

**World Trade Center Health Program
Enrollment, Treatment, Appeals & Reimbursement**

Revision

Supporting Statement A

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Table of Contents

1A. Justification

1. Circumstances Making the Collection of Information Necessary
2. Purpose and Use of Information Collection
3. Use of Improved Information Technology and Burden Reduction
4. Efforts to Identify Duplication and Use of Similar Information
5. Impact on Small Businesses or Other Small Entities
6. Consequences of Collecting the Information Less Frequently
7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5
8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency
9. Explanation of Any Payment or Gift to Respondents
10. Assurance of Confidentiality Provided to Respondents
11. Justification for Sensitive Questions
12. Estimates of Annualized Burden Hours and Costs
13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers/Capital Costs
14. Annualized Cost to the Government
15. Explanation for Program Changes or Adjustments
16. Plans for Tabulation and Publication and Project Time Schedule
17. Reason(s) Display of OMB Expiration Date is Inappropriate
18. Exceptions to Certification for Paperwork Reduction Act Submissions

Appendices

- Appendix A Zadroga Act (Sec 3301)
- Appendix B Summary of Covered Health Benefits, Health Conditions, Treatments, and Payments
- Appendix C World Trade Center Health Program FDNY Responder Eligibility Application
- Appendix D World Trade Center Health Program Responder Eligibility Application (Other than FDNY) English
- Appendix E World Trade Center Health Program Responder Eligibility Application (Other than FDNY) Spanish
- Appendix F World Trade Center Health Program Responder Eligibility Application (Other than FDNY) Polish
- Appendix G World Trade Center Health Program Pentagon/Shanksville Eligibility Application
- Appendix H World Trade Center Health Program Survivor Eligibility Application English
- Appendix I World Trade Center Health Program Survivor Eligibility Application Spanish
- Appendix J World Trade Center Health Program Survivor Eligibility Application

	Polish
Appendix K	World Trade Center Health Program Survivor Eligibility Application Chinese
Appendix L	Web Based Application Screen Shots (samples)
Appendix M	Initial Request for Additional Information
Appendix N	30 Day Letter Reminder for Additional Information
Appendix O	60 Day Letter Reminder for Additional Information
Appendix P	90 Day Letter Reminder for Additional Information
Appendix Q	180 Day Letter Reminder for Information
Appendix R	Postcard
Appendix S	WTC-3 Request for Certification
Appendix T	WTC-5 Code or Procedure Request
Appendix U	WTC-6 Medication Request for Codebook
Appendix V	Prior Authorization Form – Standard
Appendix W	Prior Authorization Form – Dental
Appendix X	Prior Authorization Form – Transplant
Appendix Y	Outpatient Prescription Pharmaceuticals
Appendix Y-1	Non-Formulary Prior Authorization - Prescription (General)
Appendix Y-2	Non-Formulary Prior Authorization – Prescription (Renewal)
Appendix Y-3	Non-Formulary Prior Authorization – Airway Medication
Appendix Y-4	Non-Formulary Prior Authorization – Antidepressant
Appendix Y-5	Non-Formulary Prior Authorization – Antiemetic
Appendix Y-6	Non-Formulary Prior Authorization – Antipsychotic
Appendix Y-7	Non-Formulary Prior Authorization – Epinephrine
Appendix Y-8	Non-Formulary Prior Authorization – Insulin
Appendix Y-9	Non-Formulary Prior Authorization – Methadone
Appendix Y-10	Non-Formulary Prior Authorization – Nucala
Appendix Y-11	Non-Formulary Prior Authorization – Opioid Abuse
Appendix Z	Enrollment Denial Letter and Appeal Notification
Appendix AA	Certification Denial Letter and Appeal Notification
Appendix BB	Treatment Denial Letter and Appeal Notification
Appendix CC	WTC Health Program Medical Travel Refund Request
Appendix DD-1	Federal Register Notice
Appendix EE	IRB Determination
Appendix FF	Translated Initial Request for Information (Spanish, Chinese, Polish)
Appendix GG	Translated 30 Day Request for Information (Spanish, Chinese, Polish)
Appendix HH	Translated 60 Day Request for Information (Spanish, Chinese, Polish)
Appendix II	Translated 90 Day Request for Information (Spanish, Chinese, Polish)
Appendix JJ	Translated 180 Day Request for Information (Spanish, Chinese, Polish)
Appendix KK	Translated Enrollment Denial and Appeal Notification (Spanish)
Appendix LL	Designated Representative Form
Appendix MM	HIPAA Release
Appendix NN	Petition for the Addition of a New WTC-Related Health Condition for Coverage under the World Trade Center (WTC) Health Program Form
Appendix OO	Disenrollment Letter and Appeal Notification
Appendix PP	Decertification Letter Template—Administrative Error

Appendix QQ Decertification Letter Template—Denial and Decertification Exposure
Appendix RR Decertification Letter Template—Latency Prostate Cancer/Cancer
Appendix SS Overview of WTC Health Program Forms, Standard Correspondence, and
Changes to the Information Collection Request
Appendix TT Reimbursement Denial Letter and Appeal Notification



Goal of the Study: The World Trade Center (WTC) Health Program is a limited healthcare program administered by the National Institute for Occupational Safety and Health (NIOSH) at the Centers for Disease Control and Prevention (CDC). The goal of the WTC Health Program is to provide healthcare monitoring and treatment to responders of the 9/11/2001 terrorist attacks at the World Trade Center in New York City, the Pentagon in Washington, D.C., and Shanksville, Pennsylvania, as well as survivors in the New York City area.

Intended Use of the Resulting Data: As authorized by the James Zadroga 9/11 Health and Compensation Act of 2010, CDC collects information to determine the eligibility of individuals for WTC Health Program benefits, to provide or pay for authorized healthcare services, to assess requests for the inclusion of new health conditions in the list of conditions covered by the Program, and to adjudicate appeals.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The mission of the National Institute of Occupational Safety and Health (NIOSH), located within the Centers for Disease Control and Prevention (CDC), is to develop new knowledge in the field of occupational safety and health and to transfer that knowledge into practice. NIOSH seeks OMB approval to revise an ongoing information collection, “World Trade Center Health Program Enrollment, Appeals & Reimbursement” (OMB No. 0920-0891, expiration date 9/30/2018). The revised clearance will incorporate information previously collected under a related clearance (see OMB No. 0920-0929, expiration date 7/31/2018, “World Trade Center Health Program Petition for the Addition of a New WTC-Related Health Condition for Coverage under the World Trade Center (WTC) Health Program”), which has been discontinued. OMB approval of the revised and consolidated information collection plan for 0920-0891 is requested for 3 years.

On September 11, 2001 (“9/11”), terrorists attacked the World Trade Center (WTC) in New York City and the Pentagon in Washington, D.C. Terrorists also attacked a commercial airplane that subsequently crashed near Shanksville, Pennsylvania. Emergency responders for these events included firefighters, law enforcement officers, and emergency medical service providers – many of whom were injured and/or exposed to smoke, fumes, ash, dust, and other contaminants during their participation in rescue, recovery, and cleanup tasks (“responders”). In addition, many individuals who were not professional emergency responders had similar experiences and exposures (“survivors”).

In 2002, NIOSH and the American Red Cross provided grants to launch the WTC Medical Monitoring and Treatment Program (MMTP) in response to individuals developing health issues related to the 9/11 disasters. Congress also passed appropriations to provide limited health screening and treatment services to WTC responders. Over 57,000 responders met the program's initial eligibility requirements. In addition to the WTC MMTP, the WTC Environmental Health Center (EHC) was also established after the 9/11 terrorist attacks to treat WTC-related illnesses. This program consisted of three locations in and around New York City. On September 30, 2008, the CDC awarded the New York City Health and Hospitals Corporation (HHC) a grant, administered by the NIOSH, to provide health services to non-responder populations in New York City affected by the WTC terrorist attacks. Under the grant, HHC provided medical examinations, diagnostic testing, referral and treatment for residents, students, and others in the community that were directly affected by the dust and debris from the collapse of the WTC buildings.

On December 22, 2010, the James Zadroga 9/11 Health and Compensation Act of 2010 (Zadroga Act) established a Federal program, the World Trade Center (WTC) Health Program, to support health monitoring and treatment for emergency responders; recovery and cleanup workers in New York City, the Pentagon and Shanksville, Pennsylvania; and residents, building occupants, and area workers in New York City who were directly impacted and adversely affected by the terrorist attacks of September 11, 2001. The Zadroga Act mandated the authority of this program to the Department of Health and Human Services and with the Director of NIOSH serving as the WTC Program

Administrator, supported by a WTC Steering Committee and a WTC Scientific/Technical Advisory Committee. On July 1, 2011, the WTC MMTP and the WTC EHC became a part of the WTC Health Program.

On December 18, 2015, President Obama signed the “Consolidated Appropriations Act, 2016” (Public Law 114-113), which includes the “James Zadroga 9/11 Health and Compensation Reauthorization Act.” Public Law 114-113 amends Title XXXIII of the Public Health Service Act (codified at 42 U.S.C. §§ 300mm – 300mm-61) to reauthorize the World Trade Center (WTC) Health Program for 75 years, ending in 2090 (see **Appendix A**).

In accordance with the Zadroga Act, all responders and survivors to the New York City attack who will be newly seeking medical monitoring and treatment who were not covered by the Medical Monitoring and Treatment Program (MMTP) or the NYC Health and Hospitals Corporation, WTC Environmental Health Center prior to Zadroga, may apply to obtain coverage under the new WTC Health Program. In its current form, the WTC Health Program serves as the first payer for medical and mental health treatment services deemed necessary for qualifying emergency responders. The Program also provides assistance to qualifying survivors whose medical needs are not covered by other benefit plans. For responders and survivors in the New York/New Jersey area, medical monitoring and treatment services are provided by WTC-designated Clinical Centers of Excellence. Responders outside the New York/New Jersey area receive medical monitoring and treatment services through a Nationwide Provider Network of affiliated providers.

In order to receive healthcare monitoring and treatment through the WTC Health Program, responders and survivors must be enrolled as WTC Health Program members and submit documentation of a WTC-certified health condition. The list of adverse health consequences certified by the WTC Program includes acute traumatic injuries, musculoskeletal disorders, respiratory and digestive disorders, blood and lymphoid tissue disorders, some cancers, and selected mental health disorders, among others. A summary of WTC-related health conditions, treatments, and covered health benefits is provided in **Appendix B**. NIOSH may add new conditions to the list upon review and approval of the evidence by qualified subject matter experts.

Under two separate information collection requests, NIOSH has obtained approval from OMB to collect the information needed to administer the WTC Health Program (see OMB No. 0920-0891 and OMB No. 0920-0929). Respondents are WTC Program members and affiliated medical providers. In this Revision request, NIOSH requests OMB approval to consolidate the information collections under 0920-0891 and to update reporting requirements for consistency with changes in the WTC Health Program regulations, 42 C.F.R. Part 88. Such changes include:

- Clarifying that Program members who are disenrolled may submit an appeal request under 42 C.F.R. § 88.14.
- Clarifying that members appealing decertification and certification and treatment authorization denial under § 88.21 may submit new information and present an

oral statement.

- A new appeal process under § 88.23 allows Program medical providers (including both Clinical Centers of Excellence and Nationwide Provider Network-affiliated providers) to submit an appeal request (42 C.F.R. § 88.23).

The Program has also added:

- A HIPAA Release Form (**Appendix MM**).
- A revised Designated Representative Form (**Appendix LL**).
- Copies of translated enrollment forms (**Appendices E-F, I-K**).
- Adjustments to the expected number of respondents, where applicable. When this original information collection request was submitted in 2011, the Program was just starting. We now have data since 2011 to estimate the usage of the forms and have readjusted the expected number of respondents where appropriate.
- The WTC Health Program Petition for the Addition of a New WTC-Related Health Condition for Coverage under the World Trade Center (WTC) Health Program is being incorporated into 0920-0891. This form was previously approved under OMB No. 0920-0929 (discontinued 7/31/2018).

Appendix SS provides a summary of forms, by type/function; a summary of the changes described in this Revision request; and specifies the impact of these changes on burden estimates.

2. **Purpose and Use of Information Collection**

This information collection request describes four types of information needed to administer the WTC Health Program: I) information required by NIOSH to determine the eligibility of applicants and to enroll them as members of the WTC Health program; II) information needed to provide authorized medical services for certified medical conditions to WTC program members; III) information needed to assess new conditions or treatments for coverage; and IV) information submitted by WTC members or providers to appeal requests for enrollment, certification of health conditions, or coverage of services that have been denied. **Appendix SS** provides an overview of WTC Health Program forms, standard correspondence, and changes.

I. Determination of Eligibility

NIOSH developed four different eligibility forms to address the different criteria for each group covered by the WTC Health Program. In addition, translations are readily available for languages other than English that are highly prevalent among WTC responders and survivors. Applicants may apply for WTC Health Program benefits using one of the following: the Fire Department of New York (FDNY) Responder Form (**Appendix C**); the WTC Health Program Responder Form which is used for NYC responders who were not members of the FDNY (see **Appendix D**; also available in Spanish (**Appendix E**) or Polish (**Appendix F**)); the Pentagon/Shanksville Responder Form (**Appendix G**), and the

WTC (NYC) Survivor Form (**Appendix H**; also available in Spanish (**Appendix I**), Polish (**Appendix J**), or Chinese (**Appendix K**)). The eligibility application forms collect general contact information as well as information regarding the WTC, Pentagon, and Shanksville, Pennsylvania experiences. Because terrorists are not eligible for WTC Health Program benefits, some of the information provided is shared with the Federal Bureau of Investigation in order to screen an individual against the terrorist watch list maintained by the Federal government. This information is be shared with the WTC Program Administrator and is kept in a secure manner. If the application is not complete, prospective members receive a letter explaining that more information is needed before a decision can be made. There is an initial decision letter that is mailed (**Appendix M**) as well as a 30, 60, 90, and 180 day letter (**Appendices N-Q**). These follow-up reminder letters (**Appendix N-Q**) are being provided to OMB as supplemental materials.

Letters to applicants requesting more information, as well as enrollment and certification denial letters, are translated on an as-needed basis. Translations are done based on need of each letter and the language the application was submitted. Translations for the current Program letters are attached (**Appendices FF-KK**).

WTC Health Program members also have the opportunity to request that a designated representative act on their behalf. Members wishing to do so must use the Designated Representative Form (**Appendix LL**). The designated representative can act on the member's behalf for the enrollment and appeal process.

II. Routine Administration of Medical Monitoring and Treatment Services

Once enrolled, responders in the NYC area receive a postcard to choose which clinic they would like to attend (**Appendix R**). Responders receive monitoring benefits and survivors receive an initial screening upon enrollment. In order to receive treatment benefits, the WTC physician must submit a certification request, WTC-3, to the Program for approval (**Appendix S**). Once approved, then the member can receive treatment benefits.

In limited situations, members of the Nationwide Provider Network can request travel reimbursement for medically necessary information. This form includes demographic information and information related to the member's expenses (see **Appendix CC**).

A member can permit the Program to share information with a third party using the HIPAA Release form (**Appendix MM**). The HIPAA Release Form is an optional, but when applicable, allows Program members and those applying to the Program to allow the Program the authority for this exchange of information to occur. The HIPAA form is distinct from the Designated Representative Form. A member may also choose to share their health information with a third party, but may not necessarily want the third party to have the ability to act on their behalf.

Pharmacies transmit reimbursement claims to the WTC Health Program. The following data elements are collected for pharmacy reimbursement: pharmacy name, pharmacy address, drug name, prescription number, patient name, patient ID number, and cost (no form available as this is an electronic submission from the pharmacy to the Pharmacy Benefits Manager sub-contractor).

Additional medical forms are being provided as supplemental documents, as requested by OMB. This includes the WTC-5 (Code or Procedure Request), the WTC-6 (Medication Request for Codebook), the Standard Prior Authorization form and the special purpose Prior Authorization forms for Transplants, Dental and member specific Pharmacy requests (**Appendices T-Y**).

III. Assessment of New Conditions or Treatments for Coverage

The Zadroga Act identified a list of health conditions (**Appendix B**) for which individuals who are enrolled in the WTC Health Program may be monitored or treated [Title XXXIII, § 3312(a)(3)]; those conditions are reiterated and expanded in the associated WTC Health Program regulations at 42 C.F.R. § 88.15. Under WTC Health Program regulation 42 C.F.R. § 88.16, interested parties may submit a petition to request that a new health condition be added to the list of conditions specified in § 88.15. To aid the petitioner, the WTC Health Program created petition form (**Appendix NN**) to be completed and then sent to the Program for review. However, the petitioner is not required to use the form, and may submit a petition in a different format, provided it contains all of the data elements requested on the form and identified below.

- Name – First, Middle, and Last
- Organization
- Mailing Address – Address, City, State, Zip Code
- Phone Number
- Email Address
- Signature
- Medical basis for addition of the health condition (although not required by the Program, we anticipate that petitioners might include medical records to substantiate their petition)

WTC Health Program applicants and enrolled members have opportunities to appeal adverse decisions made by the WTC Program Administrator. The first opportunity to appeal arises after a determination that an applicant does not meet the eligibility requirements (**Appendix Z**). Once enrolled in the Program, members also have the opportunity to appeal the Program's decision to deny a certification request (WTC-3) or a determination that treatment is not authorized as medically necessary. In the notification letter explaining the adverse determination, the applicant is advised that an appeal can be requested by submitting in writing their name, contact information, and an explanation for the basis of the appeal (**Appendices AA-BB**).

3. Use of Improved Information Technology and Burden Reduction

The eligibility forms may be collected via online, hard copy mail, or fax. In order to reduce the burden on the respondents and survivors, the WTC Health program makes the form available to be downloaded from the internet or obtained in hard copy and

submitted by mail. The enrollment forms are available for download on the NIOSH website at <http://www.cdc.gov/wtc/apply.html> (**Appendices C-K**). Additionally, the application is available to complete online through a web-based application system (**Appendix L**). Offering alternatives for application submission allows applicants to choose the option easiest for them. The burden should be similar regardless of the submission method. The appeal letter and travel reimbursement and designated representative request must be submitted in writing by mail or fax. Treatment forms and WTC-3 requests can be submitted by fax or mail.

4. **Efforts to Identify Duplication and Use of Similar Information**

This information in its totality is only being collected to determine eligibility for WTC Health Program services and initial treatment approval, to appeal reasons for denying membership or claims, and to request travel reimbursement. The information collected in each of these processes is distinct and collected for varying reasons. Additional information may be collected by physicians or other health care providers, however, such information is not reported to CDC/NIOSH.

5. **Impact on Small Businesses or Other Small Entities**

There will be no impact on small business.

6. **Consequences of Collecting the Information Less Frequently**

Without collection of these data, NIOSH would not be able to implement the provisions of the Act, to establish the process for an individual to apply to the WTC Health Program, to conduct an initial health evaluation, monitoring, and treatment, and to appeal eligibility and treatment decisions.

7. **Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

There are no special circumstances.

8. **Comments in Response to the Federal Register Notice/Outside Consultation**

A. A 60-day Federal Register Notice was published in the Federal Register on May 11, 2018 [Volume 83, No. 93, pages 22067-22069; see **Appendix DD-1**]. No public comments were received.

B. The WTC Health Program consulted with HHS Office of General Counsel on the legal requirements needed for data collection. The Program also consulted with Clinical Centers of Excellence (CCEs) and the Steering Committees (both legal entities created by Zadroga) on the availability of data to applicants supporting their 9/11 activities, clarity of instructions, disclosures, reporting format, and data elements requested.

9. Explanation of any Payment/Gift to Respondents

Respondents will not receive any form of payment or gifts.

10. Assurance of Confidentiality Provided to Respondents

On May 27, 2011, HHS published in the Federal Register (76 Fed. Reg. 31212) a proposal to alter System of Records, 09-20-0147. In order to comply with the tight statutory deadline for implementation of the Zadroga Act, the changes proposed in that notice went into effect 30 days from the publication, “Occupational Health Epidemiological Studies and EEOICPA Program Records, HHS/CDC/NIOSH” (51 Fed. Reg. 42474, May 24, 1986). In accordance with the requirements of the Privacy Act, CDC published the notice of proposal to: add routine uses; amend the categories of individuals covered by the system; amend the categories of records in the system; amend authority for maintenance of the system; and amend the purpose. The purpose of these modifications is to provide notice that NIOSH, in executing its responsibilities under the Zadroga Act, will release personally identifiable information to other Federal agencies and its contractors, as necessary, in order to make eligibility and qualification determinations for purposes of the WTC Health Program and as otherwise required in carrying out Title XXXIII. In addition, NIOSH is also revising the name of the system of records to “Occupational Health Epidemiological Studies, EEOICPA Program Records and WTC Health Program Records, HHS/CDC/NIOSH.”

- A. An overview of the data collection system: The data collection system starts with receipt of the application by either mail, secure fax, or a secure online application system. Once the applications are received, the data will be entered into secure databases at Karna/Computer Sciences Corporation (CSC). Hard copies will be saved in a secure location by Karna/CSC. Access to data will be limited to authorized NIOSH project staff and authorized CSC contractors. All electronic data will be stored on secure servers accessible only with passwords. Karna/CSC will be required to follow equivalent procedures.

Records are retained and disposed of according to the provisions of the CDC Electronic Records Control Schedule for NIOSH records. Research records are maintained in the agency for three years after the close of the study. Records transferred to the Federal Records Center when no longer needed for evaluation and analysis are destroyed after 75 years for epidemiologic studies, unless needed for further study. WTC Health Program records are transferred to the Federal Records Center 15 years after the case file becomes inactive and are destroyed after 75 years. Any records provided to the Department of Justice for the purpose of screening individuals against the “terrorist watch list” will be destroyed (and not retained by the Department of Justice) once it is determined that an individual is not on the “terrorist watch list.”

- B. A description of the information to be collected: The applications ask for the member’s demographic information (name, address, email, and date of birth)

as well as their activities on 9/11. The application also requests supporting documentation to support the activities listed. The follow up letters request information on supporting documentation that was not included in the application. The postcard is for the NY/NJ responder to choose their clinic selection. The WTC-3 certification request form is for the WTC physician to request certification for a WTC-related condition from the Program. This form asks information about the member's exposure, medical condition, and onset or diagnosis of the condition being submitted for certification. The WTC-5 and 6 as well as the Prior Authorization documents are for the WTC Physician to submit for approval to add treatment outside of the Program's existing treatment and pharmacy plan. The appeal letters instruct the individual to submit an explanation for why they disagree with the decision to disenroll or deny enrollment and/or decertify or deny certification or treatment authorization. The travel form requests demographic information and information related to the logistics (cost, type of travel accommodation, etc.) to be reimbursed for travel expenses.

- C. A description of how the information will be shared and for what purpose: See **“Privacy Act Statement and Additional Permitted Disclosures of Personally Identifiable Information and Records”** in the **“Notices Regarding WTC Health Program Requirements”** in **Appendices C-K**.
- D. A statement detailing the impact the proposed collection will have on the respondent's privacy: This information is provided in the notices section of all applications.
- E. Whether individuals are informed that providing the information is voluntary or mandatory: Applying to the Program is voluntary. This is also included in the notices section of the application (see **Appendices C-K**).
- F. Opportunities to consent, if any, to sharing and submission of information: Information regarding sharing of information is included in the initial application (see **Appendices C-K**).
- G. How the information will be secured: All information is secured in accordance with HIPAA and the Privacy Act. All information is collected and transmitted through secure channels and materials are stored in secure databases or locations.
- H. Whether a system of records is being created under the Privacy Act: See <http://www.gpo.gov/fdsys/pkg/FR-2011-05-27/pdf/2011-13470.pdf> and its clarification: <http://www.gpo.gov/fdsys/pkg/FR-2011-06-14/pdf/2011-14807.pdf>

11. **Justification for Sensitive Questions**

No sensitive questions will be asked.

12. Estimates of Annualized Burden Hours

World Trade Center Health Program FDNY Responder Eligibility Application (**Appendix C**), World Trade Center Health Program Responder Eligibility Application (Other than FDNY) (**Appendix D**; new translations in **Appendix E** and **Appendix F**), World Trade Center Health Program Pentagon/Shanksville Eligibility Application (**Appendix G**), and World Trade Center Health Program Survivor Eligibility Application (**Appendix H**; new translations in **Appendix I**, **Appendix J**, and **Appendix K**): Four different eligibility forms were developed to address the different criteria for each group covered by the WTC Health Program: Fire Department of New York responders, general responders, Pentagon/Shanksville responders, and survivors. Based on past enrollment numbers, we receive approximately 4,500 applications per year. The burden table reflects the annualized total burden broken into the four separate applicant groups: we estimate that 45 Fire Department of New York (FDNY) responders (1% of applicants); 2,475 general responders (55%); 630 Pentagon/Shanksville responders (14%); and 1,350 survivors (30%) will submit applications. The burden estimates for these three different forms are: FDNY = 23 hours; general responders = 1,238 hours; Pentagon/Shanksville responders = 315 hours; survivors = 675 hours.

Clinic Selection Postcard (**Appendix R**): Of the 4,500 applications we expect to receive per year, we estimate that 55% (2,475) of them are general responder applications from the NY/NJ area and will have to select which clinic they would like to visit. It is expected that it will take the member 0.25 hours to complete the postcard. The burden hours are 619 hours.

WTC-3 (**Appendix S**): We expect that WTC physicians will request an estimated 20,000 certification requests a year. These forms will take the physician's 0.5 hours to complete for an estimated 10,000 burden hours.

Denial Letter and Appeal Notification – Enrollment (**Appendix Z**): Of the 4,500 applications we expect to receive per year, we expect that 10% will fail due to ineligibility. We further assume that 10% of those individuals, or 45 respondents, will appeal the decision. The burden estimate is 23 hours.

Disenrollment Letter and Appeal Notification – Enrollment (**Appendix OO**): This is a new line item in the Estimates of Annual Burden Hours. This is based on the revisions that were made to WTC Health Program regulations in 42 C.F.R. Part 88. The revisions impacted the collection of information from Program members and one of the revisions included clarifying that Program members who are disenrolled may submit an appeal request under 42 C.F.R. § 88.14. Of the over 70,000 Program members, we expect that 0.014 percent (10) will be subsequently disenrolled from the Program. This can occur if during a certification request or during the quality assurance of enrollment decisions, it is discovered that the person did not meet eligibility requirements when they were enrolled initially or the member can request to be disenrolled. Of those, we expect that 30 percent

(3) will appeal the disenrollment decisions. We estimate that the appeal requests will take no more than 0.5 hours per respondent. The annual burden estimate is 2 hours.

Denial Letter and Appeal Notification – Health Condition Certification (Appendix AA): The total estimated burden hours for this line item has increased based on the revisions to 42 C.F.R. Part 88. Under section § 88.21, members may now submit new information and present an oral statement. We estimate that Program members (enrolled responders and survivors) request certification for 20,000 health conditions each year. Of those 20,000, we estimate that 1% (200) of certification requests are denied by the WTC Health Program. We further expect that 30% of denied certifications, or 60 individuals, will be appealed. We estimate that the appeals letter takes no more than 0.5 hours and providing additional information and/or an oral statement will take no more than 1 hour. The burden estimate is 90 hours.

Decertification Letter Template—Denial and Decertification Exposure (Appendix QQ): This is a new line item in the Estimates of Annual Burden Hours. This is based on the revisions that were made to WTC Health Program regulations in 42 C.F.R. Part 88. The revisions impacted the collection of information from Program members and one of the revisions included appealing decertification and certification and treatment authorization denial under § 88.21 may submit new information and present an oral statement. Decertification can occur when (1) new medical and exposure information is submitted on a member that causes a reevaluation of current certifications and it is determined that a condition they were previously certified for treatment for should be decertified or (2) a member requests to be decertified for a certain health condition. Of the estimated 51,472 Program members who have at least one health condition certification, we estimate that 0.02 percent (10) will be decertified, and 50% (5) of those will appeal a decertification. We estimate that the appeal request will take no more than 0.5 hours per respondent and providing additional information and/or an oral statement will take no more than 1 hour per respondent. The annual burden estimate is 8 hours.

Denial Letter and Appeal Notification – Treatment Authorization (Appendix BB): The total estimated burden hours for this line item has increased based on the revisions to 42 C.F.R. Part 88. Under section § 88.21, members may now submit new information and present an oral statement. Of the projected 51,472 Program members who receive medical care, we estimate that 0.05% (26) will appeal a determination by the WTC Health Program that the treatment being sought is not medically necessary. We estimate that the appeals letter will take no more than 0.5 hours and providing additional information and/or an oral statement will take no more than 1 hour. The burden estimate is 39 hours.

WTC Health Program Medical Travel Refund Request (Appendix CC): WTC responders or certified eligible survivors who travel more than 250 miles to a nationwide network provider for medically necessary treatment may be provided necessary and reasonable transportation and other expenses. These individuals may submit a travel refund request form, which should take respondents 0.17 hours (10 minutes) to complete. HHS expects no more than 10 claims per year. The burden estimate is 2 hours.

Designated Representative Form (Appendix LL): This item has been revised however, the extent of the revision were minor and do not impact the burden hours required for this form. Individuals applying to the Program, or members, can designate a representative to act on their behalf. In order for the Program to speak to a third person about a member's application or case, we would need the individual to complete a designated representative form authorizing us to speak with that third person. It is estimated that the Program will receive 30 designated representative forms a year (an increase from our previous estimate of 10). The forms should take no longer than 0.25 hours (15 minutes) to complete. The increase in the estimated number of forms increases the estimated burden from 3 hours to 8 hours.

HIPAA Release Form (Appendix MM): This is a new form added to the Program. Individuals applying to the Program, or members, have the option to give the Program permission to share information about their case with a third party. In order for the Program to share information with a third person about a member's application or case, we would need the individual to complete a HIPAA Release form authorizing us to speak with that third person. It is estimated that the Program will receive 30 HIPAA Release forms a year. The forms should take no longer than 0.25 hours (15 minutes) to complete for a burden estimate of 8 burden hours.

Outpatient prescription pharmaceuticals (Appendix Y): Pharmacies will electronically transmit reimbursement claims to the WTC Health Program. HHS estimates that 150 pharmacies will submit reimbursement claims for 39,192 prescriptions per year, or 261 per pharmacy; we estimate that each submission will take 0.02 hours (1 minute). The burden estimate is 653 hours.

Reimbursement Denial Letter and Appeal Notification – Providers (Appendix TT): This is a new line item in the Estimates of Annual Burden Hours. This is based on the revisions that were made to WTC Health Program regulations in 42 C.F.R. Part 88. A new appeal process under § 88.23 allows Program medical providers to submit an appeal request for reimbursement denials. Of the nearly 52,000 Program providers, we estimate that 1.15% (600) annually will be denied reimbursement for treatment found to be not medically necessary or in accordance with treatment protocols, and will appeal the decision. We estimate that the appeal letter will take no more than 0.5 hours to compile. The burden estimate is 300 hours.

Petition for the Addition of a New WTC-Related Health Condition for Coverage under the World Trade Center (WTC) Health Program Form (Appendix NN): This form was previously approved under 0920-0929. From the time of approval to the current, the Program can more accurately estimate the number of respondents and the burden hours required for this form. The Zadroga Act identified a list of health conditions for which individuals who are enrolled in the WTC Health Program may be monitored or treated [Title XXXIII, § 3312(a)(3)]; those conditions are reiterated and expanded in the associated WTC Health Program regulations at 42 C.F.R. § 88.15. Under WTC Health Program regulations (42 C.F.R. § 88.16), interested parties may submit a petition to request that a new health condition be added to the list of conditions specified in § 88.15.

It is estimated that the Program will receive 60 petition forms a year. The forms should take no longer than 1 hour to complete for a burden estimate of 60 burden hours.

The total estimated annualized burden is 14,063 hours.

12A. Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
FDNY Responder	World Trade Center Health Program FDNY Responder Eligibility Application	45	1	30/60	23
General Responder	World Trade Center Health Program Responder Eligibility Application (Other than FDNY)	2,475	1	30/60	1,238
Pentagon/Shanksville Responder	World Trade Center Health Program Pentagon/Shanksville Responder	630	1	30/60	315
WTC Survivor	World Trade Center Health Program Survivor Eligibility Application (all languages)	1,350	1	30/60	675
General responder	Clinic Selection Postcard for new general responders in NY/NJ to select a clinic	2,475	1	15/60	619
Program Medical Provider	Physician Request for Certification (WTC-3)	20,000	1	30/60	10,000
Responder (FDNY and General Responder)/Survivor	Denial Letter and Appeal Notification – Enrollment	45	1	30/60	23
Responder (FDNY and	Disenrollment Letter and Appeal	3	1	30/60	2

General Responder)/ Survivor	Notification – Enrollment				
Responder (FDNY and General Responder)/ Survivor	Decertification Letter and Appeal Notification – Health Condition	5	1	1.5	8
Responder (FDNY and General Responder)/ Survivor	Denial Letter and Appeal Notification – Health Condition Certification	60	1	1.5	90
Responder (FDNY and General Responder)/ Survivor	Denial Letter and Appeal Notification – Treatment Authorization	26	1	1.5	39
Responder (FDNY and General Responder)/ Survivor	WTC Health Program Medical Travel Refund Request	10	1	10/60	2
Program Members	Designated Representative Form	30	1	15/60	8
Program Member	HIPAA Release Form to allow the sharing of member information with a third party	30	1	15/60	8
Pharmacy	Outpatient prescription pharmaceuticals	150	261	1/60	653
Program Medical Provider	Reimbursement Denial Letter and Appeal Notification – Providers	600	1	30/60	300
Responder/ Survivor/ Advocate (physician)	Petition for the addition of health conditions	60	1	1	60
Total					14,063

12B. Estimated Annualized Burden Costs

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Average Hourly Wage	Total Burden Cost
FDNY Responder	World Trade Center Health Program FDNY Responder Eligibility Application	45	1	30/60	\$24.08	\$558
General Responder	World Trade Center Health Program Responder Eligibility Application (Other than FDNY)	2,475	1	30/60	\$18.20	\$22,523
Pentagon/Shanksville Responder	World Trade Center Health Program Pentagon/Shanksville Responder	630	1	30/60	\$18.20	\$5,733
WTC Survivor	World Trade Center Health Program Survivor Eligibility Application (all languages)	1,350	1	30/60	\$12.00	\$8,100
General responder	Clinic Selection Postcard for new general responders in NY/NJ to select a clinic	2,475	1	15/60	\$18.20	\$11,261
Program	Physician	20,000	1	30/60	\$100.00	\$1,000,000

Medical Provider	Request for Certification (WTC-3)					
Responder (FDNY and General Responder) /Survivor	Denial Letter and Appeal Notification – Enrollment	45	1	30/60	\$18.00* **	\$405
Responder (FDNY and General Responder) / Survivor	Disenrollment Letter and Appeal Notification – Enrollment	3	1	30/60	\$18.00* **	\$27
Responder (FDNY and General Responder) / Survivor	Decertification Letter and Appeal Notification – Health Condition	5	1	1.5	\$18.00* **	\$135
Responder (FDNY and General Responder) / Survivor	Denial Letter and Appeal Notification – Health Condition Certification	60	1	1.5	\$18.00* **	\$1,620
Responder (FDNY and General Responder) /Survivor	Denial Letter and Appeal Notification – Treatment Authorization	26	1	1.5	\$18.00* **	\$702
Responder (FDNY and General Responder) /Survivor	WTC Health Program Medical Travel Refund Request	10	1	10/60	\$15.00*	\$25
Program Members	Designated Representative Form	30	1	15/60	18.20*	\$137
Program	HIPAA	30	1	15/60	18.20*	\$137

Member	Release Form to allow the sharing of member information with a third party					
Pharmacy	Outpatient prescription pharmaceuticals	150	261	1/60	\$14.10* *	\$9,200
Program Medical Provider	Reimbursement Denial Letter and Appeal Notification –Providers	600	1	30/60	\$100.00	\$30,000
Responder/ Survivor/ Advocate (physician)	Petition for the addition of health conditions	60	1	1	\$36.00** *	\$2,160
Total						\$1,092,723

*Data from Bureau of Labor Statistics 2001 State Occupational Employment and Wage Estimates New York. We used an adjusted hourly wage rate of \$18.00 to represent the responders hourly wage cost.

** Data from Bureau of Labor Statistics 2010 Healthcare Practitioners and Technical Occupations

*** We used an adjusted hourly wage rate of \$18.00 to represent the responders hourly wage cost.

The total estimated annualized burden cost to respondents is \$1,092,723.

13. Estimates of other Total Annual Cost Burden to Respondents or Record Keepers/Capital Costs

There are no additional recordkeeping/capital costs.

14. Annualized Cost to Federal Government

Type of Federal employee support	Total Burden Hours	Hourly Wage Rate	Total Federal Costs
Contractor (review of eligibility forms)	2940	\$25.00	\$73,500

Medical and non-medical staff (review of healthcare requests and eligibility appeals)	10,068	\$100.00	\$1,006,800
Total			\$1,080,300

The total cost to the Federal Government is \$1,080,300

15. Explanation for Program Changes or Adjustments

In this Revision, total annualized burden will increase from 13,594 hours to 14,063 hours (+469 hours). A complete summary of WTC Health Program forms, supplementary materials, and changes is provided in **Appendix SS**. Highlights are summarized below.

A portion of the increase in annualized burden (60 hours) is due to the incorporation of one form, previously approved under OMB No. 0920-0969 (exp. 7/31/2018), into the World Trade Center Health Program information collection (see the Petition for the addition of health conditions, **Appendix NN**).

The greatest increase in burden (+300 hours) is the result of a new appeal process authorized under 42 CFR Part 88.23 (see **Appendix TT**, Reimbursement Denial Letter and Appeal Notification – Providers).

Additional changes to WTC Health Program regulations in 42 C.F.R. Part 88 impact the collection of information from Program members and affiliated medical providers. Such revisions include clarifying that Program members who are disenrolled may submit an appeal request under 42 C.F.R. § 88.14 (+2 hours) and that members appealing decertification and certification and treatment authorization denial under § 88.21 may submit new information and present an oral statement (+94 hours).

The Program has also increased the estimated number of responses for the Designated Representative Form (+5 hours) and added a HIPAA Release Form (+8 hours).

This Revision also describes changes supporting the administration of appropriate medications to WTCHP members and the efficient management of the WTCHP Pharmacy, which dispenses medications from the WTCHP’s formulary of approved medications. With prior authorization, medications that are not listed in the formulary may also be provided to members as WTCHP covered benefits. In the previous OMB clearance period for 0920-0891, the Prescription Prior Authorization Level 3 Individual Request Form was included as a supplementary document (i.e., it was included as an adjunctive document related to program administration but did not constitute burden to respondents). In this Revision,

- the form is being updated (see **Appendix Y-1, Non Formulary Prior Authorization – Prescription (General)**);
- a specialized version is being added to facilitate approval of non-formulary prescription renewals (see **Appendix Y-2 Non-Formulary Prior Authorization – Prescription (Renewal)**); and

- specialized versions will be fielded for designated categories of medication (see **Appendix Y-3 Non-Formulary Prior Authorization – Airway Medication**, **Appendix Y-4 Non-Formulary Prior Authorization – Antidepressant**, **Appendix Y-5 Non-Formulary Prior Authorization – Antiemetic**, **Appendix Y-6 Non-Formulary Prior Authorization – Antipsychotic**, **Appendix Y-7 Non-Formulary Prior Authorization – Epinephrine**, **Appendix Y-8 Non-Formulary Prior Authorization – Insulin**, **Appendix Y-9 Non-Formulary Prior Authorization – Methadone**, **Appendix Y-10 Non-Formulary Prior Authorization – Nucala**, **Appendix Y-11 Non-Formulary Prior Authorization – Opioid Abuse**).

The specialized versions will support efficient management of the WTCHP Pharmacy by allowing staff to more easily identify the frequency of requested exceptions to the formulary, by type of medication/prescription. They also promote the use of standardized criteria for prescribing behavior. Approximately 250 non-formulary prior authorization requests are submitted to the WTCHP Pharmacy per year. Using the Change Request mechanism, the WTCHP may submit to OMB additional versions of the Non-Formulary Prior Authorization form for further improvement in the classification of these requests.

Finally, this Revision includes enrollment forms that have been translated from English into other languages. The translations are provided as a convenience to WTC members but do not change the estimated annualized burden.

16. Plans for Tabulation and Publication and Project Time Schedule

Data collection will continue on approval of this OMB package.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB expiration date will be displayed on the applications, WTC-3 form, clinic postcard, travel reimbursement form, and designated representative form.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.