

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

**Supporting Statement
For an Emergency Clearance Request
(12/14/11)**

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Table of Contents

A. 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
- Appendix B Eligibility and Qualification for the WTC Health Program
- Appendix C World Trade Center Health Program FDNY Responder Eligibility Application
- Appendix D World Trade Center Health Program Responder Eligibility Application (Other than FDNY)
- Appendix E World Trade Center Health Program Survivor Eligibility Application
- Appendix F Denial Letter and Appeal Notification (example)
- Appendix G WTC Health Program Medical Travel Refund Request

A. Justification

1. Circumstances Making the Collection of Information Necessary

This is a request for extension of an currently approved emergency clearance from the National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC). The James Zadroga 9/11 Health and Compensation Act of 2010 (Zadroga Act), promulgated on December 22, 2010, establishes a Federal program to support health monitoring and treatment for emergency responders; recovery and cleanup workers; 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. In order to provide medical monitoring and treatment to eligible individuals, the World Trade Center (WTC) Health Program will collect eligibility and appeals data as well as information from medical and prescription pharmaceutical providers. The Zadroga Act mandates that no individual who is on the terrorist watch list maintained by the Federal government will qualify as an enrolled participant in the Program consequently, certain information will be requested of some individuals to refine the screening process. (Appendix A)

All responders to the New York City attack who will be newly seeking medical monitoring and treatment and survivors of the attack who were not covered by the Medical Monitoring and Treatment Program (MMTP) prior to January 2, 2011, may apply to obtain coverage under the new WTC Health Program. In order to begin the determination eligibility process, an enrollment form must be completed. After an eligibility application is submitted to the Program, an unsuccessful applicant has an opportunity to appeal the decision; enrolled participants have further appeal rights. Health care and prescription pharmaceutical providers will be required to submit medical determinations to the WTC Program Administrator and request reimbursement.

This emergency clearance is warranted because it is essential that individuals who wish to apply to the WTC Health Program or appeal a determination made by the WTC Program Administrator have the opportunity to do so as soon as the Program begins.

2. Purpose and Use of Information Collection

This information is being collected in order to determine the eligibility of applicants, as well as to provide Program participants with the opportunity to appeal. Finally, information will be collected to reimburse physicians and pharmacies for their services, and to reimburse certain enrolled participants for travel.

Approximately 58,000 individuals are enrolled in the MMTP, and will be automatically enrolled in the WTC Health Program. Because the Zadroga Act requires terrorist watch list screening, we believe that we may need to contact some of these individuals, in writing, in order to collect additional information that may provide a determination. The individual will be asked to fill out a short form, asking for such data as place of birth and government identification number. (Appendix B)

There are three separate enrollment forms for each population of responders (FDNY responders, general responders, and survivors). The following information includes the definition of each population:

- "FDNY responder" is defined as a member of the Fire Department of New York City (whether fire or emergency personnel, active, or retired) who participated at least one day in the rescue and recovery effort at any of the former World Trade Center sites.
- "General Responder" is a worker or volunteer who provided Rescue, Recovery, Demolition, Debris, Removal and related support services in the aftermath of the September 11, 2001 attacks on the World Trade Center but was not affiliated with the Fire Department of New York.
- "Survivor" is a person who was present in the disaster area in the aftermath of the September 11, 2001 attacks on the World Trade Center as a result of their work, residence, or attendance at school, childcare, or adult daycare.

The eligibility application form will collect general contact information as well as information regarding the WTC disaster area experience. Some of the information provided will be 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 will also be shared with the WTC Program Administrator and will be kept in a secure manner. In order to reduce the burden on the respondents and survivors, the WTC Health program will make the form available to be downloaded from the internet or obtained in hard copy and submitted by mail. The enrollment forms will be available for download on the NIOSH website at <http://www.cdc.gov/niosh/topics/wtc/enroll.html>. (Appendices C-E)

WTC Health Program applicants and enrolled participants 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. Once enrolled in the Program, participants will also have the opportunity to appeal a decision not to certify a WTC-related health condition or a determination that treatment will not be authorized as medically necessary. In the notification letter explaining the adverse determination, the applicant will be advised that an appeal can be requested by submitting in writing their name, contact information, and an explanation

for the basis of the appeal (Attachment F).

Certain enrolled participants may be reimbursed for necessary and reasonable transportation and expenses incident to the securing of medical treatment. Individuals requesting reimbursement must fill out a 1-page written form requesting such information as date of travel, distance, and total expense. (Appendix G)

Pharmacies will transmit reimbursement claims to the WTC Health Program. The following data elements will likely be collected for pharmacy reimbursement: pharmacy name, pharmacy address, drug name, prescription number, patient name, patient ID number, and cost.

Finally, Program physicians will submit a request that the Program certify an enrolled participant's health condition. The certification request may include, but may not be limited to, the following data elements: exposure assessment summary, mental health assessment summary, date of enrollment, medical diagnosis of WTC-related health condition, recordkeeping (including exposure assessment, medical history, physical and/or mental status exam findings, specific medical testing finding).

3. Use of Improved Information Technology and Burden Reduction

Due to the fact that the eligibility forms require a signature, they may be collected via hard copy, scan, or fax. The appeal letter must be submitted in writing.

4. Efforts to Identify Duplication and Use of Similar Information

This is a new program. Information has not been previously collected for this purpose.

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 will not be able to implement the provisions of the Act, to establish the process for an individual to apply to the WTC Health Program, obtain an initial health evaluation, monitoring, and treatment, and 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

Due to the emergency nature of the program announcement, OMB has waived the FRN requirements for this collection.

9. Explanation of any Payment/Gift to Respondents

Not applicable.

10. Assurance of Confidentiality Provided to Respondents

As published in the Federal Register (76 Fed. Reg. 31212, May 27, 2011), HHS proposes to alter System of Records, 09-20-0147, "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.”

Information in identifiable form will be collected in the eligibility application forms. This includes individuals name, date of birth, social security number, driver’s license number, phone number, and mailing address. Access to data will be limited to authorized NIOSH project staff and authorized Computer Sciences Corporation (CSC) contractors. All electronic data will be stored on secure servers accessible only with passwords. CSC will be required to follow equivalent procedures.

11. Justification for Sensitive Questions

The last 4 digits of an applicant's Social Security Numbers (SSN) may be requested for screening an individual against the watch list maintained by the Federal government. The 4 digits of the SSN will be shared with the FBI. This screening requirement is mandated by the Zadroga Act; however, all respondents will be made aware that the providing the last 4 digits of the SSN is voluntary. This information appears on each enrollment form.

12. Estimates of Annualized Burden Hours

Eligibility and Qualification for the WTC Health Program: Approximately 58,000 WTC responders and survivors have received medical monitoring and treatment benefits under the previous MMTP program. HHS estimates that approximately .5 percent of those currently identified responders and survivors, or 290 individuals, will be asked to provide the Program with additional information, in writing, to ensure that the individual meets all criteria to be eligible for the program. We expect that responding to this inquiry by filling out a 1-page form will take no more than 10 minutes. The burden estimate is 48 hours.

World Trade Center Health Program FDNY Responder Eligibility Application, World Trade Center Health Program Responder Eligibility Application (Other than FDNY), and World Trade Center Health Program Survivor Eligibility Application:

Three 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, and survivors. We expect that to receive approximately 4,728 applications per year. The burden table reflects the annualized total burden broken into the three separate applicant groups: we estimate that 189 Fire Department of New York

(FDNY) responders (4% of applicants); 2,979 general responders (63%); and 1,560 survivors (33%) will submit written applications. The burden estimates for these three different forms are: FDNY = 95 hours; general responders = 1,490; survivors = 390 hours.

Denial Letter and Appeal Notification -- Eligibility: Of the 4,728 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 47 respondents, will appeal the decision. The burden estimate is 24 hours.

Denial Letter and Appeal Notification -- Health Condition: We expect that program participants (enrolled responders and survivors) will request certification for 32,361 health conditions each year. Of those 32,361, we expect that .001% (32) of certification requests will be denied by the WTC Program Administrator. We further expect that 95% of denied certifications, or 30 individuals, will be appealed. The burden estimate is 15 hours.

Denial Letter and Appeal Notification -- Treatment: Of the projected 19,596 enrollees who will receive medical care, it is estimated that 3 percent (588) 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 30 minutes. The burden estimate is 294 hours.

WTC Health Program Medical Travel Refund Request: 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 10 minutes to complete. HHS expects no more than 10 claims per year. The burden estimate is 2 hours.

WTC Health Condition Certification Request: Physicians will report this data electronically and on paper. HHS expects that 2,300 program physicians will spend approximately 30 minutes extracting the required elements from the patient records and transmitting them to NIOSH, and that approximately 32,361 diagnoses, or 14 per provider, will be reported to the WTC Health Program each year. The burden estimate is 16,100 hours.

Outpatient prescription pharmaceuticals: 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 1 minute. The burden estimate is 653 hours.

12A. Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. Responses	Average Burden	Total Burden
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			per Respondent	per Response (in hours)	Hours
Responder (FDNY and General Responder)/Su rvivor	Eligibility and Qualification for the WTC Health Program	290	1	10/60	48
FDNY Responder	World Trade Center Health Program FDNY Responder Eligibility Application	189	1	30/60	95
General Responder	World Trade Center Health Program Responder Eligibility Application (Other than FDNY)	2979	1	30/60	1490
WTC Survivor	World Trade Center Health Program Survivor Eligibility Application	1560	1	15/60	390
Responder (FDNY and General Responder)/Su rvivor	Denial Letter and Appeal Notification -- Eligibility	47	1	30/60	24
Responder (FDNY and General Responder)/Su rvivor	Denial Letter and Appeal Notification -- Health Conditions	30	1	30/60	15
Responder (FDNY and General Responder)/Su rvivor	Denial Letter and Appeal Notification -- Treatment	588	1	30/60	294
Responder (FDNY and General Responder)/Su rvivor	WTC Health Program Medical Travel Refund Request	10	1	10/60	2
Physician	WTC Health	2,300	14	30/60	16,100

	Condition Certification Request				
Pharmacy	Outpatient prescription pharmaceuticals	150	261	1/60	653
Total					19,111

12B. Estimated Annualized Burden Costs

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
FDNY Responder (eligibility)	41	\$24.08*	\$987
General Responder (eligibility)	3	\$18.20*	\$55
Survivor (eligibility)	4	\$12.00	\$48
FDNY Responder (application)	95	\$24.08*	\$2,288
General Responder (application)	1490	\$18.20*	\$271
Survivor (application)	390	\$12.00	\$4,680
FDNY Responder (eligibility appeal)	16	\$24.08*	\$385
General Responder (eligibility appeal)	1	\$18.20*	\$1,820
Survivor (eligibility appeal)	7	\$12.00	\$84
FDNY Responder (health condition appeal)	13	\$24.08*	\$313
General Responder (health condition appeal)	1	\$18.20*	\$1,820
Survivor (health condition appeal)	2	\$12.00	\$24
FDNY Responder (treatment appeal)	247	\$24.08*	\$5,948
General Responder (treatment appeal)	18	\$18.20*	\$328
Survivor (treatment appeal)	30	\$12.00	\$360
General Responder (travel expenses)	2	\$18.20*	\$36
:Physician	2,300	\$91.10**	\$2095.30
Pharmacy technician	653	\$14.10**	\$9,207

*Data from Bureau of Labor Statistics 2001 State Occupational Employment and Wage Estimates New York

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

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)	1500	\$25.00	\$37,500
Medical and non-medical staff (review of healthcare and eligibility appeals)	580	\$100.00	\$58,000

15. Explanation for Program Changes or Adjustments

This is a currently approved ICR being submitted as an extension without change data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Data collection will began on July 1, 2011.

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

Not applicable.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

B. Collection of Information Employing Statistical Methods

The applications will be reviewed but the data will not be analyzed using statistical methods.