of the 1970 Occupational Safety and Health Act. Influenza continues to be a major public health concern because of the substantial health burden from seasonal influenza and the potential for a severe pandemic. Although influenza is known to be transmitted by infectious secretions, these secretions can be transferred from person to person in many different ways, and the relative importance of the different pathways is not known. The likelihood of the transmission of influenza virus by small infectious airborne particles produced during coughing and breathing is particularly unclear. The question of airborne transmission is especially important in healthcare facilities, where influenza patients tend to congregate during influenza season, because it directly impacts the infection control and personal protective measures that should be taken by healthcare workers. The purpose of this study is to measure the amount of viable influenza virus in airborne particles that are produced by patients when they cough, and the size and quantity of the particles carrying the virus. A better understanding of the amount of potentially infectious material released by patients and the size of the particles carrying the virus will assist in determining the possible role of airborne transmission in the spread of influenza and in devising measures to prevent it.

Volunteer adult participants will be recruited by a test coordinator using a poster and flyers describing the study. Interested potential participants will be screened verbally to verify that they have influenza-like symptoms and that they do not have any medical conditions that would preclude their participation. Qualified participants who agree to participate in the study will be asked to read and sign an informed consent form, and then to complete a short health questionnaire. After completing the forms, two nasopharyngeal swabs and one oropharyngeal swab will be collected from the participant. They then will be asked to cough repeatedly into an aerosol particle collection system, and the airborne particles produced by the participant during coughing will be collected and tested. The sounds produced during coughing will also be recorded for analysis and comparison to the amount of virus expelled. The study will require 60 volunteer test subjects each year for 3 years, for a total of 180 test participants.

The following revisions have been made to the previous approved information collection request:

(1) Initially, potential participants will be screened verbally rather than through the health questionnaire.

(2) The number of potential participants has been increased from 132 to 360. In a previous similar study, the number of potential participants who agree to join the study was 50%, which was lower than anticipated. The increase will allow the study to recruit 180 participants.

(3) The number of qualified participants has been increased from 120 to 180. This is necessary to provide a sufficient number of cough aerosol samples with detectable amounts of viable influenza and is based on a previous study, where 10% of aerosol samples had culturable virus.

(4) The Informed consent form has been substantially revised to make it easier to read and understand. As a result of the revisions, the burden per response for that form has been reduced from 20 to 15 minutes.

(5) Because of the increases in the number of potential and qualified participants, the total burden hours has increased from 51 to 78 hours.

(6) The title of the ICR has been changed to ''Factors Influencing the Transmission of Influenza'' in order to reflect the new focus of the project on influenza viability and to match the title of the human subjects protocol approved by the Institutional Review Board.

There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)	Total burden (in hrs.)
Potential participant	Initial verbal screening	360	1	3/60	18
Qualified participant	Informed consent form	180	1	15/60	45
Qualified participant	Health questionnaire	180	1	5/60	15
Total					78

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Deputy Director, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30-Day–14–13AHA]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call (404) 639–7570 or send an email to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, D.C. 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

World Trade Center Health Program Enrollment & Appeals—Pentagon & Shanksville, Pennsylvania Responders—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The James Zadroga 9/11 Health and Compensation Act of 2010 (Zadroga Act), promulgated on December 22,

2010, established 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. Section 3311(a)(2)(C) of the PHS Act authorizes the WTC Program Administrator (Administrator) to develop eligibility criteria for enrollment of Shanksville, Pennsylvania and Pentagon responders. Pentagon and Shanksville responders who believe they may be eligible for enrollment in the Program must complete an enrollment form. The following information includes the definition of each population:

- A Pentagon responder is someone who was a member of a fire or police department (whether fire or emergency personnel, active or retired), worked for a recovery or cleanup contractor, or was a volunteer; and performed rescue, recovery, demolition, debris cleanup, or other related services at the Pentagon site of the terrorist-related aircraft crash of September 11, 2001, during the period beginning on September 11, 2001, and ending on November 19, 2001.
- A Shanksville responder is someone who was a member of a fire or police department (whether fire or emergency personnel, active or retired), worked for a recovery or cleanup contractor, or was a volunteer; and performed rescue, recovery, demolition, debris cleanup, or other related services at the Shanksville, Pennsylvania site of the terrorist-related aircraft crash of September 11, 2001, during the period beginning on September 11, 2001, and ending on October 3, 2001.

This information is being collected in order to determine the eligibility of Pentagon and Shanksville, Pennsylvania responders as well as to provide program participants with the opportunity to appeal. This includes individuals' names, mailing address, telephone number, date of birth, and gender.

The World Trade Center Health Program (WTCHP) expects to receive approximately 1,605 applications in the first year. The application is expected to take 30 minutes to complete. Of the 1,605 applications it is expected that that 10 percent of those individuals found ineligible (4 respondents) will appeal the decision. We also expect that program participants will request certification for 874 health conditions each year. Of those 874, it is expected that 1 percent (<1) will be denied certification by the WTC Program Administrator. We further expect that such a denial will be appealed 95 percent of the time.

Of the projected 454 enrollees who will receive medical care, it is estimated that 3 percent (14) 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 to complete.

Pharmacies will electronically transmit reimbursement claims to the WTCHP. HHS estimates that 4 pharmacies will submit reimbursement claims for 1,058 prescriptions per year, or 265 per pharmacy; we estimate that each submission will take 1 minute.

WTC responders 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.

There is no cost to respondents other than their time. The total estimated burden is 831 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Pentagon or Shanksville, Pennsylvania Responder.	World Trade Center Health Program Pentagon & Shanksville, Pennsylvania Responder Eligibility Application.	1,605	1	30/60
Pentagon or Shanksville, Pennsylvania Responder.	Appeals to Eligibility Denial	4	1	30/60
Pentagon or Shanksville, Pennsylvania Responder.	Appeals regarding certification of health conditions.	1	1	30/60
Pentagon or Shanksville, Pennsylvania Responder.	Appeals regarding treatment	14	1	30/60
Pharmacies	Outpatient prescription pharmaceuticals	4	265	1/60
Pentagon or Shanksville, Pennsylvania Responder.	WTC Health Program Medical Travel Refund Request.	1	1	10/60

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Deputy Director, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–R–216]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our