availability of various economic factors affecting product cost and supply.

The ACBSA consists of 20 voting members. The Committee is composed of 14 public members, including the Chair, and six (6) representative members. The public members are selected from State and local organizations, advocacy groups, provider organizations, academic researchers, ethicists, private physicians, scientists, consumer advocates, legal organizations, and from among communities of persons who are frequent recipients of blood or blood products. The six individuals who are appointed as official representative members are selected to serve the interests of the blood and blood products industry or professional organizations associated with transfusion or transplantation safety. The representative members are selected from the following groups: The AABB, the plasma protein fraction community, one of the two major distributors of blood on a rotating basis, a trade organization or manufacturer of blood, plasma, or other tissue test kits or equipment, and a purchaser of blood and blood products from major hospital organization.

All ACBSA members are authorized to receive the prescribed per diem allowance and reimbursement for travel expenses that are incurred to attend meetings and conduct Committee-related business, in accordance with Standard Government Travel Regulations. Individuals who are appointed to serve as public members are authorized to also receive a stipend for attending Committee meetings and to carry out other Committee-related business. Individuals who are appointed to serve as representative members for a particular interest group or industry are not authorized to receive a stipend for the performance of these duties.

This announcement is to solicit nominations of qualified candidates to fill positions on the ACBSA that are scheduled to be vacated in both membership categories. Qualified applicants are being sought to represent the specific interests of the following blood and blood products industries or professional organizations: State and local organizations, advocacy groups, provider organizations, academic researchers, private physicians, scientists, consumer advocates, legal organizations, one of the two major distributors of blood, a trade organization, or manufacturer of blood, plasma, infectious disease screening assays or other tissue test kits or equipment and a major health care organization that purchases blood and blood products. The positions are scheduled to be vacated between March 30, 2012 and May 29, 2012.

Nominations

In accordance with the charter, persons nominated for appointment as members of the ACBSA should be among authorities knowledgeable in blood banking, transfusion medicine, plasma therapies, transfusion organ and tissue transplantation, bioethics, and/or related disciplines. Nominations should be typewritten. The following information should be included in the package of material submitted for each individual being nominated for consideration of appointment: (a) The name, return address, daytime telephone number, and affiliation(s) of the individual being nominated, the basis for the individual's nomination, the category for which the individual is being nominated, and a statement bearing an original signature of the nominated individual that, if appointed, he or she is willing to serve as a member of the Committee; (b) the name, return address, and daytime telephone number at which the nominator may be contacted. Organizational nominators must identify a principal contact person in addition to the contact; and (c) a copy of a current curriculum vitae or resume for the nominated individual.

Individuals can nominate themselves for consideration of appointment to the Committee. All nominations must include the required information. Incomplete nominations will not be processed for consideration. The letter from the nominator and certification of the nominated individual must bear original signatures; reproduced copies of these signatures are not acceptable.

The Department of Health and Human Services is committed to ensuring that women, minority groups, and physically challenged individuals are adequately represented on the Committee. Nominations of qualified candidates from these categories are encouraged. The Department also seeks to have geographic diversity reflected in the composition of the Committee.

The Standards of Ethical Conduct for Employees of the Executive Branch are applicable to individuals who are appointed as public members of Federal advisory committees. Individuals appointed to serve as public members of Federal advisory committees are classified as special Government employees (SGEs). SGEs are Government employees for purposes of the conflict of interest laws. Therefore, individuals appointed to serve as public members of the ACBSA are subject to an ethics review. The ethics review is conducted to determine if the individual has any interests and/or activities in the private sector that may conflict with performance of their official duties as a member of the Committee. Individuals appointed to serve as public members of the Committee will be required to disclose information regarding financial holdings, consultancies, and research grants and/or contracts.

Dated: November 30, 2011.

James J. Berger,

Executive Secretary, Advisory Committee on Blood Safety and Availability.

[FR Doc. 2011–31534 Filed 12–7–11; 8:45 am]

BILLING CODE 4150–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30 Day-12–12AZ]

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 the CDC Reports Clearance Officer at (404) 639–5960 or send an email to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 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, Reimbursement and Certification—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, 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.

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) (for responders) or the Community Program (for survivors) 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.

Data are being collected in order to determine the eligibility of applicants. If an applicant is denied enrollment based on the information provided, the applicant will receive a letter that gives the reason for the denial and the opportunity to appeal the decision.

Once someone is enrolled, he or she may request approval for reimbursement of travel if the individual must travel more than 250 miles to receive healthcare services. Healthcare providers and pharmacies will file claims electronically or by paper form to be paid for their services. There are three separate enrollment forms for each population of responders (Fire Department of New York City 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 his or her 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.

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 his or her name, contact information, and an explanation for the basis of the appeal.

Certain enrolled participants may be reimbursed for necessary and reasonable transportation and expenses incident to the securing of medically necessary treatment through the nationwide network if the care involves travel of more than 250 miles. Individuals requesting reimbursement must fill out a 1-page written form requesting such information as date of travel, distance, and total expense.

Pharmacies will transmit reimbursement claims to the WTC Health Program. The following data elements will be collected for pharmacy reimbursement: Pharmacy name, pharmacy address, drug name, prescription number, patient name, patient ID number, and cost. Pharmacies utilize Electronic Data Interchange (EDI) processing at the point-of-sale to transmit claims to the World Trade Center Health Program (WTCHP). The EDI transmission conforms to ANSI standards developed by the National Council for Prescription Drug Programs. The information collection burden occurs as the WTCHP member information is copied from the membership card at the point-of-sale. The EDI transmission occurs in real-time as the prescription transaction is made.

The Zadroga Act of 2010 requires that all qualifying WTC-related health conditions or health conditions medically associated with a WTC-related health condition be certified by member to enable reimbursement of treatment services for care rendered to that member for a given qualifying condition(s). To meet the requirement for certification and maintain continuity of care for an individual who had been enrolled in the prior MMTP or Community Program, the WTC Health Program physician shall attest that a prior determination was rendered in the previous federally sponsored program. The attestation will include the physician's name and signature, the name of the patient, and the name of the health condition and its diagnostic (ICD–9) code.

An individual who is new to the WTC Health Program must have a certified WTC-related health condition or health condition medically associated with WTC-related health condition to receive reimbursement for treatment and other services. If a new medical determination is being made, the Program clinician must provide to the WTC Health Program the patient's name and program identification number, the name and diagnostic code of the health condition, and a brief narrative explaining the key exposure findings. The narrative will include information such as the time and duration of the individual's presence in defined geographic areas (of exposure), whether the individual was caught in the dust cloud on September 11, 2001, whether the individual conducted strenuous activity while in the exposure zone(s), the individual's symptom time course relative to September 11, 2001, and the reasons a person might be more likely to get sick from given exposures (family history or coexisting medical problems).

A Program physician will also submit a form to the WTC Health Program when a member needs medical treatment for a condition that has not yet been certified. In that case, the physician will request authorization to treat the condition because of the urgency of the medical scenario. The physician will sign a form attesting that a determination was made, and indicate the patient's name and the name of the health condition and its diagnostic code. Physicians will be compensated through administrative expenses invoiced by their respective Clinical Center of Excellence that is under contract with the Federal government. There are no costs to respondents other than their time. The total estimated annual burden hours are 19,161.

Estimated Annualized Burden Hours

Currently Identified Responders and Currently Identified Survivors: HHS estimates that approximately .5 percent of responders and survivors who had been enrolled in the prior MMTP or Community Program (currently identified responders and survivors), or 290, will be asked to provide the Program with additional information to ensure that the individual meets all criteria to be eligible for the program. There is no form associated with this request. Rather, the Program staff will collect the information provided and make a note of it in the patient files. We expect responding to this inquiry to take no more than 10 minutes.

World Trade Center Health Program 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 responders = 95 hours; general responders = 1,490 hours; and 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 (Attachment F)

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 (Attachment G).

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 (Attachment H).

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 (Attachment I).

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 (Attachment J).

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.

Standard Form 3881, for reimbursement for medically necessary treatment, monitoring, initial health evaluations: Standard U.S. Treasury form SF 3881 (OMB No. 1510–0056) will be used to gather necessary information from Program healthcare providers so that they can be reimbursed directly from the Treasury Department. HHS expects that approximately 200 providers and provider groups will submit SF 3881, which is estimated to take 15 minutes to complete. Providers will submit only one SF 3881.

Type of respondent	Form name	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
Currently Identified Responders and Currently Identified Survivors.	No Form	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
FDNY Responder, General Responder and WTC Survivor.	Denial Letter and Appeal Notification—Eligibility	47	1	30/60	24
FDNY Responder, General Responder and WTC Survivor.	Denial Letter and Appeal Notification—Health Conditions.	30	1	30/60	15
FDNY Responder, General Responder and WTC Survivor.	Denial Letter and Appeal Notification—Treatment.	588	1	30/60	294
FDNY Responder, General Responder and WTC Survivor.	WTC Health Program Medical Travel Refund Request.	10	1	10/60	2
Physician	WTC Health Condition Certification Request	2,300	14	30/60	16,100
Pharmacy	Outpatient prescription pharmaceuticals	150	261	1/60	653

Type of respondent	Form name	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
Physician	Standard Form 3881, for reimbursement for medically necessary treatment, monitoring, initial health evaluations.	200	1	15/60	50

Dated: December 2, 2011.

Daniel Holcomb,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2011–31562 Filed 12–7–11; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30–Day–12–11GU]

Agency Forms Undergoing Paperwork Reduction Act Review

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Proposed Project

Survey of Rapid Influenza Diagnostic Test (RIDT) Practices in Laboratories-NEW—the Office of Surveillance, Epidemiology, and Laboratory Services (OSELS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Survey of Rapid Influenza Diagnostic Testing Practices in Laboratories is a national systematic study investigating rapid influenza diagnostic testing practices in clinical laboratories. The survey will be funded in full by the Office of Surveillance, Epidemiology, and Laboratory Services (OSELS) of the Centers for Disease Control and Prevention (CDC).

Influenza epidemics usually cause an average of more than 200,000 hospitalizations and 36,000 deaths per year in the U.S. Respiratory illnesses caused by influenza viruses are not easily differentiated from other respiratory infections based solely on symptoms. Also influenza viruses may adversely affect different subpopulations. The effective use of rapid influenza diagnostic testing practices is an important component of the differential diagnosis of influenza-like-illness in both inpatient and outpatient treatment facilities. Test results are used for making decisions about antiviral vs. antibiotic use, and in making admission or discharge decisions. In many cases, rapid influenza tests are the only tests that can provide results while the patient is still present in the facility. Thus, the appropriate use of the tests, and interpretation of test results is critical to the treatment and control of influenza. More than a dozen rapid tests have been approved by the U.S. Food and Drug Administration and are in widespread use. The reliability of rapid influenza tests is influenced by the individual test product used and the setting. Reported sensitivities range from 10–75%; while the median specificities reported are 90–95%. Other factors influencing accuracy are the stage (or duration) of illness when the diagnostic specimen is collected, type and adequacy of the specimen collected, variability in user technique for specimen collection or assay performance, and disease activity in the community. Given these and other collective findings, it is imperative for public health and for response planning that CDC develops sector-specific guidance and effective outreach to the clinicians on appropriate use of RIDT in their practices.

Previous studies by CDC of outpatient facilities showed that clinical laboratories usually perform the rapid tests for emergency departments, and provide results for both inpatient and outpatient treatment. Thus, understanding the use of rapid influenza testing in clinical laboratories, how the laboratories report results to emergency departments and treatment facilities and health departments, and what quality assurance practices are used will guide future efforts of the CDC to develop appropriate influenza testing guidelines and sector-specific training materials for clinicians and improve health outcomes of the American public.

The survey covers basic laboratory demographic characteristics, specimen collection and processing, testing practices, reporting of results to emergency departments and other treatment facilities, reporting results to health departments, quality assurance practices, and methods of receiving updated influenza-related information. The majority of the questions request information about laboratory influenza testing practices.

To date, no systematic study has been conducted to investigate how laboratories use these tests, how they report results, or how they interact with outpatient treatment facilities. The survey will be conducted on a national sample of clinical laboratories. There are no costs to respondents except their time. The total estimated annual burden hours are 1020.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Avg. burden per response (in hrs)
Clinical Laboratory Supervisors	Survey of Rapid Influenza Diagnostic Test Practices in Laboratories.	2040	1	30/60