DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–13–13AHA]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–7570 or send comments to LeRoy Richardson, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email to *omb@cdc.gov.*

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 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 four pharmacies will submit reimbursement claims for 1,060 prescriptions per year, or 265 per pharmacy; we estimate that each submission will take one 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.

The total estimated burden is approximately 832 hours. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
Pentagon or Shanksville, Pennsylvania Responder.	World Trade Center Health Program Pentagon & Shanksville, Pennsylvania Responder Eligibility Application.	1,605	1	30/60	803
Pentagon or Shanksville, Pennsylvania Responder.	Appeals to Eligibility Denial	4	1	30/60	2
Pentagon or Shanksville, Pennsylvania Responder.	Appeals regarding certification of health conditions.	1	1	30/60	1

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
Pentagon or Shanksville, Pennsylvania Responder.	Appeals regarding treatment	14	1	30/60	7
Pharmacies	Outpatient prescription pharmaceuticals.	4	265	1/60	18
Pentagon or Shanksville, Pennsylvania Responder.	WTC Health Program Medical Travel Refund Request.	1	1	10/60	1
Total					832

Leroy Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2013–21467 Filed 9–3–13; 8:45 am]

BILLING CODE 4163–18–P

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Proposed Project

Risk Factors for Community-Associated *Clostridium difficile* Infection through the Emerging Infections Program (EIP)—New—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The epidemiology of *C. difficile* has changed dramatically during recent years, with increases in incidence and severity of disease being reported across several countries. In addition, populations previously thought to be at low risk, such as young, healthy individuals residing in the community, are now being identified with severe *C. difficile* infection (CDI). Community-associated CDI is estimated to represent 32% of all CDI based on population-based CDI surveillance data, with an incidence of 30–40 per 100,000 population in the United States. Previous reports have shown that approximately 40% of patients acquiring community-associated CDI (CA–CDI) were not exposed to antibiotics, which is a well-recognized risk factor for CDI; suggesting that additional factors may contribute to infections. Other factors such as proton pump inhibitors have been raised as a risk factor for CDI in the community and on February 8, 2012, the U.S. Food and Drug Administration issued a communication advising physicians to consider the diagnosis of CDI among patients taking proton pump inhibitors. However, the data on the association of CDI with proton pump inhibitors are still controversial and studies to quantify this association are needed. In addition to the understanding of the factors that predispose patients to CDI, further evaluation of potential *C. difficile* exposure sources in the community is necessary to guide prevention efforts.

The sources of *C. difficile* and the risks for developing CDI in previously thought to be low-risk community populations are not well defined. Although initial evaluation of CA–CDI cases identified several potential risk factors (e.g., outpatient healthcare exposures, infants in the home, and proton pump inhibitor use), the magnitude of association of these risks with disease development using a control population has not been evaluated to date. This proposed case-control study will enable investigators to evaluate these associations and focus future investigations and prevention strategies on those factors identified as significantly associated with disease development.

CDC requests OMB approval to collect information from the public using a standardized questionnaire over a three-year period. The study will have a pediatric and an adult component given that *C. difficile* exposure sources in the community may vary by age. For example, *C. difficile* has been isolated from daycare centers' environment which may be a potential source for *C. difficile* acquisition in pediatric population, but less likely to be a source for adults.

For this project, we estimate that 129 persons ≥18 years of age with *C. difficile* infection (case-patients) will be contacted for the CDI study interview annually. Of those, 71 will agree and be eligible to participate in the study and will proceed to the full telephone interview. A total of 142 persons ≥ 18 years of age without C. *difficile* infection (control-patients) will be contacted for the interview annually. Of those, 71 will agree and be eligible to participate in the study and will complete the full interview. Among the pediatric group, we estimate that 141 and 194 parents of children between 1 and 5 years of age with and without *C. difficile* infection will be contacted for the interview, respectively. Among the case- and