



Shanksville



New York City



Pentagon

Overview of Policy and Procedures to Add Cancer Conditions

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WTC-Related Health Conditions¹

- “[A]n illness or health condition for which exposure to airborne toxins, any other hazard, or any other adverse condition resulting from the September 11, 2001, terrorist attacks, based on an examination by a medical professional with experience in treating or diagnosing the health conditions included in the applicable list of WTC-related health conditions, **is substantially likely to be a significant factor in aggravating, contributing to, or causing the illness or health condition...;**” or
- “[A] mental health condition for which such attacks, based on an examination by a medical professional with experience in treating or diagnosing the health conditions included in the applicable list of WTC-related health conditions, **is substantially likely to be a significant factor in aggravating, contributing to, or causing the condition...**”

¹ See 42 U.S.C. § 300-22(a)(1); 42 C.F.R. § 88.1

List of WTC-Related Health Conditions (List)

Aerodigestive Disorders:

- Interstitial lung diseases
- Chronic respiratory disorder
- Asthma
- Reactive airways dysfunction syndrome (RADS)
- WTC-exacerbated and new onset COPD
- Chronic cough syndrome
- Upper airway hyperreactivity
- Chronic rhinosinusitis
- Chronic nasopharyngitis
- Chronic laryngitis
- Gastroesophageal reflux disorder (GERD)
- Sleep apnea associated with one of the above

Musculoskeletal Disorders (responders only)

Mental Health Conditions:

- Post-traumatic stress disorder (PTSD)
- Major depressive disorder
- Panic disorder
- Generalized anxiety disorder
- Anxiety disorder
- Depression
- Acute stress disorder
- Dysthymic disorder
- Adjustment disorder
- Substance abuse

Acute Traumatic Injuries

Cancers (24 specific categories)

Pathways to Add a Cancer Condition to the List:

1. The Administrator of the WTC Health Program initiates the process at his own discretion.
 2. The Administrator initiates the process after receiving a valid petition from an interested party.
- Both pathways require rulemaking.

Petition Form

Form Approved
OMB No. 0920-0891
Exp. Date 12/31/2021

Petition for the Addition of a New WTC-Related Health Condition for Coverage under the World Trade Center (WTC) Health Program



U.S. Department of Health and Human Services
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

General Instructions

Any interested party may petition the WTC Program Administrator to add a condition to the List of WTC-Related Health Conditions (List) in 42 C.F.R. Part 88 (see <http://www.cdc.gov/wtc/faq.html#hlthcond> for the complete list).

Please use this form to petition the Administrator to add a health condition (any recognized medical condition requiring treatment or medication) to the List. Please use a separate form for each health condition.

Use of this petition *form* is voluntary, but any petition must include all of the information identified below, as required by 42 C.F.R. Part 88. Petitions that do not provide the required information will not be considered by the WTC Program Administrator. Additional supporting materials may be submitted and are encouraged.

Please note, however, the petition and all supporting materials submitted to the WTC Health Program are part of the public record and may be subject to public disclosure. Personal information will be redacted prior to public disclosure.

Please TYPE or PRINT all information clearly on the form.

If you need more space to provide the required information, please attach additional pages to this form.

Mail or email this form to: World Trade Center Health Program
395 E. Street, S.W., Suite 9200
Washington, D.C. 20201
WTC@cdc.gov

A. Interested Party Information

A1. Do you represent an organization (are you submitting this petition on behalf of an organization)?
 Yes (Go to A2) No (Go to A3)

A2. Organization Information:

Name of organization _____

A3. Name of Individual Petitioner or Organization Representative:

First name _____

Last name _____

Position, if representative of organization _____

A4. Mailing Address:

Street _____

City _____

State _____

Zip code _____

A5. Telephone Number: _____

A6. Email Address: _____

B. Proposed WTC-Related Health Condition Information

B1. Health Condition Information:

Name of health condition you wish to petition to add to the List of covered conditions _____

If the name of the condition is not known, please provide a description of the condition or the name of the diagnosis provided by a physician or other healthcare provider.

Policies and Procedures (P&P) – Petition Process

- “Policy and Procedures for Handling Submissions and Petitions to Add a Health Condition to the List of WTC-Related Health Conditions” -- and determines whether the submission meets the requirements to be a valid petition specified in 42 C.F.R. § 88.16(a)(1).

<http://www.cdc.gov/wtc/pdfs/WTCHPPPetitionHandlingProcedures14May2014.pdf>

- “Policy and Procedures for Adding Types of Cancer to the List of WTC-Related Health Conditions”

https://www.cdc.gov/wtc/pdfs/policies/WTCHP_PP_Addition_of_Cancer_Policy_UPD_ATED_050719-508.pdf

P&P for Handling Submissions and Petitions

Determining Validity of Submission as a Petition

- Policy Team evaluates submission to determine if the submission meets the requirements for a valid petition.
- The medical basis may be demonstrated by:
 - Reference to a peer-reviewed, published, epidemiologic study about the health condition among 9/11-exposed populations;
 - Reference to a peer-reviewed, published, epidemiologic study about an association between a 9/11 agent and the requested health condition; or
 - Clinical case reports/series of health conditions in WTC responders or survivors.
- First-hand accounts or anecdotal evidence are not sufficient to establish medical basis.
- The submitter is notified if submission is considered a valid petition or not.

P&P Cancer – Literature Review

- Administrator’s Discretion or Valid Petition
- Program Science Team leads a review of the scientific literature:
 - Systematic Literature Search
 - Peer-reviewed, published, epidemiologic studies of 9/11-exposed populations;
 - Studies of potential causal association between requested cancer and condition already on List;
 - Classifications of the World Health Organization’s International Agency for Research on Cancer (IARC) and the National Toxicology Program (NTP) *Report on Carcinogens*; and
 - If process was initiated in response to a petition, the medical basis is also reviewed.

P&P Cancer – Evaluation of Literature

- WTC Health Program Science Team evaluates:
 - Quantity and quality of the evidence, including limitations such as:
 - Selection bias;
 - Recall error;
 - Healthy worker effect;
 - Confounders such as family cancer history or pre-9/11 exposures.
- Findings are documented and discussed with the Administrator.

P&P Cancer - Administrator Determination

1. If the evidence does not provide a sufficient basis for a decision:
 - Evaluation is documented and archived;
 - If initiated by a petition, determination published in the *Federal Register* and petitioner is notified in writing.
2. If the available evidence has the potential to provide a basis for a decision, the Administrator may:
 - Direct the Science Team to assess the scientific and medical evidence;
 - Request advice from the STAC.

P&P Cancer - Assessment of Information

- Science Team conducts an assessment of the available evidence under four methods. At least one of the methods must be fulfilled:
 - Method 1.** Epidemiologic Studies of 9/11-Exposed Populations.
 - Method 2.** Established Causal Associations with a Health Condition Already on the List of WTC-Related Health Conditions.
 - Method 3.** Review of Evaluations of Carcinogenicity in Humans.
 - Method 4.** Review of Information Provided by the STAC upon Request by the Administrator.
- Science team ensures that the results of the assessment are documented and discussed with the Administrator.

Method 1

- Peer-reviewed, published, epidemiologic studies of 9/11-exposed populations are assessed by applying criteria extrapolated from the Bradford Hill criteria:
 - Strength of the association between a 9/11 exposure and the health condition, including the precision of the risk estimate.
 - Consistency of the findings across multiple studies.
 - Biological gradient, or dose-response relationships between 9/11 exposures and the health condition.
 - Plausibility and coherence with known facts about the biology of the health condition.
- No cancers have been added under Method 1 to date, but several epidemiologic studies of cancer in 9/11-exposed populations beginning in 2011 have been suggestive of a causal association between 9/11 agents and various cancers.

Method 2

- A type of cancer may be added to the List of WTC-Related Health Conditions if there is well-established scientific support published in multiple epidemiologic studies for a causal association between that cancer and a condition already on the List.
- Example:
 - Adenocarcinoma of the esophagus that progresses from gastroesophageal reflux disease (GERD).

Method 3

Both of the following criteria must be satisfied:

- **9/11 agent** included in the *Inventory of 9/11 Agents* is identified; and
- The **National Toxicology Program (NTP)** has determined that the 9/11 agent is *known to be a human carcinogen* or *is reasonably anticipated to be a human carcinogen*, and the **International Agency for Research on Cancer (IARC)** has determined there is *sufficient* or *limited* evidence that the 9/11 agent causes a type of cancer.

Method 3 - Inventory of 9/11 Agents

Definition of 9/11 agents:

“Chemical, physical, biological, or other hazards reported in a published, peer-reviewed exposure assessment study of responders, recovery workers, 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 C.F.R. § 88.1, as well as those hazards not identified in a published, peer-reviewed exposure assessment study, but which are reasonably assumed to have been present at any of the three sites.”

https://wwwn.cdc.gov/ResearchGateway/Content/pdfs/Development_of_the_Inventory_of_9-11_Agents_20180717.pdf

Method 3 Examples

1. Malignant neoplasm of lip
2. Malignant neoplasm of base of tongue
3. Malignant neoplasms of other and unspecified parts of tongue
4. Malignant neoplasm of parotid gland
5. Malignant neoplasm of other and unspecified major salivary glands
6. Malignant neoplasm of floor of mouth
7. Malignant neoplasm of gum
8. Malignant neoplasm of palate
9. Malignant neoplasm of other and unspecified parts of mouth
10. Malignant neoplasm of tonsil
11. Malignant neoplasm of oropharynx
12. Malignant neoplasm of nasopharynx
13. Malignant neoplasm of piriform sinus
14. Malignant neoplasm of hypopharynx
15. Malignant neoplasms of other and ill-defined conditions in the lip, oral cavity, and pharynx
16. Malignant neoplasm of nasal cavity
17. Malignant neoplasm of accessory sinuses
18. Malignant neoplasm of larynx
19. Malignant neoplasm of the stomach
20. Malignant neoplasm of colon
21. Malignant neoplasm of rectosigmoid junction
22. Malignant neoplasm of rectum
23. Malignant neoplasm of other and ill-defined digestive organs
24. Malignant neoplasm of liver and intrahepatic bile duct
25. Malignant neoplasm of retroperitoneum and peritoneum

Method 3 Examples (continued)

26. Malignant neoplasm of trachea
27. Malignant neoplasm of the bronchus and lung
28. Malignant neoplasm of heart, mediastinum and pleura
29. Malignant neoplasm of other ill-defined sites in the respiratory system and intrathoracic organs
30. Mesothelioma
31. Malignant neoplasm of peripheral nerves and autonomic nervous system
32. Malignant neoplasm of other connective and soft tissue
33. Other malignant neoplasms of skin
34. Malignant neoplasm of scrotum
35. Malignant neoplasm of ovary
36. Malignant neoplasm of bladder
37. Malignant neoplasm of the kidney
38. Malignant neoplasm of the renal pelvis
39. Malignant neoplasm of ureter
40. Malignant neoplasm of other and unspecified urinary organs
41. Hodgkin's disease
42. Follicular [nodular] non-Hodgkin lymphoma
43. Diffuse non-Hodgkin lymphoma
44. Peripheral and cutaneous T-cell lymphomas
45. Other and unspecified types of non-Hodgkin lymphoma
46. Malignant immunoproliferative diseases
47. Multiple myeloma and malignant plasma cell neoplasms
48. Lymphoid leukemia
49. Myeloid leukemia
50. Monocytic leukemia
51. Other leukemias of specified cell type
52. Leukemia of unspecified cell type
53. Other and unspecified malignant neoplasms of lymphoid, hematopoietic and related tissue

Method 4

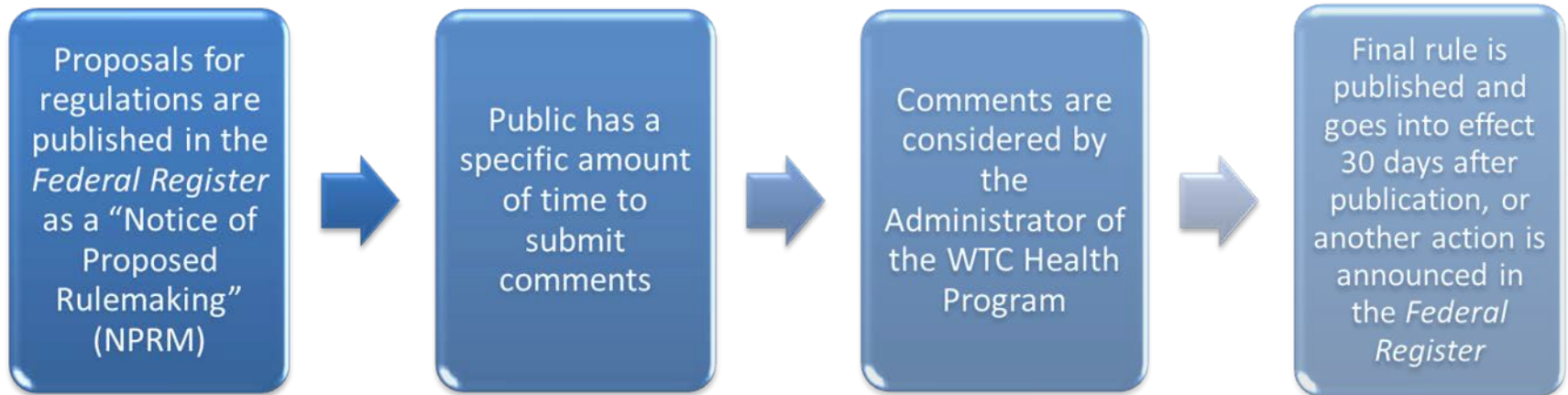
- A type of cancer may be added to the List of WTC-Related Health Conditions if the STAC has provided a reasonable basis for adding a type of cancer.
- Examples:
 - Skin cancer;
 - Breast cancer (since addition, scientific evidence to support Method 3);
 - Eye and orbit cancer;
 - Thyroid cancer;
 - Childhood cancers;
 - Rare cancers.

P&P Cancer - Administrator Actions

- If the assessment was performed in response to a petition:
 - The Administrator publishes a NPRM in the *Federal Register* if at least one of the four methods is fulfilled;
 - The Administrator publishes a determination not to propose a rule and the basis for such determination in the *Federal Register* if none of the four methods are fulfilled and evidence demonstrates that 9/11 exposures are not causally related to the type of cancer; or
 - The Administrator publishes a determination in the *Federal Register* that the review of the evidence indicates the information is insufficient to take either of these actions.
- If the assessment was initiated by the Administrator, the Administrator may take one of the actions described above.

P&P Cancer – Rulemaking to Add Cancer to List

Process for Rules (Regulations)



- Public comment and independent peer review
- Peer reviewers are identified with consideration of STAC's input to conduct an independent peer review.

P&P Cancer – Final Rule

- If Administrator decides to add cancer to List:
 - Final rule becomes effective 30 days after publication;
 - Implementation procedures are developed;
 - Exposure requirements
 - Latency period
 - Documentation for certification
 - Screening (U.S. Preventive Services Taskforce recommendations)

Questions?

