DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–13–0852]

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, DC 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Prevalence Survey of Healthcare-Associated Infections (HAIs) in Acute Care Hospitals in the United States—Extension—(0920–0852 exp.5/31/13)—National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Preventing healthcare-associated infections (HAIs) is a CDC priority. An essential step in reducing the occurrence of HAIs is to estimate accurately the burden of these infections in U.S. hospitals, and to describe the types of HAIs and causative organisms. The scope and magnitude of HAIs in the United States were last directly estimated in the 1970s by CDC's Study on the Efficacy of Nosocomial Infection Control (SENIC), in which comprehensive data were collected from a sample of 338 hospitals; 5% of hospitalized patients acquired an infection not present at the time of admission. Because of the substantial resources necessary to conduct hospital-wide surveillance in an ongoing manner, most of the more than 4,500 hospitals now reporting to the CDC's current HAI surveillance system, the National Healthcare Safety Network (NHSN 0920–0666 expires 1/31/15), focus instead on device-associated and procedure-associated infections in a selected patient locations, and do not report data on all types of HAIs occurring hospital-wide. Periodic assessments of the magnitude and types of HAIs occurring in all patient populations within acute care hospitals are needed to inform decisions by local and national policy makers and by hospital infection control personnel regarding appropriate targets and strategies for HAI prevention. Such assessments can be obtained in periodic national prevalence surveys, such as those that have been conducted in several European countries.

In 2008–2009, CDC developed a pilot protocol for a HAI point prevalence survey, conducted over a 1-day period at each of 9 acute care hospitals in one U.S. city. This pilot phase was followed in 2010 by a phase 2, limited roll-out HAI and antimicrobial use prevalence survey, conducted during July and August in 22 hospitals across 10 Emerging Infections Program sites (in California, Colorado, Connecticut, Georgia, Maryland, Minnesota, New Mexico, New York, Oregon, and Tennessee). Experience gained in the phase 1 and phase 2 surveys was used to conduct a full-scale, phase 3 survey in 2011, involving 183 hospitals in the 10 EIP sites. Over 11,000 patients were surveyed, and analysis of HAI and antimicrobial use data is ongoing at this time. Preliminary HAI prevalence results were presented at the 52nd Interscience Conference on Antimicrobial Agents and Chemotherapy (San Francisco, CA, September 8–12, 2012) and preliminary antimicrobial use results were presented at the 2012 IDWeek conference (San Diego, CA, October 17–21, 2012).

An extension of the prevalence survey's existing OMB approval is sought, to allow a repeat HAI and antimicrobial use prevalence survey to be performed in 2014. A repeat survey will allow further refinement of survey methodology and assessment of changes over time in prevalence, HAI distribution, and pathogen distribution. It will also allow for a re-assessment of the burden of antimicrobial use, at a time when antimicrobial stewardship is an area of active engagement in many acute care hospitals. The 2014 survey will be performed in a sample of up to 500 acute care hospitals, drawn from the acute care hospital populations in each of the 10 EIP sites (and including participation from many hospitals that participated in prior phases of the survey). Infection prevention personnel in participating hospitals and EIP site personnel will collect demographic and clinical data from the medical records of a sample of eligible patients in their hospitals on a single day in 2014, to identify CDC-defined HAIs. The surveys will provide data for CDC to make estimates of the prevalence of HAIs across this sample of U.S. hospitals as well as the distribution of infection types and causative organisms. These data can be used to work toward reducing and eliminating healthcare-associated infections—a DHHS Healthy People 2020 objective (*http://www.healthypeople.gov/2020/topicsobjectives2020/overview.aspx?topicid=17*). This survey project also supports the CDC Winnable Battle goal of improving national surveillance for healthcare-associated infections (*http://www.cdc.gov/winnablebattles/Goals.html*).

The total burden is 9,375 hours, which represents an increase of 250 hours over the previously approved burden. The increase is requested because the median number of responses per respondent in the 2011 phase 3 survey was 75. Previously, we had estimated 73 responses per respondent. There are no costs to respondents. The total estimated annualized burden is 9,375.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Number of respondents	Number of responses per respondent	Average burden per response in hours
Infection Prevention Personnel in Participating Hospitals	500	75	15/60

*Assumptions: One respondent per hospital, collection of data on median of 75 patients per hospital, average data collection time of 15 minutes per patient.

Kimberly S. Lane,

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

[30Day–13–0263]

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

Requirements for the Importation of Nonhuman Primates into the United States (formerly Requirements for a Special Permit to Import Cynomolgus, African Green, or Rhesus Monkeys into the United States) (OMB Control No. 0920–0263 Exp.6/30/2014)—Revision—National Center Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Since May 1990, CDC has monitored the arrival and/or uncrating of certain shipments of non-human primates imported into the United States under a special permit program specific to Cynomolgus, African Green, or Rhesus Monkeys. CDC has monitored compliance with this special permit through the collection of information focused on determining whether or not importers conduct adequate disease control practices. Importers were required to renew their special permit every 180 days.

In February 2013, CDC promulgated two regulations pertaining to the importation of nonhuman primates. The first rule rule, Requirements for Importers of Nonhuman Primates (2/15/2013, Vol. 78, No. 32/p. 11522) consolidates into 42 CFR 71.53 the requirements previously found in 42 CFR part 71.53 with those found in the Special Permit to Import Cynomolgus, African Green, or Rhesus Monkeys into the United States. It also extended the time period for registration/permit renewal from 180 days to 2 years. The Special Permit has been withdrawn. The requirements found therein are now incorporated into the revised final rule for 42 CFR 71.53. The second rule, Establishment of User Fees for Filovirus Testing of Nonhuman Primate Liver Samples (2/12/2013, Vol.78, No. 29, p.9828), outlines a process by which importers can send liver tissues to CDC from primates that die during importation from reasons other than trauma. CDC performs these tests due to the absence of a private sector option. CDC feels these regulatory changes balance the public health risks posed by the importation of nonhuman primates with the burden imposed on regulating their importation.

These rule changes have prompted CDC to modify how it administers the information collected from the public in the enforcement of nonhuman primate regulations. CDC is requesting the following changes:

1. CDC requests that this information collection request be re-named ''Requirements for the Importation of Nonhuman Primates into the United States'' to more accurately reflect the type of information that is requested from respondents.

2. To streamline administration of this information collection request, CDC requests that CDC form 75.10A Application for Registration as an Importer of Nonhuman Primates and the Recordkeeping requirement currently approved under OMB Control Number 0920–0134 Foreign Quarantine Regulations, be moved and included in this revision to OMB Control Number 0920–0263. This action places all nonhuman primate information collection requirements and requests into one information collection request administered by CDC.

3. CDC is renaming the different portions of the information collected in this information collection to more accurately list the types of forms and documentation CDC collects from importers of nonhuman primates. Therefore, the former information categories of Businesses (limited permit), Businesses (extended permit), and Organizations (extended permit) are being renamed and reorganized. The information contained in these categories will now be accounted for in the Documentation sections of the burden table. This categorization will more accurately reflect CDC's interaction with the importers.

4. CDC also requests additional burden hours to account for notification to CDC from importers of shipment arrivals and requests for release from quarantine.

5. CDC further requests the addition of the Filovirus Diagnostic Specimen Submission Form for Non-human Primate Materials, which will be used to collect all of the necessary information from nonhuman primate importers to test nonhuman primate liver samples for filovirus and communicate the results of this test. This action adds approximately 50 hours of burden to this information collection request.

This information collection involves minimal personally identifiable information and should have limited impact on an individual's privacy. There are no costs to respondents other than their time.

The total burden requested for this information collection is 146.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name/CFR reference	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Nonhuman Primate Importer	71.53(g) New Importer Registration—Nonhuman Primates.	1	1	10/60
Nonhuman Primate Importer	71.53(g) Importer Re-Registration—Nonhuman Primates.	12	1	10/60