIP requirements for the 1997 ozone, 1997 $PM_{2.5,}$ 2006 $PM_{2.5}$, 2008 Pb, 2008 ozone, 2010 NO_2, and 2010 SO_2 NAAQS. EPA therefore proposes that Wisconsin has met the infrastructure SIP requirements of this portion of section 110(a)(2)(E)(ii) with respect to the 1997 ozone, 1997 $PM_{2.5}$, 2006 $PM_{2.5}$, 2008 Pb, 2008 ozone, 2010 NO_2, and 2010 SO_2 NAAQS.

V. What Action is EPA Taking?

EPA is proposing to incorporate *Wis. Stats.* 15.05, 19.45(2), and 19.46 into Wisconsin's SIP. EPA is further proposing to approve these submissions as meeting CAA obligations under section 128, as well as 110(a)(2)(E)(ii) for the 1997 ozone, 1997 $PM_{2.5,}$ 2006 $PM_{2.5}$, 2008 Pb, 2008 ozone, 2010 NO_2, and 2010 SO_2 NAAQS.

VI. Incorporation by Reference

In this rule, EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is proposing to incorporate by reference *Wis. Stats.* 15.05, effective July 2, 2013, *Wis. Stats.* 19.45(2), effective May 11, 1990, and *Wis. Stats.* 19.46, effective February 17, 2007. EPA has made, and will continue to make, these documents generally available electronically through *www.regulations.gov* and/or in hard copy at the appropriate EPA office (see the **ADDRESSES** section of this preamble for more information).

VII. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- 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 CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides.

Dated: August 28, 2015.

Susan Hedman,

Regional Administrator, Region 5.

[FR Doc. 2015–22713 Filed 9–10–15; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 88

[Docket No. CDC–2015–0063, NIOSH–287]

RIN 0920–AA61

World Trade Center Health Program; Addition of New-Onset Chronic Obstructive Pulmonary Disease and Acute Traumatic Injury to the List of WTC-Related Health Conditions

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The World Trade Center (WTC) Health Program, at the direction of the Administrator, conducted a review of published studies regarding potential evidence of chronic obstructive pulmonary disease (COPD) and acute traumatic injury among individuals who were responders to or survivors of the September 11, 2001, terrorist attacks. The Administrator of the WTC Health Program found that

these studies provided substantial support for a causal relationship between the health conditions and 9/11 exposures. As a result, the Administrator has determined to publish a proposed rule to add new-onset COPD and to add acute traumatic injury to the List of WTC-Related Health Conditions eligible for treatment coverage in the WTC Health Program.

DATES: Comments must be received by October 26, 2015.

ADDRESSES: *Written Comments:* You may submit comments by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* NIOSH Docket Office, 1090 Tusculum Avenue, MS C–34, Cincinnati, OH 45226–1998.

Instructions: All submissions received must include the agency name (Centers for Disease Control and Prevention, HHS) and docket number (CDC–2015–0063) or Regulation Identifier Number (0920–AA61) for this rulemaking. All relevant comments, including any personal information provided, will be posted without change to *http://www.regulations.gov.* For detailed instructions on submitting public comments, see the ''Public Participation'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Rachel Weiss, Program Analyst, 1090 Tusculum Ave, MS: C–46, Cincinnati, OH 45226; telephone (855)818–1629 (this is a toll-free number); email *NIOSHregs@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose of Regulatory Action

This rulemaking is being conducted in order to add new-onset COPD and acute traumatic injury to the List of WTC-Related Health Conditions (List). Following requests by the directors of the WTC Health Program Clinical Centers of Excellence (CCE) and Data Centers to the WTC Health Program to consider adding the two conditions,[1] the Administrator conducted literature reviews regarding COPD and acute traumatic injury among 9/11 responders and survivors. Based on the findings of those reviews, he determined that the evidence for causal relationships between 9/11 exposures and COPD and acute traumatic injury, respectively, provides bases for the addition of both health conditions. The Administrator proposes adding new-onset COPD and acute traumatic injury to the List.

B. Summary of Major Provisions

This rule proposes the addition of new-onset COPD and acute traumatic injury to the List of WTC-Related Health Conditions in 42 CFR 88.1. As a result, these conditions will be eligible for treatment and monitoring coverage by the WTC Health Program.

C. Costs and Benefits

The proposed addition of new-onset COPD and acute traumatic injury by this rulemaking is estimated to cost the WTC Health Program between $5,124,477 and $9,350,966 in 2015 and 2016. All of the costs to the WTC Health Program are transfers. Benefits to current and future WTC Health Program members may include improved access to care and better treatment outcomes than in the absence of Program coverage.

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 proposed rule. The Administrator invites comments specifically on the following questions related to this rulemaking:

1. Is September 11, 2003 an appropriate deadline by which an individual must have received initial medical treatment for an acute traumatic injury?

2. Is there evidence of acute traumatic injuries that occurred as a result of the September 11, 2001, terrorist attacks that would not be covered by the proposed definition? What are the types of long-term consequences or medically associated health conditions that result from the treatment or progression of acute traumatic injuries like those sustained on or after September 11, 2001?

3. Are data available on the chronic care needs of individuals who suffered acute traumatic injuries during the September 11, 2001, terrorist attacks, and its aftermath that the Administrator can use to estimate the number of current and future WTC Health Program members who may seek certification of WTC-related acute traumatic injuries as well as treatment costs?

4. Are data available on the prevalence and cost estimates for new-onset COPD?

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 submitted electronically or by mail should be titled ''Docket No. CDC–2015–0063'' and should identify the author(s) and contact information in case clarification is needed. Electronic and written comments can be submitted to the addresses provided in the **ADDRESSES** section, above. All communications received on or before the closing date for comments will be fully considered by the Administrator of the WTC Health Program.

[1] Crane M, Lucchini R, Moline J, Prezant D, Kelly K, Udasin I, Luft B, Harrison D, Reibman J, Markowitz S [2014]. Letter from CCE and Data Center Directors to Dori Reissman and John Halpin, WTC Health Program regarding ''Musculoskeletal Conditions;'' and Crane M, Lucchini R, Moline J, Prezant D, Kelly K, Udasin I, Luft B, Harrison D, and Reibman J [2014]. Letter from CCE and Data Center Directors to Dori Reissman and John Halpin, WTC Health Program regarding ''Rationale for the continued certification of COPD as a World Trade Center related and covered condition.'' These letters are included in the docket for this rulemaking.

The Administrator has determined that good cause exists to extend the traditional 30-day comment period to 45 days. The comment period is extended to provide interested parties, including peer-reviewers, adequate time to review the proposed rule and supporting scientific literature and to submit written comments to the docket.

III. 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,[2] establishing the WTC Health Program within the Department of Health and Human Services (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 who responded to the September 11, 2001, terrorist attacks in New York City, at the Pentagon, and in Shanksville, Pennsylvania (responders), and to eligible persons who were present in the dust or dust cloud on September 11, 2001 or who worked, resided, or attended school, childcare, or adult daycare in the New York City disaster area (survivors).

All references to the Administrator of the WTC Health Program (Administrator) in this notice mean the Director of the National Institute for Occupational Safety and Health (NIOSH) or his or her designee. Section 3312(a)(6) of the PHS Act requires the Administrator to conduct rulemaking to propose the addition of a health condition to the List of WTC-Related Health Conditions (List) codified in 42 CFR 88.1.

B. Methods Used by the Administrator to Determine Whether to Add Non-Cancer Health Conditions to the List of WTC-Related Health Conditions

Consideration of an addition to the List of WTC-Related Health Conditions (List) may be initiated at the Administrator's discretion [3] or following receipt of a petition by an interested party.[4] Under 42 CFR 88.17, the Administrator has established a process by which health conditions may be considered for addition to the List of WTC-Related Health Conditions in § 88.1. Pursuant to sec. 3312(a)(6)(D) of Title XXXIII of the PHS Act, the Administrator is required to publish a notice of proposed rulemaking and allow interested parties to comment on the proposed rule.

The Administrator has established a methodology for evaluating whether to add non-cancer health conditions to the List of WTC-Related Health Conditions; this methodology is published online in the Policies and Procedures section of the WTC Health Program Web site.[5] The Administrator will direct the WTC Health Program Associate Director for Science (ADS) to conduct a review of the scientific literature to determine if the available scientific information has the potential to provide a basis for a decision on whether to add the condition to the List. The literature review will include published, peer-reviewed direct observational and/or epidemiological studies about the health condition among 9/11-exposed populations. The studies will be reviewed for their relevance, quantity, and quality to provide a basis for deciding whether to propose adding the health condition to the List. Where the available evidence has the potential to provide a basis for a decision, the ADS will further assess the scientific and medical evidence to determine whether a causal relationship between 9/11 exposures and the health condition is supported. A health condition may be added to the List if published, peer-reviewed direct observational or epidemiologic studies provide substantial support [6] for a causal relationship between 9/11 exposures and the health condition in 9/11-exposed populations. If only epidemiologic studies are available and they provide only modest support [7] for a causal relationship between 9/11 exposures and the health condition, the Administrator may then evaluate additional published, peer-reviewed epidemiologic studies, conducted among non-9/11-exposed populations, evaluating associations between the health condition of interest and 9/11 agents.[8] If that additional assessment establishes substantial support for a causal relationship between a 9/11 agent or agents and the health condition, the health condition may be added to the List.

IV. COPD

A. CCE and Data Center Request to Consider Adding New-Onset COPD

On May 13, 2014, the Administrator received a letter from the directors of the WTC Health Program Clinical Centers of Excellence (CCEs) and Data Centers, asking that the Administrator consider all requests for certification of COPD.[9] The Zadroga Act and WTC Health Program regulations identify ''WTC-exacerbated chronic obstructive pulmonary disease (COPD)'' as a covered health condition.[10] However, the CCE and Data Center directors requested that the Administrator determine that COPD is a certifiable WTC condition, regardless of the date of onset.[11] In order to certify all cases of COPD, including cases diagnosed after the September 11, 2001, terrorist attacks, new-onset COPD would need to be added to the List of WTC-Related Health Conditions. The Administrator directed the ADS to initiate a review of research regarding COPD in 9/11-exposed populations in order to determine whether there was support for such an addition.

B. Literature Review

In accordance with the established methodology for the addition of non-cancers to the List, the Administrator charged the ADS with conducting a review of the relevant, peer-reviewed, published studies of 9/11-exposed populations.

Because definitions of COPD vary among authorities, the ADS first had to identify the best definition for the purposes of the WTC Health Program.

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[2] 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.

[3] PHS Act, sec. 3312(a)(6)(A); 42 CFR 88.17(b).

[4] PHS Act, sec. 3312(a)(6)(B); 42 CFR 88.17(a).

[5] Howard J, Administrator of the WTC Health Program. Policy and procedures for adding non-cancer conditions to the List of WTC-Related Health Conditions. October 21, 2014. *http://www.cdc.gov/wtc/pdfs/WTCHP_PP_Adding_NonCancers_21_Oct_2014.pdf.*

[6] The substantial evidence standard is met when the Program assesses all of the available, relevant information and determines with high confidence that the evidence supports its findings regarding a causal association between the 9/11 exposure(s) and the health condition.

[7] The modest evidence standard is met when the Program assesses all of the available, relevant information and determines with moderate confidence that the evidence supports its findings regarding a causal association between the 9/11 exposure(s) and the health condition.

[8] 9/11 agents are chemical, physical, biological, or other agents or hazards reported in a published, peer-reviewed exposure assessment study of responders or survivors who were present in the New York City disaster area, or at the Pentagon site, or the Shanksville, Pennsylvania site as those locations are defined in 42 CFR 88.1.

[9] *See:* Crane M, Lucchini R, Moline J, Prezant D, Kelly K, Udasin I, Luft B, Harrison D, Reibman J [2014]. Rationale for the continued certification of COPD as a World Trade Center related and covered condition. Letter from WTC Health Program Data Center and Clinical Centers of Excellence Directors to Drs. Dori Reissman and John Halpin, WTC Health Program. This letter is included in the docket for this rulemaking.

[10] PHS Act, sec. 3312(a)(3)(A)(v); 42 CFR 88.1.

[11] COPD letter from WTC Health Program CCE and Data Center Directors to Drs. Dori Reissman and John Halpin, WTC Health Program at 8.

The ADS looked to the Global Initiative for Chronic Obstructive Lung Disease (GOLD), a collaboration between the National Heart, Lung, and Blood Institute of the National Institutes of Health and the World Health Organization as a point of reference. GOLD defines COPD as persistent airflow limitation that is usually progressive and associated with an enhanced chronic inflammatory response in the airways and the lung to noxious particles or gases.[12] COPD is an umbrella term that encompasses those pulmonary conditions exhibiting chronic inflammation of the airways, lung tissue, and pulmonary blood vessels and persistent airflow limitation: A combination of large and small airways disease (obstructive chronic bronchitis [13] and obstructive bronchiolitis, respectively) and parenchymal destruction (emphysema).[14] According to GOLD, the three principal symptoms of COPD are dyspnea (shortness of breath), chronic cough, and sputum production; the most common early symptom is dyspnea on exertion (DOE). COPD should always be considered when these lower respiratory symptoms and history of exposure to risk factors for the disease are present. Because many of the symptoms of COPD are similar to asthma symptoms, both conditions are classified as obstructive airways diseases (OAD). The airway obstruction in asthma is usually reversible after bronchodilator therapy, whereas the obstruction in COPD is poorly-reversible or irreversible.[15] While asthma is not included under the term COPD, people with asthma may develop COPD over time.[16]

Diagnosis of COPD requires the use of a spirometry test, which measures how much and how quickly an individual inhales and exhales air from his or her lungs. The diagnosis of COPD is confirmed by a spirometry test demonstrating poorly-reversible or irreversible airways obstruction (*i.e.*, the proportion of vital capacity that an individual is able to expire in the first second of expiration [FEV1/FVC or FEV1%] is below 70 percent) after use of a bronchodilator. Although spirometry is the standard diagnostic test for COPD, in some circumstances, impulse oscillometry (IOS) can be complementary to spirometry, especially in patients at advanced age and with physical or mental disorders who cannot be diagnosed through spirometry. IOS assesses airway resistance and frequency dependence of resistance (FDR). FDR provides a measure of nonuniformity of airflow distribution, which may reflect regional functional abnormalities in the distal airways not captured by the spirometry test.

In accordance with the GOLD definition, described above, the ADS initiated a literature search for ''chronic obstructive pulmonary disease,'' ''chronic bronchitis,'' ''pulmonary emphysema,'' ''pulmonary function decline,'' ''respiratory insufficiency,'' ''airways obstruction,'' and ''airflow limitation.'' [17] The literature search yielded 108 study citations; the associated study abstracts were reviewed for relevance to 9/11-exposed populations.[18] Of the 108 citations identified, 36 were determined to be relevant epidemiologic studies of 9/11-exposed populations. Relevant papers were then further reviewed for their quality and potential to provide a basis for deciding whether to propose adding the health condition to the List of WTC-Related Health Conditions. Only papers that reported post-9/11 lower respiratory symptomatology and objective measurements of airways obstruction, such as pre- and post-9/11 spirometry with bronchodilator administration or IOS, were found to exhibit potential support for an addition recommendation. Quality was assessed by the presence or absence of major limitations, such as small size or poor comparability of study groups; use of unreliable or invalid measurement instruments; and if little or no attention was given to key confounders which would call into question the validity of the study results. Based on these criteria, the ADS found six relevant papers which exhibited potential to provide a basis for a decision regarding whether to propose the addition of new-onset COPD to the List. The six papers are summarized below.

Weiden *et al.* [2010] [19] sought to determine the pathophysiologic basis for observed reductions in lung function among 1,720 Fire Department of New York (FDNY) rescue workers (firefighters and emergency medical service personnel) who presented for pulmonary evaluation between September 12, 2001 and March 10, 2008. Exposure intensity was categorized based on first arrival time at the WTC site as follows: High exposure if they arrived during the morning of September 11, 2001, intermediate exposure if they arrived after the morning of September 11, 2001, but within the first 2 days, and low exposure if they arrived between days 3 and 14. Pre-9/11 spirometry results were available for 92 percent of participants. Researchers obtained 919 full pulmonary function tests (bronchodilator response, lung volumes, diffusing capacity); 1,219 methacholine challenge tests to screen for asthma; and 982 high-resolution computed tomography (HRCT) scans, allowing them to report correlations between physiologic and radiographic measures. All physiologic tests pointed to airway obstruction with air trapping (demonstrated by the increase in residual volume) which correlated with the decline in FEV1 post-9/11, bronchodilator responsiveness, and hyperreactivity. HRCT findings of bronchial wall thickening (which reflects proximal airway inflammation and/or remodeling) and emphysema were reported in 26 percent and 12 percent of the participants, respectively.

[12] Global Initiative for Chronic Obstructive Lung Disease (GOLD), Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease, updated 2014. *http://www.goldcopd.org/uploads/users/files/GOLD_Report_2014_Jan23.pdf.*

[13] Chronic bronchitis is defined by the presence of a productive cough of more than 3 months' duration for more than two successive years. It becomes obstructive chronic bronchitis if spirometric evidence of airflow obstruction develops. *See:* Chronic Obstructive Pulmonary Disease (COPD) [2014]. In R.S. Porter *et al.* (Eds.), The Merck manual of diagnosis and therapy. *http://www.merckmanuals.com/professional/pulmonary_disorders/chronic_obstructive_pulmonary_disease_and_related_disorders/chronic_obstructive_pulmonary_disease_copd.html.*

[14] Emphysema is destruction of lung parenchyma (the portion of the lung involved in gas transfer, including the alveoli, alveolar ducts and respiratory bronchioles) leading to loss of elastic recoil and loss of alveolar septa and radial airway traction, which increases the tendency for airway collapse. Lung hyperinflation, airflow limitation, and air trapping are present. *See:* Chronic Obstructive Pulmonary Disease (COPD) [2014]. In R.S. Porter *et al.* (Eds.), The Merck manual of diagnosis and therapy. *http://www.merckmanuals.com/professional/pulmonary_disorders/chronic_obstructive_pulmonary_disease_and_related_disorders/chronic_obstructive_pulmonary_disease_copd.html.*

[15] American Thoracic Society [1987]. Standards for the diagnosis and care of patients with chronic obstructive pulmonary disease (COPD) and asthma. Official statement of the American Thoracic Society was adopted by the Board of Directors, November 1986. Am Rev Respir Dis. 136(1):225–244.

[16] Global Initiative for Asthma [2015]. Global strategy for asthma management and prevention; updated 2015. *http://www.ginasthma.org/local/uploads/files/GINA_Report_2015.pdf.*

[17] Databases searched include: PubMed, Embase, CINAHL, Web of Science, Health & Safety Science Abstracts, and Toxline.

[18] Only epidemiologic studies of 9/11-exposed populations were considered to be relevant. Case series and review papers were not found to be relevant.

[19] Weiden MD, Ferrier N, Nolan A, Rom WN, Comfort A, Gustave J, Zeig-Owens R, Zheng S, Goldring RM, Berger KI, Cosenza K, Lee R, Webber MP, Kelly KJ, Aldrich TK, Prezant D [2010]. Obstructive airways disease with air trapping among firefighters exposed to World Trade Center dust. Chest. 137(3):566–574.

Importantly, airway abnormalities on CT scans also correlated with physiologic measures. The authors concluded that airways injury and obstruction were the predominant pathophysiologic characteristics among study participants.

Aldrich *et al.* [2010][20] evaluated the long-term effects of exposure to WTC dust on FDNY members who responded to the September 11, 2001, terrorist attacks. The authors analyzed the pulmonary function (FEV1) of both active and retired FDNY rescue workers on the basis of spirometry routinely performed at intervals of 12 to 18 months from March 12, 2000 to September 11, 2008. The authors observed a large decline in FEV1 values at 6 months and 12 months after September 11, 2001, especially among the firefighters with the heaviest dust exposure (those arriving at the WTC site on the morning of September 11, 2001). After the initial decline in the first year, the adjusted FEV1 continued to decline in smokers and non-smokers with little or no recovery in lung function during the subsequent 6 years. The authors concluded that the large decline in FEV1 after September 11, 2001, was indicative of airways injury due to 9/11 exposures.

Webber *et al.* [2011][21] examined the prevalence of physician-diagnosed respiratory conditions in FDNY members up to 9 years after rescue/recovery efforts in the New York City disaster area. The authors reviewed self-reported physician diagnoses of asthma, chronic bronchitis, COPD/emphysema, and sinusitis from the most recent physical health survey conducted by the FDNY Bureau of Health Services and physician diagnoses obtained from FDNY electronic medical records. The study population consisted of 10,943 firefighters and EMS workers who first arrived at the site within 2 weeks of the terrorist attacks. All participants were free of COPD and emphysema before September 11, 2001, and less than 1 percent had asthma. The authors found the prevalence rates of both self-reported and physician diagnoses of OAD, *i.e.*, asthma, chronic bronchitis, COPD/emphysema, and sinusitis were elevated, exceeding rates in the general population for individuals of a similar age. The highest proportion of FDNY responders with physician-diagnosed OAD had the lowest lung function (FEV1% predicted), indicating that 9/11 exposure had resulted in disease. The authors were unable to attribute these diagnoses to any other occupational exposures.

Weakley *et al.* [2011][22] compared the prevalence of self-reported post-9/11 physician-diagnosed respiratory conditions (sinusitis, asthma, COPD/emphysema, and bronchitis) in 9/11-exposed FDNY firefighters to the prevalence in demographically similar National Health Interview Survey (NHIS) participants by year. The authors analyzed 45,988 questionnaires completed by 10,999 firefighters from October 2001 to September 2010. They reported higher rates of respiratory diagnoses in 9/11-exposed firefighters compared to the U.S. male general population, regardless of smoking status. Prevalence ratios, comparing FDNY to NHIS rates, were highest for COPD/emphysema and bronchitis. Because of the decrease in structural fires, improvement in personal protective equipment, and the decline in smoking rates among firefighters, the authors discounted normal firefighting activities as the cause of the increase in respiratory diagnoses.

Friedman *et al.* [2011][23] also examined the relationship between 9/11 exposures, post-9/11 lower respiratory symptoms, and pulmonary function in a nested case-control study of exposed survivors 7–8 years after September 11, 2001. The cases examined in the study were 274 WTC Health Registry participants who reported post-9/11 onset of a lower respiratory symptom. One-third of the cases further reported post-9/11 physician diagnoses of asthma, chronic bronchitis, chronic obstructive pulmonary disease, or emphysema. Registry participants without lower respiratory symptoms or inhaler use and no current or past lung disease were used as control subjects. Only never-smokers participated in this study. Pulmonary function was assessed by spirometry and IOS. A higher proportion of abnormal spirometry results (obstructive and restrictive patterns) was found among cases than control subjects. IOS measurements of airway resistance and FDR (indicative of distal airways dysfunction) were significantly higher in cases than in control subjects, even when spirometry was normal. Lower respiratory symptoms were found significantly associated with IOS measurements but not with spirometry. Both exposure factors and IOS outcomes were associated with persistent symptoms, but exposure was not associated with IOS outcomes in the absence of symptoms. Certain exposure factors, including dust cloud density, smoke at home or work, and dust at home or work, were the strongest predictors of case status. The authors concluded that the association between post-9/11 onset of lower respiratory symptoms and lung function abnormalities detected by spirometry and IOS several years later were indicative of persistent airway disease with distal airways dysfunction as a contributing mechanism for these symptoms.

In a follow-up to the Friedman study reviewed above, Maslow *et al.* [2012][24] assessed associations between repeatedly reported lower respiratory symptoms and detailed measures of both acute and chronic 9/11-related exposures. Acute exposures involved contact with the dust cloud created by the towers' collapse. Chronic factors were based on conditions in the home or work site through December 31, 2001, such as the extent of dust coverage; the duration of detectable smoke, fumes, and other odors; and whether the participant engaged in or was exposed to cleaning. The authors concluded that both acute and chronic exposures to the events of 9/11 were independently associated, often in a dose-dependent manner, with lower respiratory symptoms reported 2 to 3 years and again 5 to 6 years after September 11, 2001 by individuals who lived and worked in the WTC area.

C. Administrator's Determination Concerning New-Onset COPD

The ADS assessed each of the six studies described above according to the methodology established by the Administrator. The studies were assessed for relevance, quality, bias, and confounding by applying criteria extrapolated from the Bradford Hill criteria.[25]

[20] Aldrich TK, Gustave J, Hall CB, Cohen HW, Webber MP, Zeig-Owens R, Cosenza K, Christodoulou V, Glass L, Al-Othman F, Weiden MD, Kelly KJ, Prezant D [2010]. Lung function in rescue workers at the World Trade Center after 7 years. N Engl J Med. 362(14):1263–1272.

[21] Webber MP, Glaser MS, Weakley J, Soo J, Ye F, Zeig-Owens R, Weiden MD, Nolan A, Aldrich TK, Kelly K, Prezant D [2011]. Physician-diagnosed respiratory conditions and mental health symptoms 7–9 years following the World Trade Center disaster. Am J Ind Med. 54(9):661–671.

[22] Weakley J, Webber MP, Gustave J, Kelly K, Cohen HW, Hall CB, Prezant DJ [2011]. Trends in respiratory diagnoses and symptoms of firefighters exposed to the World Trade Center disaster: 2005–2010. Prev Med. 53(6):364–369.

[23] Friedman SM, Maslow CB, Reibman J, Pillai PS, Goldring RM, Farfel MR, Stellman SD, Berger KI [2011]. Case-control study of lung function in World Trade Center Health Registry area residents and workers. Am J Respir Crit Care Med. 184(5):582–589.

[24] Maslow CB, Friedman SM, Pillai PS, Reibman J, Berger KI, Goldring R, Stellman SD, Farfel M [2012]. Chronic and acute exposures to the world trade center disaster and lower respiratory symptoms: Area residents and workers. Am J Public Health. 102(6):1186–1194.

[25] Criteria extrapolated from Bradford Hill criteria include: (i) Strength of the association between a

First, the studies were assessed for strength of the association between 9/11 exposures and a health condition (including the magnitude of the effect and statistical significance). Weiden *et al.* reported statistically significant longitudinal declines in FEV1, greater than expected by age or weight gain, among firefighters with documented high levels of exposure. Aldrich *et al.* reported significant substantial declines in FEV1 over the first year after the September 11, 2001, terrorist attacks and little lung function recovery among the FDNY participants 6 years after the disaster. The firefighters with the heaviest dust exposure (those arriving at the WTC site on the morning of the disaster) had significantly larger declines than did those arriving at later times. Importantly, the findings of both studies were independent of smoking history. A major limitation of both studies was the lack of spirometry during the first days after September 11, 2001, preventing the authors from determining whether some workers had an even more severe immediate decline in FEV1 and subsequent incomplete recovery. The possibility of systematic bias occurring due to the change of spirometer equipment between measurements and a loss-to-follow-up effect due to drop out of severely affected participants from the study over time (survivor effect) were additional concerns [Aldrich *et al.*]; however, these appeared to have been minimized by further statistical analyses and strong cohort retention rate, respectively.

In addition to the Weiden and Aldrich studies, strength of association was also demonstrated by Weakley *et al.*, who found that annual estimates from 2007–2009 indicated prevalence ratios of chronic bronchitis and COPD/emphysema that were significantly higher among exposed white male firefighters than unexposed white males (stratified by age and smoking status), with greater disparity in the younger age group (18–44 years). Similarly, Webber *et al.* reported significant associations of 9/11 exposures and reduced pulmonary function with physician-diagnosed asthma, chronic bronchitis, and COPD/emphysema in a high proportion of FDNY rescue workers, indicating that persistent respiratory injury since exposure to the WTC had resulted in obstructive airways disease. A major limitation of both studies was the use of self-reported diagnoses, including diagnoses made by any physician (FDNY or otherwise) and self-diagnoses, which may have over-inflated the prevalence rates. This limitation is a concern, especially for COPD/emphysema, which can be defined in a variety of ways; the definition used can have a significant impact on the population estimates of the burden of disease. However, many cases of COPD/emphysema in this cohort were also diagnosed by FDNY physicians [Webber *et al.*] who were trained to diagnose respiratory diseases using defined diagnostic criteria after integrating the history, physical examination, spirometry, pulmonary function testing and chest imaging findings.

Finally, among WTC Health Registry (Registry) participants, exposure factors (dust cloud density, smoke at home or work, and dust at home or work) and IOS outcomes (indicative of distal airways obstruction) were statistically associated with persistent post-9/11 onset of lower respiratory symptoms [Friedman *et al.*]. Both acute and chronic exposures to the events of September 11, 2001 were independently associated with lower respiratory symptoms among individuals who lived and worked in the area of the WTC site [Maslow *et al.*]. Limitations of these studies include the use of spirometry and IOS measurements from a single visit and the possibility of selection bias from Registry surveys. However, the demographics were similar among Registry participants and those who were eligible but chose not to participate in the studies.

The studies were next assessed for consistency of their findings. Objective findings of new onset, post-9/11 and persistent airflow limitation, as well as physician-diagnosed cases of COPD, including chronic bronchitis and COPD/emphysema, were identified among symptomatic FDNY responders for whom pre-9/11 results were available [Weiden *et al.*; Aldrich *et al.*; Webber *et al.*; Weakley *et al.*]. Elevated rates of lung function abnormalities, including distal airway dysfunction, new and persistent lower respiratory symptomatology, and a few post-9/11 self-reported physician diagnoses of chronic bronchitis, COPD, and emphysema were also described among non-FDNY residents and area workers up to 9 years after September 11, 2001 [Friedman *et al.*; Maslow *et al.*].

The studies were also reviewed to assess the biological gradient or dose-response relationships between 9/11 exposures and the health condition. Newly developed lower respiratory symptoms and persistent pulmonary function abnormalities suggestive of airways injury and obstruction were significantly associated with 9/11 exposure in the FDNY studies, even after accounting for cigarette smoking. [Weiden *et al.*; Aldrich *et al.*; Webber *et al.*; Weakley *et al.*] Maslow *et al.* observed strong, significant associations and dose-response relationships between lower respiratory symptoms and every measure of severity of dust cloud exposure among WTC Health Registry participants. Weiden *et al.* also found a dose-response gradient (upward trend) in FDNY responders presenting for pulmonary evaluation due to reports of functional impairment or abnormalities in screening spirometry or chest radiographs. However, in this group of patients, exposure intensity had a significant impact only when spirometry obtained within 1 year post-9/11 was compared to spirometry from 1 year pre-9/11. This suggests that while initial exposure intensity is the critical determinant of acute inflammation and early reductions in lung function, the clinical course of non-resolving airway inflammation and airways obstruction appears to be dependent not only on the intensity of the initial insult, but also on the host's inflammatory response, reflecting the complexity of genetic-environmental interactions.

Finally, the studies were reviewed for plausibility and coherence with known facts about the biology of the health condition. Exposure to the massive alkaline dust cloud produced by the collapse of the WTC buildings was reportedly associated with upper and lower airway irritation with penetration into the bronchial tree, distal airways, and alveoli leading to respiratory symptoms, pulmonary function changes, and chronic inflammation. These are known contributing risk factors for the development of COPD.[26] Persistent pulmonary function findings of reduced FEV1, FVC and the ratio of FEV1/FVC, bronchial hyperreactivity, variable response to bronchodilator, and abnormal oscillometry were indicative of airway injury. Airway disease was also identified as bronchial wall thickening and air trapping by HRCT [Weiden *et al.*]. Air trapping (demonstrated by increased residual volume) was correlated with

9/11 exposure and a health condition (including the magnitude of the effect and statistical significance); (ii) Consistency of the findings across multiple studies; (iii) Biological gradient, or dose-response relationships between 9/11 exposures and the health condition; and (iv) Plausibility and coherence with known facts about the biology of the health condition. *See:* Howard J, Administrator of the WTC Health Program. Policy and procedures for adding non-cancer conditions to the List of WTC-Related Health Conditions. October 21, 2014. *http://www.cdc.gov/wtc/policies.html#46.*

[26] Rom WN, Reibman J, Rogers L, Weiden MD, Oppenheimer B, Berger K, Goldring R, Harrison D, Prezant D [2010]. Emerging exposures and respiratory health: World Trade Center dust. Proc Am Thorac Soc. 7(2):142–145.

bronchodilator responsiveness; however, the lack of quantitative radiographic measurement of air trapping was a limitation of this study. Interestingly, the authors noted that bronchodilator response can be seen in COPD patients when air trapping is present. Epidemiologically, identification of occupationally-related COPD is based on observing excess occurrence of COPD among exposed workers.[27] Among 9/11-exposed populations, this excess occurrence can be expressed not only by the increased prevalence ratios of new-onset post-9/11 self-reported and physician-diagnosed chronic bronchitis and emphysema/COPD in the FDNY cohort [Webber *et al.*; Weakley *et al.*], but also by evidence of persistent and progressive airflow limitation among all other symptomatic exposed groups [Friedman *et al.*; Maslow *et al.*].

In summary, obstructive airways disease is a category that includes both asthma and the umbrella term COPD, which itself includes obstructive chronic bronchitis, obstructive bronchiolitis, and emphysema. Upon assessment of the literature discussed above, the Administrator has found evidence that exposure to WTC dust is associated with the development of new-onset lower respiratory symptoms, prolonged airway inflammation and persistent airflow limitation, which are the main indicators of chronic airways obstruction. While it is difficult to demonstrate that the airway obstruction found in WTC survivors and responders is due to COPD versus asthma, three studies reported cases of physician-diagnosed COPD/emphysema, one reported on IOS findings of air trapping and increased small airways resistance, and another study reported on HRCT findings of bronchial wall thickening, air trapping and emphysema, indicating that some proportion of OAD cases found in WTC survivors and responders could be interpreted as COPD. Further, because some cases of asthma are known to progress to COPD, it is likely that some of the diagnosed cases of asthma seen in these and other epidemiologic studies of the 9/11-exposed populations have already progressed to COPD.

In order to propose the addition of a health condition to the List, the Administrator must determine with high confidence that the evidence supports the findings regarding a causal association between 9/11 exposure(s) and the health condition. In this instance, the Administrator finds there is substantial evidence that the 9/11 exposures produced chronic airway inflammation manifested by persistent lower respiratory symptomatology and decline in pulmonary function which may have progressed to new-onset COPD in a proportion of exposed subjects in the period since exposure, independently from any cigarette smoking among the cohort. This evidence provides substantial support for a causal relationship between 9/11 exposures and new-onset COPD.

V. Acute Traumatic Injury

A. CCE and Data Center Request To Consider Adding Acute Traumatic Injury

On May 13, 2014, the Administrator received a letter from the directors of the WTC Health Program CCEs and Data Centers supporting ''coverage of not only heavy lifting or repetitive strain but significant traumatic injuries like head trauma, burns, fractures, tendon tears and serious complex sprains'' within the WTC Health Program.[28] The directors suggested that such significant traumatic injuries should be included under the Program's existing coverage of musculoskeletal disorders. The directors offered data collected by the WTC Health Program Data Centers and the WTC Health Registry, demonstrating the numbers of individuals who might need chronic care for traumatic injuries. The Administrator was also aware that some individuals have experienced certain musculoskeletal injuries or other injuries caused by known hazards present at sites of the September 11, 2001, terrorist attacks that may not meet the definition provided in the Act for musculoskeletal disorders. Based on these concerns, the Administrator requested that the ADS conduct a literature review regarding acute traumatic injuries among 9/11-exposed individuals.

B. Literature Review

In accordance with the methodology discussed above, the ADS initiated a search of published, peer-reviewed studies of traumatic injuries suffered by responders, recovery workers, and survivors as a result of the terrorist attacks on September 11, 2001, and the subsequent response and recovery efforts. Search terms used in the literature review included, ''wounds,'' ''lacerations,'' ''brain injury(ies),'' ''injury(ies),'' ''crush(ing),'' ''burn(s),'' ''ocular,'' and ''fracture(s).''[29]

The literature search yielded over 300 citations; the associated study abstracts were reviewed for relevance to 9/11-exposed populations.[30] Of the 300 citations identified, nine were determined to be relevant direct observational studies of 9/11-exposed populations. Relevant papers were then further reviewed for their quality and potential to provide a basis for deciding whether to propose adding the health condition to the List of WTC-Related Health Conditions. Only papers that reported on acute traumatic injuries that occurred in at least one of the three September 11, 2001, terrorist attack sites during the period from September 11, 2001 to July 31, 2002 were found to exhibit potential for a recommendation. Quality was assessed by the absence of major study limitations and the use of standardized data collection methods such as standard forms or checklists. Based on these criteria, one relevant study was not found to be of sufficient quality to be included in the analysis because it did not identify the authors' data collection methods. Of the remaining eight studies, the methods used to collect the information and the definitions of the types of injuries vary. The time frame studied and the populations covered sometimes overlap between the studies, but taken together the studies provide an overview of the types of traumatic injuries that were sustained at the sites of the September 11, 2001, terrorist attacks. Accordingly, the ADS found the eight relevant papers exhibited potential to provide a basis for a decision regarding whether to propose the addition of acute traumatic injury to the List. The studies are summarized below.

Berrios-Torres *et al.* [2003][31] reviewed the data collected by five Disaster Medical Assistance Teams (DMATs) deployed by the U.S. Public Health Service to the site of the terrorist attack in New York City and by four hospital emergency departments (EDs) located within a 3-mile radius of the site. The DMATs and EDs were tasked with conducting surveillance of injury and illness among construction workers,

[27] Balmes J, Becklake M, Blanc P, Henneberger P, Kreiss K, Mapp C, Milton D, Schwartz D, Toren K, Viegi G [2003]. American Thoracic Society Statement: Occupational contribution to the burden of airway disease. Am J Respir Crit Care Med. 167:787–797.

[28] Musculoskeletal Conditions letter from WTC Health Program CCE and Data Center directors to Dori Reissman and John Halpin, WTC Health Program at 1. This letter is included in the docket for this rulemaking.

[29] Databases searched include: PubMed, CINAHL, Web of Science, EMBASE, Health & Safety Science Abstracts, and NIOSHTIC–2.

[30] Only direct observational studies of 9/11-exposed populations were considered to be relevant.

[31] Berrios-Torres SI, Greenko JA, Phillips M, Miller JR, Treadwell T, Ikeda RM [2003]. World Trade Center rescue worker injury and illness surveillance, New York, 2001. Am J Prev Med 25:79–87.

FDNY and other fire department members, New York Police Department (NYPD) and other police department members, emergency medical service technicians (EMS), and the Federal Emergency Management Agency's Urban Search and Rescue members, all of whom were considered rescue and recovery workers. Of the 5,222 rescue workers who received medical care from either the DMATs or EDs between September 14, 2001 and October 11, 2001, 89 percent visited DMAT facilities and 12 percent visited EDs. Injuries including, but not limited to, sprain/strain, laceration, abrasion, contusion, fracture, and crush were the leading cause of visits to DMATs and EDs (19 percent) and hospital admissions (40 percent). Other visits and admissions were caused by burns, concussions, and eye-related conditions, including corneal abrasion and eye irritation.

Perritt *et al.* [2005] [32] analyzed DMAT data collected between September 14, 2001 and November 20, 2001. Patients who presented to the DMAT stations included rescue and recovery workers, as well as some members of the general public. Of the 9,349 patient visits recorded by the DMATs, more than 25 percent were attributed to traumatic injuries, not including eye injuries. Among the 22 patients with the highest triage severity classification, five involved traumatic injuries such as carbon monoxide poisonings, abrasions, needlesticks, electrical injuries, and first or second degree burns. Of the 149 patients with a moderate level of severity, 58 had traumatic injuries. For the 6,237 patients classified into the lowest severity category, 1,984 had traumatic injuries. Of the 116 patients transferred to a hospital emergency department, 67 were treated for traumatic injuries.

Banauch *et al.* [2002] [33] reported on all injuries and illnesses during the 24 hours after the September 11, 2001, terrorist attacks and all traumatic injuries (including those sustained within the first 24 hours) sustained in the first 3 months after the attacks. Researchers identified cases from the FDNY Bureau of Health Services computerized medical data base. During the first 24 hours after the terrorist attacks, 240 FDNY rescue workers sought emergency medical treatment, including 28 individuals who required hospitalization. Twenty-four of the hospitalized FDNY workers had traumatic injuries including fractures, back trauma, knee meniscus tears, and facial burns. Researchers compared monthly mean incidence rates for crush injuries, lacerations, and fractures for the 9 months preceding the attacks with rates during the month after the attacks and found a 200 percent increase in the incident rate for crush injuries, a 35 percent increase for lacerations, and a 29 percent increase for fractures. Incident rates for such traumatic injuries after the first month following the attack then returned to levels similar to those observed before the attacks. According to the authors, nearly a year after the terrorist attacks, a total of 90 FDNY rescue workers were on medical leave or light duty assignments because of orthopedic injuries reported during the first 3 months of activity at the New York City site.

The New York City Department of Health (NYCDOH) [2002] [34] issued a report summarizing findings of a field investigation to assess injuries and use of healthcare services by survivors of the terrorist attack. The researchers reviewed emergency department (ED) and inpatient medical records at the four hospitals closest to the WTC site and a fifth hospital that served as a burn referral center. Of 790 injured survivors treated within 48 hours of the terrorist attacks, 50 percent received care within the first 7 hours and 18 percent were hospitalized. Among those hospitalized survivors, many sustained burns. Survivors with fractures, burns, closed head injuries, and crush injuries were hospitalized for additional treatment.

Perritt *et al.* [2011] [35] reviewed data collected between July 2002 and April 2004 from the WTC Worker and Volunteer Medical Screening Program (which would later be known as the WTC Medical Monitoring and Treatment Program, the precursor to the WTC Health Program) to monitor the health of qualified New York City responders who worked and/or volunteered south of Canal Street in Manhattan, on the barge loading piers in Manhattan, or at the Staten Island landfill for at least 24 hours during September 11–30, 2001 or for at least 80 hours between September 11 and December 31, 2001. The screening program did not include FDNY members. Records from 7,810 participants were analyzed, with most participants' activities associated with work in either the construction industry or law enforcement. Approximately a third of the participants reported at least one injury or illness requiring medical treatment that was sustained during response activities. A total of 4,768 injuries/illnesses were reported by these participants, with 961 individuals reporting traumatic injuries such as lacerations, punctures, sprain/strains, tears, abrasions, contusions, burns, fractures, dislocations and 709 individuals reporting eye injuries.

Yurt *et al.* [2005] [36] reported on the number of burn patients (the authors did not specify whether the patients were responders or survivors) that had been transported to any of five burn units near the WTC site shortly after the attack. A total of 42 patients were transported from the WTC site and treated at one of the five burn units.

Rutland-Brown *et al.* [2007] [37] reviewed the medical records of hospitalized responders (the authors do not clarify whether FDNY members are included in the study) and survivors of the terrorist attacks in New York City with the goal of identifying diagnosed and undiagnosed traumatic brain injuries (TBIs).[38] The authors identified 14 cases of diagnosed and 21 cases of undiagnosed TBIs, from records provided by 36 hospitals. The leading cause of TBI was being hit by falling debris (22 cases), with other cases caused by being trampled or falling. One-third of the TBIs (13 cases) occurred among rescue workers. More than 3 years after the event, four out of six persons with an undiagnosed TBI who were contacted reported they currently were experiencing symptoms consistent with a TBI.

Wang *et al.* [2005] [39] reported on the experience of hospitals in the area around the Pentagon after the terrorist attacks. According to the authors, few

[32] Perritt KR, Boal WL, Helix Group [2005]. Injuries and illnesses treated at the World Trade Center, 14 September–20 November 2001. Prehosp Disast Med 20:177–183.

[33] Banauch G, McLaughlin M, Hirschhorn R, Corrigan M, Kelly K, Prezant D [2002]. Injuries and illnesses among New York City Fire Department rescue workers after responding to the World Trade Center attacks. MMWR September 11, 2002, 51(Special Issue):1–5.

[34] New York City Department of Health (NYCDOH) [2002]. Rapid assessment of injuries among survivors of the terrorist attacks on the World Trade Center—New York City, September 2001. MMWR January 11, 2002, 51(01):1–5.

[35] Perritt KR, Herbert R, Levin SM, Moline J [2011]. Work-related injuries and illnesses reported by World Trade Center response workers and volunteers. Prehosp Disast Med 26(6): 401–407.

[36] Yurt RW, Bessey PQ, Bauer GJ, Dembicki R, Laznick H, Alden N, Rabbits A [2005]. A regional burn center's response to a disaster: September 11, 2001, and the days beyond. J Burn Care Rehab 26: 117–124.

[37] Rutland-Brown W, Langlois JA, Nicaj L, Thomas RG, Wilt SA, Bazarian JJ [2007]. Traumatic brain injuries after mass-casualty incidents: Lessons from the 11 September 2001 World Trade Center attacks. Prehosp Disast Med 22(3):157–164.

[38] Undiagnosed or undetected TBIs were identified by an adjudication team of TBI experts that reviewed the abstracted medical record information for signs and symptoms of TBIs.

[39] Wang D, Sava J, Sample G, Jordan M [2005]. The Pentagon and 9/11. Crit Care Med 33:S42–S47.

severely injured patients were treated at these hospitals and the traumatic injuries treated at these hospitals included orthopedic injuries, head injuries, burns, and lacerations. No reports of traumatic injuries that may have been treated at the site were identified.

C. Administrator's Determination Concerning Acute Traumatic Injury

The ADS assessed each of the identified studies according to the methodology established by the Administrator. All of the studies discussed above were observational reports of visits by responders and survivors to area hospitals, burn units, and DMATs. Because these were direct observational studies rather than epidemiologic studies, they were assessed for relevance, quality, and quantity to determine whether, taken together, they provide substantial evidence supporting the addition of acute traumatic injury to the List.

First, the ADS assessed the relevance of the eight studies described above. Because most of the individuals who were treated at the DMATs and in area hospitals sustained injuries from fires and falling debris in the conduct of rescue operations or fleeing from the site, all of the studies reference the period of time immediately following the September 11, 2001, terrorist attacks, and several refer to data collected for months after. The studies assessed by the ADS demonstrate the occurrence of the same types of acute traumatic injuries identified by the directors of the CCEs and Data Centers in their letter: Severe burns, head trauma, fractures, tendon tears, and complex sprains. Other similar injuries identified in the studies include eye injuries, lacerations, and orthopedic injuries. There were no severe types of injuries referenced in the surveillance literature that have not been documented by the CCEs. Furthermore, the ADS determined that all of the referenced types of injuries could be described as being caused by a brief exposure to energy. Accordingly, the ADS found these eight studies to be relevant.

Next, the ADS assessed the quality of the studies and found that many shared common limitations, such as: incomplete data sets (*e.g.,* potential inability to include individuals who sustained only minor injuries, or who were treated outside of Manhattan, by private doctors, or by themselves); missing or inconsistent information on hastily-completed medical forms, including lack of information about patients' work activity or residency; and recall bias. It is understandable that certain demographic data were not captured by healthcare providers in the chaotic days and weeks after the September 11, 2001, terrorist attacks; the missing data are not essential to the Administrator's understanding of the types of acute traumatic injuries sustained. Although injury rates are used to develop the economic analysis found in this document, the consideration of whether to propose the addition of acute traumatic injury to the List is not contingent upon knowing the exact prevalence of types of injuries sustained by responders or survivors. Accordingly, the ADS finds that the studies reviewed above are of sufficient quality and quantity to allow the Administrator to develop an understanding of the type and scope of the traumatic injuries suffered on September 11, 2001, or in its aftermath.

Finally, the ADS assessed the quantity of the studies and found it to be sufficient. The eight relevant studies analyzed and reviewed overlapping populations affected by the attacks and response activities. Taken together, the studies provide a broad coverage of the affected populations and consistent information on the types of acute traumatic injuries that occurred. Because data regarding responders to the Pentagon and Shanksville, Pennsylvania sites is limited, the ADS found it appropriate to extrapolate the findings discussed above, which predominantly concern the New York City site, to all responder populations because of the similar hazards at all three sites.

In summary, the 9/11 exposures for acute traumatic injuries were the conditions at the sites during the attacks, collapses, evacuations, recovery, and clean-up. Acute traumatic injuries documented in the published scientific literature were sustained by construction workers, police officers, firefighters, emergency medical service technicians, others engaged in response activities, and survivors. Hazards at the WTC site, at the Pentagon, and in Shanksville, Pennsylvania may have included, but are not limited to, falling debris, fires, chemical reactions, explosions, and other dangers. These hazards caused a range of injuries, such as abrasions, burns, concussions, contusions, corneal abrasions, crushes, dislocations, eye irritation, fractures, head trauma, lacerations, orthopedic injuries, punctures, sprains/strains, and tears. Many of these types of injuries were likely minor, and did not require substantial or on-going attention. In their letter to the Administrator, the CCE and Data Center directors identified severe burns, head trauma, fractures, tendon tears, and complex sprains as those types of acute traumatic injuries that should be added to the List of WTC-Related Health Conditions for all WTC Health Program members. Accordingly, the Administrator has determined that the types of injuries most likely to have resulted in the need for medical treatment and monitoring by the WTC Health Program are those types identified by the CCE and Data Center directors and in the injury surveillance literature reviewed above.

Upon review of the evidence provided by the relevant published, peer-reviewed direct observational studies discussed above, the Administrator finds substantial support for a causal association between 9/11 exposures and acute traumatic injuries.

VI. Effects of Rulemaking on Federal Agencies

Title II of the James Zadroga 9/11 Health and Compensation Act of 2010 (Pub. L. 111–347) reactivated the September 11th Victim Compensation Fund (VCF). Administered by the U.S. Department of Justice (DOJ), the VCF provides compensation to any individual or representative of a deceased individual who was physically injured or killed as a result of the September 11, 2001, terrorist attacks or during the debris removal. Eligibility criteria for compensation by the VCF include a list of presumptively covered health conditions, which are physical injuries determined to be WTC-related health conditions by the WTC Health Program. Pursuant to DOJ regulations, the VCF Special Master is required to update the list of presumptively covered conditions when the List of WTC-Related Health Conditions in 42 CFR 88.1 is updated.[40]

VII. Summary of Proposed Rule

For the reasons discussed above, the Administrator proposes to amend 42 CFR 88.1, List of WTC-Related Health Conditions, paragraph (1)(v), to add ''new-onset'' to the existing ''WTC-exacerbated chronic obstructive pulmonary disease (COPD).'' This will permit the WTC Health Program to certify cases of COPD determined to have been caused or contributed to by 9/11 exposures (considered ''new-onset'' cases), in addition to those cases of COPD which were exacerbated by 9/11 exposures and which are already included on the List.

For the reasons discussed above, the Administrator also proposes to add ''acute traumatic injury'' to the List of

[40] 28 CFR 104.21(b).

WTC-Related Health Conditions. The Administrator proposes to define the term ''acute traumatic injury'' as a type of injury characterized by physical damage to a person's body, including, but not limited to, eye injuries, severe burns, head trauma, fractures, tendon tears, complex sprains, and similar injuries. The injury must have been caused by and occurred immediately after exposure to hazards or adverse conditions characterized by a one-time exposure to energy resulting from the terrorist attacks or their aftermath; this requirement is intended to distinguish these types of injuries from musculoskeletal disorders, which are already on the List of WTC-Related Health Conditions. Musculoskeletal disorders are generally caused by repetitive motion; acute traumatic injuries are caused by a specific event or incident. Examples of acute traumatic injuries include but are not limited to a blow from falling debris, a fall from a height or a trip suffered during evacuation, rescue, or recovery activities, and burns or other injuries caused by the ignition of combustible materials, chemical reactions, and explosions. Although these types of injury occur at the time of the blow, fall, explosion, or other exposure, symptoms of the injury may not immediately manifest.

The Administrator proposes to limit the availability of certification of acute traumatic injuries to those WTC Health Program members who received initial medical treatment for the injury no later than September 11, 2003. The Administrator has determined that this date offers a reasonable amount of time in which to expect that an injured responder or survivor received treatment for an acute traumatic injury. The proposed end-date of September 11, 2003, is the date originally used to identify traumatic injuries determined to be eligible for treatment by the WTC Medical Monitoring and Treatment Program that pre-dated the WTC Health Program. In addition, the PHS Act uses this date as the treatment cut-off date to identify musculoskeletal disorders eligible for certification in responders. The Administrator seeks comment on whether September 11, 2003, is an appropriate deadline.

VIII. Regulatory Assessment Requirements

A. Executive Order 12866 and Executive Order 13563

Executive Orders (E.O.) 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 notice of proposed rulemaking has been determined not to be a ''significant regulatory action'' under sec. 3(f) of E.O. 12866. This rule proposes the addition of new-onset COPD [41] and acute traumatic injury to the List of WTC-Related Health Conditions established in 42 CFR 88.1. This rulemaking is estimated to cost the WTC Health Program between $5,124,477 and $9,350,966 for the years 2015 and 2016, the remaining years for which the WTC Health Program is currently funded under the Zadroga Act.[42] All of the costs to the WTC Health Program will be transfers due to the implementation of provisions of the Patient Protection and Affordable Care Act (ACA) (Pub. L. 111–148) on January 1, 2014. This notice of proposed rulemaking has not been reviewed by the Office of Management and Budget (OMB). The rule would not interfere with State, local, and Tribal governments in the exercise of their governmental functions.

Population Estimates

As of July 31, 2014, the WTC Health Program had enrolled 61,086 responders and 7,806 survivors (68,892 total). Of that total population, 56,334 responders and 4,754 survivors (61,088 total) were participants in previous WTC medical programs and were 'grandfathered' into the WTC Health Program established by Title XXXIII of the PHS Act.[43] From July 1, 2011 to July 31, 2014, 4,752 new responders and 3,052 new survivors (7,804 total) enrolled in the WTC Health Program. For the purpose of calculating a baseline estimate of new-onset COPD and acute traumatic injury prevalence, the Administrator projected that new enrollment would be approximately 4,000 per year (2,800 new responders and 1,200 new survivors), based on the trend in enrollees through July 31, 2014.

CCE or Nationwide Provider Network physicians will conduct a medical assessment for each patient and make a determination, which the Administrator will then use to certify or not certify the health condition (in this case, new-onset COPD or an acute traumatic injury) for treatment by the WTC Health Program. However, for the purpose of this analysis, the Administrator has assumed that all diagnosed cases of new-onset COPD and acute traumatic injury will be certified for treatment by the WTC Health Program. Finally, because there are no existing data on new-onset COPD rates related to 9/11 exposures at either the Pentagon or Shanksville, Pennsylvania sites, and only limited data on acute traumatic injuries at the Pentagon, the Administrator has used only data from studies of individuals who were responders or survivors in the New York City area.

Prevalence of New-Onset COPD

To estimate the number of potential cases of WTC-related new-onset COPD to be certified for treatment by the WTC Health Program, we first subtracted the number of current members certified for an obstructive airways disease, including WTC-exacerbated COPD, from the total number of members.[44] We then reviewed the surveillance literature to determine a prevalence rate for new-onset COPD among the non-OAD certified members. In studies of FDNY members with known pre-9/11 health status and high WTC exposure, Aldrich *et al.* reported that 2 percent of FDNY firefighters had an FEV1% below 70 percent of predicted [45] at year 1 after September 11, 2001 (a proportion that doubled 6.5 years later), and Webber *et*

[41] WTC-exacerbated COPD is a statutorily covered condition pursuant to PHS Act sec. 3312(a)(3)(A)(v); this NPRM proposes to add new-onset COPD occurring after 9/11 exposures.

[42] Future cost and prevalence estimates described below are discounted at 3% and 7% in accordance with OMB Circular A–94, Guidelines and discount rates for benefit-cost analysis of Federal programs. The estimates are discounted in order to compute net present value.

[43] These grandfathered members were enrolled without having to complete a new member application when the WTC Health Program started on July 1, 2011 and are referred to in the WTC Health Program regulations in 42 CFR part 88 as ''currently identified responders'' and ''currently identified survivors.''

[44] Cases of COPD diagnosed prior to September 11, 2001, are presumed to be eligible for coverage as WTC-exacerbated COPD and therefore would not need coverage for new-onset COPD. Members already certified for an obstructive airway disease are also removed from the analysis because any progression to COPD (*i.e.,* airflow limitation not fully reversible with bronchodilator) from their current certified WTC-related OAD condition could be considered a health condition medically-associated with the certified WTC-related OAD condition. *See:* Howard J [2014]. Health conditions medically associated with World Trade Center-related health conditions. *http://www.cdc.gov/wtc/pdfs/WTCHPMedically%20AssociatedHealthConditions7November2014.pdf.*

[45] FEV1% predicted is a marker for severity of airway obstruction. In the setting of post-bronchodilator FEV1/FVC ≤0.7, FEV1% predicted ≥80 indicates mild COPD; 50–80, moderate; 30–50, severe, and <30, very severe. *See:* American Thoracic Society COPD Guidelines [2004]. *http://www.thoracic.org/clinical/copd-guidelines/for-health-professionals/definition-diagnosis-and-staging/definitions.php.*

al. reported an approximate 4 percent prevalence of new-onset, self-reported, physician-diagnosed COPD/emphysema nearly ten years after rescue/recovery efforts at the WTC site. Because pre-9/11 health records were not available in studies of WTC survivors, the Administrator has determined that the 4 percent prevalence of new-onset COPD will be applied to survivor estimates as well.[46] We applied the 4 percent prevalence to the number of remaining members and also to the projected annual enrollment of 4,000 new members to estimate the number of potential WTC-related new-onset COPD cases for 2015 and 2016. (See Table 1, below)

TABLE 1—ESTIMATED PREVALENCE OF 2015 AND 2016 NEW-ONSET COPD CASES

	2015	2016	Total cases
Undiscounted			
Responders	2,013	2,125	4,138
Survivors	291	339	630
Total	2,304	2,464	4,768
Discounted at 3%			
Responders	1,954	2,003	3,957
Survivors	283	320	603
Total	2,237	2,323	4,560
Discounted at 7%			
Responders	1,881	1,856	3,737
Survivors	272	296	568
Total	2,153	2,152	4,305

Prevalence of Acute Traumatic Injury

While this rulemaking would make acute traumatic injuries eligible for certification, the Administrator assumes that the conditions most likely to receive treatment within the WTC Health Program will be those medically associated conditions which are the long-term consequences of the certified WTC-related acute traumatic injuries. Health conditions medically associated with WTC-related health conditions are determined on a case-by-case basis in accordance with WTC Health Program policy.[47] Examples of such health conditions medically associated with an acute traumatic injury may include chronic back pain caused by vertebrae fractures, chronic peripheral neuropathy due to severe burns, and problems with executive brain function due to closed head injuries.

Although we were able to estimate from the surveillance literature the number of responders and survivors who received medical treatment for acute traumatic injuries on or in the aftermath of September 11, 2001, we do not know the number of individuals who still experience health problems because of those traumatic injuries and are in need of chronic care. First, we estimated the number of persons in the responder and survivor populations with 9/11-related acute traumatic injuries by reviewing the studies referenced above in the acute traumatic injury literature review; we derived estimates from Berrios-Torres *et al.* [2003], Banauch *et al.* [2002], Perritt *et al.* [2011], and NYCDOH [2002]. Using the estimated prevalence for injury types, we then calculated the prevalence for these injuries among the responder[48] and survivor[49] populations. We applied that prevalence to the number of current and expected WTC Health Program members to find the number of individuals who may have suffered a WTC-related acute traumatic injury. Next, in order to estimate the proportion of those in the responder and survivor populations who suffered WTC-related acute traumatic injuries that require chronic care, we assumed that all patients with permanent partial and permanent total impairment caused by acute traumatic injuries will require chronic medical care and will enroll in the WTC Health Program. The National Safety Council estimated that 3.8 percent of non-fatal disabling injuries[50] are associated with permanent partial or permanent total impairment.[51] We applied that estimate to the estimated number of current and expected WTC Health Program members who may have suffered a WTC-related acute traumatic injury to determine the number of individuals with WTC-related acute traumatic injuries who are in need of chronic care. (See Table 2,

[46] The 4 percent prevalence of new-onset COPD that was observed among firefighters was used to estimate the number of expected cases of new-onset COPD in the entire exposed cohort and may result in an overestimation because of the differences in initial exposure intensity between responders and survivors.

[47] Howard J [2014]. Health conditions medically associated with World Trade Center-related health conditions. *http://www.cdc.gov/wtc/pdfs/WTCHP Medically%20AssociatedHealthConditions7 November2014.pdf.*

[48] The responder estimate is subject to two main assumptions. First, Banauch *et al.* report on FDNY members from September 11 to December 10, 2001, and we assume no additional injuries from December 11, 2001 until the site was closed in July 2002. The time period reported on by Banauch *et al.* likely encompasses a large majority of the injuries suffered by FDNY members. Second, Perritt *et al.* does not report directly on closed head injuries; therefore the number of closed head injuries reported by Berrios-Torres *et al.* for responders is used.

[49] We estimate the survivor prevalence from the NYCDOH study reports on survivors during the period from September 11–13, 2001. Although we understand that this reporting period likely encompasses a majority of the survivors who were injured, because the number of cases is based on those survivors who were treated for injuries only within the first 48 hours after the terrorist attacks, the reported number of cases likely underestimates the total number of survivors who sustained acute traumatic injuries as a result of the September 11, 2001, terrorist attacks.

[50] In 2011, the National Safety Council replaced the term ''disabling injury'' with ''medically consulted injury.'' *See* National Safety Council [2014]. Injury facts.

[51] A non-fatal disabling injury is one which results in some degree of permanent impairment or renders the injured person unable to effectively perform his regular duties or activities for a full day beyond the day of the injury. National Safety Council [1986]. Injury facts.

below.) The Administrator welcomes input on the assumptions and estimates used to determine the number of current and future WTC Health Program members who may seek certification of WTC-related acute traumatic injuries.

TABLE 2—ESTIMATED PREVALENCE OF 2015 AND 2016 ACUTE TRAUMATIC INJURY CASES

	2015	2016	Total cases
Undiscounted			
Responders	76	79	155
Survivors	9	10	19
Total	85	89	174
Discounted at 3%			
Responders	74	74	148
Survivors	9	9	18
Total	83	83	166
Discounted at 7%			
Responders	71	69	140
Survivors	8	9	17
Total	79	78	157

Costs of COPD Treatment

The Administrator estimated the medical treatment costs associated with COPD in this rulemaking, using the methods described below, to be between $1,032 and $1,930 per case in 2014.

The low estimate, $1,032 per case, was based on WTC Health Program costs associated with the treatment of WTC-exacerbated COPD for the period October 1, 2013 through September 30, 2014. These medical costs included medical services only.[52] Discounting future medical costs for the following year (2015) at 3 percent would result in $1,002 and at 7 percent in $965 per member. Discounting future medical costs for one more year (2016) at 3 percent would result in $973 and at 7 percent in $901 per member.

The high estimate, $1,930 per case, was based on a study by Leigh *et al.* [2002].[53] The authors estimated the cost of occupational COPD by aggregating and analyzing national data sets collected by the National Center for Health Statistics, the Health Care Financing Administration, and other government agencies and private firms. They concluded that there were an estimated 2,395,650 occupational cases of COPD in 1996 that resulted in medical costs estimated at $2.425 billion. Medical costs included payments to hospitals, physicians, nursing homes, and vendors of medical supplies, including oxygen, and also included the cost of pharmaceuticals. The medical cost per case was about $1,012 in 1996 dollars or about $1,930 in 2014, after adjusting for inflation using the Medical Consumer Price Index for all urban consumers. Discounting future medical costs for the following year (2015) at 3 percent would result in $1,874 and at 7 percent in $1,804 per COPD case. Discounting future medical costs for one more year (2016) at 3 percent would result in $1,819 and at 7 percent in $1,686 per COPD case.[54]

Table 3 below shows the net present value of the range of the medical treatment cost per COPD case for the period 2015–2016:

TABLE 3—PRESENT VALUE OF 2015 AND 2016 MEDICAL TREATMENT COST PER COPD CASE IN 2014 DOLLARS

Source	Year	Undiscounted	Discounted at 3%	Discounted at 7%
WTC Health Program	2015	$1,032	$1,002	$965
	2016	1,032	973	901
Total	.....	2,064	1,975	1,866
Leigh *et al.* (2002)	2015	1,930	1,874	1,804
	2016	1,930	1,819	1,686
Total	.....	3,860	3,693	3,490

[52] Costs may be underestimated because pharmaceuticals are not included in the analysis. Although the WTC Health Program does treat patients with WTC-exacerbated COPD, the cost of pharmaceuticals for this health condition is not readily available.

[53] Leigh JP, Romano PS, Schenker MB, Kreiss K [2002]. Costs of occupational COPD and asthma. Chest. Jan;121(1):264–272.

[54] The U.S. Preventive Services Task Force does not recommended screening for COPD. Screening for Chronic Obstructive Pulmonary Disease Using Spirometry. *http://www.uspreventiveservicestaskforce.org/uspstf/uspscopd.htm.* Accessed September 10, 2014.

Costs of Acute Traumatic Injury Treatment

The Administrator estimated the medical treatment costs associated with acute traumatic injury in this rulemaking using the methods described below. Because it is not possible to identify all possible types of acute traumatic injury for which a WTC responder or survivor might seek certification, we have identified several types of acute traumatic injury that may represent those types of acute traumatic injury that might be certified by the WTC Health Program. Representative examples of acute traumatic injuries include closed head injuries, burns, fractures, strains and sprains, orthopedic injuries (*e.g.,* meniscus tear), ocular injuries, and crush injuries. The WTC Health Program estimates the cost of providing medical treatment for acute traumatic injury to be around $11,216 per case in 2014.

This cost figure was based on a study by the National Council on Compensation Insurance (NCCI).[55] The data source used in this study was NCCI's Medical Data Call (MDC). The MDC captures transaction-level detail on workers' compensation medical bills processed on or after July 1, 2010, including dates of service, charges, payments, procedure codes, and diagnosis codes; pharmaceutical costs are also included. The data used in this study were evaluated as of March 2013 for:

- Long-term medical services provided in 2011 and 2012 (*i.e.,* 20 to 30 years post injury)
- Injuries occurring between 1983 and 1990
- Claimants with dates of birth between 1920 and 1970
- States for which NCCI collects MDC[56]

For individuals born during 1951–1970, the medical cost per case was about $11,216 in 2014 dollars, after adjusting for inflation using the Medical Consumer Price Index for all urban consumers.[57] Discounting future medical costs for the following year (2015) at 3 percent would result in $10,890 and at 7 percent in $10,482 per acute traumatic injury case. Discounting future medical costs for one more year (2016) at 3 percent would result in $10,572 and at 7 percent in $9,796 per traumatic injury case.

Table 4 below shows the present value of the range of the medical treatment cost per traumatic injury case for the period 2015–2016:

TABLE 4—PRESENT VALUE OF 2015 AND 2016 MEDICAL TREATMENT COST PER ACUTE TRAUMATIC INJURY CASE IN 2014 DOLLARS

Source	Year	Undiscounted	Discounted at 3%	Discounted at 7%
NCCI (2014)	2015	$11,216	$10,890	$10,482
	2016	11,216	10,572	9,796
Total		22,432	21,462	20,278

Summary of Costs

This rulemaking is estimated to cost the WTC Health Program between $5,124,477 and $9,350,966 for the years 2015 and 2016.[58] The analysis above offers an assumption about the number of individuals who might enroll in the WTC Health Program and estimates the number of new-onset COPD and acute traumatic injury cases and the resulting estimated treatment costs to the WTC Health Program. For the purpose of computing the treatment costs for new-onset COPD and acute traumatic injury, the Administrator assumed that all of the individuals who are diagnosed with either condition will be certified by the WTC Health Program for treatment and monitoring services. In the calculations found in Tables 5 and 6, below, estimated treatment costs were applied to the estimated number of cases of new-onset COPD and acute traumatic injuries. We assumed that 9 percent of new-onset COPD costs and 12 percent of acute traumatic injury costs for responders may be covered by workers' compensation each year;[59] accordingly, we adjusted only the responder estimates to clarify that 91 percent of COPD costs and 88 percent of acute traumatic injury costs will be paid by the WTC Health Program.[60] This analysis does not include administrative costs associated with certifying additional diagnoses of new-onset COPD or acute traumatic injuries that are WTC-related health conditions that might result from this action. Those costs were addressed in the interim final rule that established regulations for the WTC Health Program (76 FR 38914, July 1, 2011).

Since the implementation of provisions of the Affordable Care Act on January 1, 2014, all of the members and future members are assumed to have or have access to medical insurance coverage other than through the WTC Health Program. Therefore, all treatment costs to be paid by the WTC Health Program through 2016 are considered transfers. Tables 5 and 6 describe the estimated allocation of WTC Health Program transfer payments.

[55] Colón D [2014]. The impact of claimant age on late-term medical costs. NCCI Research brief, October 2014. *https://www.ncci.com/documents/Impact-Claimant-Age-Late-Term-Med-Costs.pdf.* Accessed February 4, 2015.

[56] AK, AL, AR, AZ, CO, CT, DC, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MN, MO, MS, MT, NC, NE, NH, NJ, NM, NV, NY, OK, OR, RI, SC, SD, TN, UT, VA, VT, WI, and WV

[57] Bureau of Labor Statistics. Consumer Price Index. *https://research.stlouisfed.org/fred2/series/CPIMEDSL/downloaddata?cid=32419.* Accessed November 5, 2014.

[58] The low cost estimate reflects the low COPD treatment cost estimate using WTC Health Program data, discounted at 7 percent, from Table 5 and the acute traumatic injury treatment cost estimate, discounted at 7 percent, from Table 6. The high cost estimate reflects the high COPD treatment cost estimate using data from Leigh *et al.* (2002), discounted at 3 percent, from Table 5 and the acute traumatic injury treatment cost estimate, discounted at 3 percent, from Table 6.

[59] *See:* WTC Health Program. Policy and procedures for recoupment and coordination of benefits: workers' compensation payment. *http://www.cdc.gov/wtc/pdfs/WTCHP-PP-Recoupment-WComp-16-Dec-13.pdf.*

[60] Workers' compensation rates are derived from WTC Health Program data.

TABLE 5—PRESENT VALUE OF 2015 AND 2016 MEDICAL TREATMENT COST FOR NEW-ONSET COPD CASES IN 2014 DOLLARS

Source (costs)	Year	Undiscounted	Discounted at 3%	Discounted at 7%
Responders				
WTC Health Program	2015	$1,032 * 2,013 * .91 = $1,890,449.	$1,002 * 1,954 * .91 = $1,781,696.	$965 * 1,881 * .91 = $1,651,800
	2016	$1,032 * 2,125 * .91 = $1,995,630.	$973 * 2,003 * .91 = $1,773,516.	$901 * 1,856 * .91 = $1,521,753
Survivors				
	2015	$1,032 * 291 = $300,312	$1,002 * 283 = $283,566	$965 * 272 = $262,480
	2016	$1,032 * 339 = $349,848	$973 * 320 = $311,360	$901 * 296 = $266,696
	Total	$4,536,239	$4,150,138	$3,702,729
Responders				
Leigh *et al.* (2002)	2015	$1,930 * 2,013 * .91 = $3,535,432.	$1,874 * 1,954 * .91 = $3,332,234.	$1,804 * 1,881 * .91 = $3,087,925
	2016	$1,930 * 2,125 * .91 = $3,732,138.	$1,819 * 2,003 * .91 = $3,315,546.	$1,686 * 1,856 * .91 = $2,847,587
Survivors				
	2015	$1,930 * 291 = $561,630	$1,874 * 283 = $530,342	$1,804 * 272 = $490,688
	2016	$1,930 * 339 = $654,270	$1,819 * 320 = $582,080	$1,686 * 296 = $499,056
	Total	$8,483,470	$7,760,202	$6,925,256

TABLE 6—PRESENT VALUE OF 2015 AND 2016 MEDICAL TREATMENT COST FOR ACUTE TRAUMATIC INJURY CASES IN 2014 DOLLARS

Source (costs)	Year	Undiscounted	Discounted at 3%	Discounted at 7%
Responders				
NCCI (2014)	2015	$11,216 * 76 * .88 = $750,126	$10,890 * 74 * .88 = $709,157	$10,482 * 71 * .88 = $654,915
	2016	$11,216 * 79 * .88 = $779,736	$10,572 * 74 * .88 = $688,449	$9,796 * 69 * .88 = $594,813
Survivors				
	2015	$11,216 * 9 = $100,944	$10,890 * 9 = $98,010	$10,482 * 8 = $83,856
	2016	$11,216 * 10 = $112,160	$10,572 * 9 = $95,148	$9,796 * 9 = $88,164
	Total	$1,742,966	$1,590,764	$1,421,748

Examination of Benefits (Health Impact)

This section describes qualitatively the potential benefits of the proposed rule in terms of the expected improvements in the health and health-related quality of life of potential new-onset COPD or acute traumatic injury patients treated through the WTC Health Program, compared to no treatment by the Program.

The Administrator does not have information on the health of the population that may have experienced 9/11 exposures and is not currently enrolled in the WTC Health Program. However, the Administrator assumes that all unenrolled responders and survivors are now covered by health insurance (due to the ACA) and may be receiving treatment outside the WTC Health Program.

Although the Administrator cannot quantify the benefits associated with the WTC Health Program, members with new-onset COPD or acute traumatic injury would have improved access to care and thereby the Program should produce better treatment outcomes than in its absence. Under other insurance plans, patients may have deductibles and copays, which impact access to care and timeliness of care. WTC Health Program members who are certified for these conditions would have first-dollar coverage and, therefore, are likely to seek care sooner when indicated, resulting in improved treatment outcomes.

Limitations

The analysis presented here was limited by the dearth of verifiable data on the new-onset COPD and acute traumatic injury status of responders and survivors who have yet to apply for enrollment in the WTC Health Program. Because of the limited data, the Administrator was not able to estimate benefits in terms of averted healthcare costs. Nor was the Administrator able to estimate indirect costs such as averted absenteeism, short and long-term disability, and productivity losses averted due to premature mortality.

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. The Administrator 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.*).

C. Paperwork Reduction Act

The Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* requires an agency to invite public comment on, and to obtain OMB approval of, any regulation that requires 10 or more people to report information to the agency or to keep certain records. This rule does not contain any information collection requirements; thus, HHS has determined that the PRA does not apply to this rule.

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 does not include any Federal mandate that may result in increased annual expenditures in excess of $100 million in 1995 dollars by State, local or Tribal governments in the aggregate, or by the private sector. However, the rule may result in an increase in the contribution made by New York City for treatment and monitoring, as required by Title XXXIII, sec. 3331(d)(2).

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)

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

Proposed Rule

List of Subjects in 42 CFR Part 88

Administrative practice and procedure, Health care, Lung diseases, Mental health programs.

For the reasons discussed in the preamble, the Department of Health and Human Services proposes to revise 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. In § 88.1, under the definition ''List of WTC-related health conditions,'' revise paragraph (1)(v) and add paragraph (5) to read as follows:

§ 88.1 Definitions.

* * * * *

List of WTC-related health conditions

* * *

(1) * * *

(v) WTC-exacerbated and new-onset chronic obstructive pulmonary disease (COPD).

* * * * *

(5) Acute traumatic injuries for those WTC responders and screening- and certified-eligible WTC survivors who received any medical treatment for such an injury on or before September 11, 2003. *Acute traumatic injury* means physical damage to the body caused by and occurring immediately after a one-time exposure to energy, such as heat, electricity, or impact from a crash or fall, resulting from a specific event or incident. Eligible acute traumatic injuries may include but are not limited to the following:

(i) Eye injuries.

(ii) Severe burns.

(iii) Head trauma.

(iv) Fractures.

(v) Tendon tears.

(vi) Complex sprains.

(vii) Other similar acute traumatic injuries.

* * * * *

Dated: August 31, 2015.

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. 2015–22599 Filed 9–9–15; 11:15 am]

BILLING CODE P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Parts 3160 and 3170

[15X.LLWO300000.L13100000.NB0000]

RIN 1004–AE15

Onshore Oil and Gas Operations; Federal and Indian Oil and Gas Leases; Site Security

AGENCY: Bureau of Land Management, Interior.

ACTION: Proposed rule; extension of public comment period.

SUMMARY: On July 13, 2015, the Bureau of Land Management (BLM) published in the **Federal Register** a proposed rule to establish minimum standards for site security at oil and gas facilities located on Federal and Indian (except Osage Tribe) lands. This proposed rule would