Prevalence Survey of Healthcare-Associated Infections and Antimicrobial Use in U.S. Hospitals

(OMB Control No. 0920-0852, Expiration 5/31/2013)

Request for Reinstatement with Change

Part A

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Prevalence Survey of Healthcare Associated Infections and Antimicrobial Use in U.S. Hospitals

This is a request for OMB approval of a reinstatement with change of a previously-approved data collection for the Centers for Disease Control and Prevention (CDC) Healthcare-Associated Infections (HAI) and Antimicrobial Use Prevalence Survey (OMB control number 0920-0852). This data collection was initially funded with the American Recovery and Reinvestment Act of 2009 (ARRA), and was approved through May 2013. The CDC is requesting a reinstatement with change to allow the performance of additional surveys at regular intervals over the next several years. The next surveys are planned to occur in 2014 and 2017.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Background

This is a request for reinstatement with change of a previously-approved data collection (0920-0852). Approval for three years is requested. The reinstatement is requested because (as stated in the original approved Information Collection Request) the HAI and Antimicrobial Use Prevalence Survey is anticipated to be conducted approximately once every 3 years, with the next surveys planned for 2014 and 2017. Conducting the survey at regular intervals provides important information about changes in HAI and antimicrobial use prevalence and epidemiology. This information is necessary to evaluate the success of infection control and antimicrobial stewardship interventions and to understand infections and types of antimicrobial use that should be targeted for more intensive surveillance or prevention and improvement efforts. A reinstatement with change is requested, because changes to the public data collection have been made in response to experience and knowledge gained during the performance of previous surveys in 2010 and 2011. These changes consist of: 1) minor changes (modifications, additions and deletions) to the data collection form (now called the "Patient Information Form"), and 2) addition of a Healthcare Facility Assessment (a questionnaire that collects information regarding the characteristics and infection control and antimicrobial stewardship policies and practices in place in healthcare facilities participating in the survey).

Changes to the data collection performed by agents of the government have also been made. These consist of: 1) minor changes (modifications, additions and deletions) to forms entitled the "Antimicrobial Use Form" and the "HAI Form," and 2) addition of a limited Healthcare Facility Assessment, and 3) addition of assessments of the appropriateness of antimicrobial use. These appropriateness assessments are made using antimicrobial use assessment/audit forms.

Elimination of HAIs is a priority of the U.S. Department of Health and Human Services (HHS) (see http://www.hhs.gov/ash/initiatives/hai/) and a CDC "Winnable Battle" (see http://www.cdc.gov/winnablebattles/healthcareassociatedinfections/index.html). Understanding the scope and magnitude of all types of HAIs across patient populations in U.S. healthcare facilities is essential to the development of effective prevention and control strategies and policies. CDC currently conducts HAI surveillance through the National Healthcare Safety Network (NHSN) (OMB Control No. 0920-0666, expiration date 01/31/2015). Most healthcare

facilities participating in the NHSN report incident device-associated HAIs occurring in high-risk patient locations (such as intensive care units, ICU) and infections related to selected types of surgeries; therefore CDC currently cannot estimate from NHSN data alone the scope and magnitude of all HAIs affecting the wide spectrum of patient populations. Furthermore, CDC does not currently collect detailed, patient-level data within the NHSN or other surveillance systems on inpatient antimicrobial use in a national sample of healthcare facilities. Such data are essential in the effort to develop and implement strategies to reduce inappropriate antimicrobial use and prevent the emergence and spread of resistant pathogens.

HAI prevalence estimates as well as estimates of antimicrobial use can be obtained through prevalence surveys, in which data are collected in healthcare facilities during a short, specified time period. Although providing only a snapshot of the frequency and nature of HAI and antimicrobial use, prevalence surveys represent an efficient and cost-effective alternative to prospective, hospital-wide incidence studies. In 2009, the CDC proposed to conduct two surveys (referred to as "Phase 2" and "Phase 3") to evaluate the prevalence of HAIs and antimicrobial use in acute care hospitals in multiple states. This survey development initiative was initially a three phase project. The first phase, a small, single-city pilot survey with less than 10 respondents, was completed in 2009 [1]. Phases 2 and 3 were conducted in collaboration with state public health authorities and with the CDC's Emerging Infections Program (EIP). Phase 2 was a limited roll-out survey involving 22 healthcare facilities in the 10 states with EIP sites (CA, CO, CT, GA, MD, MN, NM, NY, OR, TN). Phase 2 received OMB approval on May 18, 2010. Phase 2 data collection by local infection control personnel in participating hospitals and by EIP personnel was completed in 2010. In 2011, CDC completed the Phase 3 HAI and antimicrobial use prevalence survey using experience and knowledge gained during Phase 2. In this Phase 3 survey, approximately 4% of the 11,282 patients surveyed had one or more HAIs at the time of the survey. In addition, more than half of all HAIs detected were not associated with medical devices or procedures, and more than half of all HAIs were attributed to non-ICU patient locations. Pneumonia and other lower respiratory infections were the most common type of HAI, accounting for more than one quarter of all HAIs reported. Only 39% of pneumonias were ventilator-associated. The most common pathogens were *Clostridium difficile* and *Staphylococcus aureus*. Antimicrobial use was prevalent; approximately half of all surveyed patients were receiving at least one antimicrobial agent at the time of the survey. Vancomycin, a drug used to treat infections with resistant Gram-positive pathogens such as methicillin-resistant *S. aureus* (MRSA), was the most common antimicrobial used.

The next surveys, planned for 2014 and 2017, will include up to 500 healthcare facilities in the 10 EIP sites. Although the overall survey methods will be the same as those used in Phases 2 and 3, minor changes to the data collection instrument have been made based on experience gained in the prior surveys. Data are collected from medical records and healthcare facility information systems. Patients are not interviewed. Data collectors may consult with healthcare facility staff on inpatient units to obtain information regarding patients with selected medical devices in place, patients on antimicrobial therapy, etc. In addition to the minor data collection instrument changes for the next surveys, a healthcare facility assessment has been added. The assessment will be completed by hospital staff before the survey is conducted, and will allow for a description of the survey hospitals and their infection control and antimicrobial stewardship resources and

practices; this information was not gathered in Phases 2 and 3, and this information gap was a limitation of those survey phases.

This data collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241) (Attachment A) and the American Recovery and Reinvestment Act of 2009 (ARRA) (Attachment C).

1.1 Privacy Impact Assessment

As in Phase 2 and Phase 3, patient and healthcare facility data in the next surveys will be collected on paper forms from existing sources of information, including electronic and paper medical records and healthcare facility information systems, and entered into a CDC-developed, web-based data management system. Data collection and data entry partners will include local healthcare facility staff (e.g., infection preventionists and other staff working in their own healthcare facilities), EIP site personnel, academic collaborators, and local and state public health professionals. EIP sites will have access to data submitted from facilities within their catchment areas. The information in the CDC database will be maintained indefinitely, since this data collection will be repeated at regular intervals for comparison purposes. Information in identifiable form (potentially including name, date of birth, medical record numbers, and medical information) will be maintained by local facilities and/or EIP sites until completion of all survey activities, but names, dates of birth, and medical record numbers will not be transmitted to CDC. Medical information, including certain dates, will be transmitted to CDC as described below.

Two types of data will be collected: healthcare facility data and patient data.

Healthcare facility information will be collected using the “Healthcare Facility Assessment” (HFA) (Attachment D). The HFA will be completed by healthcare facility staff. It includes information regarding the numbers of facility beds, annual discharges, and selected staff members in the facility, and information about infection control and antimicrobial stewardship resources, policies and practices. EIP personnel will also gather a limited amount of healthcare facility information using an EIP HFA (Attachment G). Attachment G is provided as supplemental information only; the EIP data collection is not part of the public burden (see Section 14).

Patient data will be collected through review of medical records. Patients will not be interviewed. Data collectors may consult with healthcare facility staff on inpatient units to confirm information such as patients with selected medical devices in place or patients on antimicrobial therapy. Several patient-level data collection forms will be completed, including a “Patient Information Form” (PIF), “Antimicrobial Use Form” (AUF), “HAI Form” (HAIF), and antimicrobial use audit forms. Most data collection and data collection forms will be completed by EIP site personnel. Healthcare facility staff may participate in collection of data on the PIF (see Attachment E; example of draft instructions provided in Attachment F). Information from the PIF that is transmitted to CDC includes: unique patient identification code, state, data collection date, age, gender, race, ethnicity, primary payer, survey date, patient location within the healthcare facility, hospital admission and discharge date, weight and height (or birth weight

in neonatal locations), outcome, presence and numbers of medical devices (urinary catheter, central line, ventilator), and whether the patient was on antimicrobial therapy.

EIP site personnel may assist healthcare facility staff in completing PIF. EIP site personnel are responsible for completing an EIP HFA, the AUF, the HAIF, and the antimicrobial use audit forms (Attachment G). Data collection pertaining to antimicrobial use includes drug names, route of administration, dose information, start dates, indication or rationale for use, location of onset of the infection for which antimicrobials were prescribed, and therapeutic sites. Data collection pertaining to HAIs includes whether an HAI was present, the types of HAI, and details of the HAI (the specific type, whether device or procedure-associated, location and dates of onset and treatment, dates on which all definition criteria were met, causative pathogens, and antimicrobial susceptibility of those pathogens). Data collected to assess appropriateness of antimicrobial use will include detailed information on antimicrobial treatment, patient allergies or other adverse events, clinical signs and symptoms of infection, and results of laboratory and microbiological testing. Attachment G is provided as supplemental information only; the EIP data collection is not part of the public burden (see Section 14). Note that the data collection items appearing in Attachment G are subject to minor modification, based on practical and scientific considerations that may come to light during the planning, training, and implementation of the EIP data collection.

Although medical information and hospital admission and discharge date, survey dates, infection and therapy dates, and other dates pertaining to clinical information (such as date of collection of specimens for testing) will be transmitted to CDC, other patient identifiers, such as name, medical record number and address, will not be transmitted to CDC. Each patient will be assigned a unique identification code that will not contain identifying information. CDC will know the names of healthcare facilities that agree and do not agree to participate in the information collection. EIP personnel will be able to link facility codes with facility names, but CDC will not have these linkages. Local data collectors in participating healthcare facilities and EIP personnel will need to collect information in identifiable form (IIF) for patients within their own facility or catchment area, such as patient name, date of birth, medical record number, healthcare facility unit name and patient's room number. This information will not be transmitted to CDC.

If resources are available, data validation of patient-level data will be performed as part of the 2014 and/or 2017 surveys through a Contractor. The Contractor will identify and engage qualified, local or regional expert infection preventionists (referred to as the "Evaluation Team" or "EVALT") to validate data collection in each EIP site. The EVALT will perform retrospective medical record review for a sample of surveyed patients in each EIP site. We anticipate that this sample in each EIP site will consist of an approximately 10-20% random sample of patients surveyed by local hospital staff and/or EIP personnel. The EVALT will collect similar patient data as the local hospital staff and EIP personnel (Attachments E and G). The EVALT will also be asked to record on a worksheet the criteria utilized in making HAI determinations for those patients found to have HAIs.

2. Purpose and Use of Information Collection

Preventing HAIs and encouraging appropriate use of antimicrobials are HHS and CDC priorities. Essential steps in reducing the occurrence of HAIs and prevalence of resistant pathogens are to estimate accurately the burden of HAIs in U.S. healthcare facilities, describe the types of infections and causative organisms, and assess the nature and extent of antimicrobial use. The burden of HAIs in acute care hospitals in the United States was last estimated in 2002 [2]; this number, 1.7 million HAIs (causing approximately 99,000 deaths), is now a decade old, and yet it continues to be cited frequently by scientists, public health officials, and policy makers. New estimates are needed for public health priority setting, for policy-making purposes, and for communications with the public and other stakeholders. New estimates, and a current understanding of HAI and antimicrobial use epidemiology, are also needed for collaborations with partners in other parts of the world (the European Union, for example) and internally within state health departments and the CDC for setting surveillance and prevention priorities.

The 2011 Phase 3 survey results have been summarized earlier in this Information Collection Request (see Section A.1). Updated HAI burden estimates have been generated using 2011 survey data and data from the Nationwide Inpatient Sample (NIS), Healthcare Cost and Utilization Project (HCUP), Agency for Healthcare Research and Quality. The HAI survey results and burden estimates were recently submitted to a peer-reviewed scientific journal for publication. Estimation of the burden of antimicrobial use is currently underway.

Results from the 2011 survey have been used in a variety of settings, including the following:

1) State health departments of participating EIP sites have shared 2011 survey data with their HAI Committees to inform priority setting for public health initiatives to improve antimicrobial use;
2) The CDC has used the 2011 survey data to launch a targeted evaluation of the clinical correlates of events detected by surveillance definitions of non-ventilator-associated pneumonia and lower respiratory infection (the most common HAI type overall in the 2011 survey). This evaluation is a first step toward developing better surveillance definitions and prevention approaches for these common infections (which have not to date been a focus of prevention efforts).
3) The CDC has used the survey results to inform development of appropriate antimicrobial use audit tools. The current tools are based on the most common scenarios encountered in the 2011 survey, including use of antimicrobial agents for urinary tract infection and community-onset respiratory infection, and use of vancomycin (the most commonly-used antimicrobial agent overall) and piperacillin/tazobactam (a very broad-spectrum agent that was in the top 5 antimicrobial agents overall).
4) The CDC has collaborated with the European Centre for Disease Prevention and Control (ECDC) to harmonize HAI and antimicrobial use prevalence survey methods to allow for selected comparisons of prevalence and burden, and facilitate international situational awareness of HAI and antimicrobial use. Collaborations on prevalence survey methods between the CDC and the ECDC are included in the work plan for the Transatlantic Task Force on Antimicrobial Resistance (see http://ecdc.europa.eu/en/activities/diseaseprogrammes/TATFAR/Documents/210911_TATFAR_Report.pdf).

5) Burden estimates for selected HAIs generated using survey data have been used to validate estimates obtained through other surveillance systems, such as the National Healthcare Safety Network (e.g., central line-associated bloodstream infections, surgical site infections).

Because there is no ongoing surveillance for all HAI types occurring across patient populations in U.S. healthcare facilities, understanding the impact of prevention programs and ensuring that prevention initiatives are targeted to the highest-priority, highest-impact conditions requires repeating the prevalence survey at regular intervals. Without ongoing surveys, knowledge of the entire spectrum of HAIs and antimicrobial use will be lost. There are no other surveillance systems currently in the United States that can provide this information. In addition, the next survey will be the CDC's first large-scale attempt to evaluate the appropriateness of antimicrobial use in the inpatient setting, and will contribute greatly toward understanding those agents or infections that should be the focus of local, state or national stewardship programs. To our knowledge, no other large-scale surveillance of appropriate antimicrobial use is underway in the United States.

2.1 Privacy Impact Assessment

The data collected will be used to determine the prevalence of HAIs, the types of HAIs and causative pathogens, the nature and extent of antimicrobial use in healthcare facilities as well as opportunities for improvement in antimicrobial use, the prevalence of antimicrobial resistance among pathogens causing HAIs, and the prevalence of certain risk factors for infection, such as medical devices. HAIs are recognized as a major cause of morbidity and mortality in the United States, as well as a major contributor to excess healthcare costs (see http://www.hhs.gov/ophs/initiatives/hai/). Eliminating HAIs is a priority of the CDC and other federal agencies. The proposed surveys, like the 2011 survey, will provide estimates of the magnitude and burden of HAIs in a large sample of U.S. acute care inpatients forming the foundation for development and implementation of effective prevention measures, and will enable an assessment of change in burden and epidemiology of HAIs and antimicrobial use over time. During this data collection, CDC will neither receive nor share IIF, with the exception of medical information as described above. With the exception of race and ethnicity and the presence of HAIs, no sensitive information is being collected on individual patients. Data will be entered into the electronic data management system and retrieved by CDC using identification codes that do not contain patient identifiers. CDC will analyze and report aggregated data obtained during the survey. The results of the surveys may be shared in local, state, national and international presentations and publications, and will be used by local, state and federal public health authorities to inform the development of HAI prevention and antimicrobial stewardship strategies and policies. Individual healthcare facilities may also use the data to inform institution-level practice and policy.

3. Use of Improved Information Technology and Burden Reduction

As in Phases 2 and 3, the proposed surveys will use paper data collection forms because survey personnel will in some cases need to travel to multiple patient units within healthcare facilities to collect data and will not necessarily have reliable, timely access to computers or the internet.

Electronic health record systems are not currently in use in all healthcare facilities, and information technology resources vary widely among healthcare facilities. All survey data will be entered by EIP site personnel into a CDC-developed, web-based, electronic data management system. No paper forms with personal identifiers such as name or medical record number will be submitted to CDC. Dates as noted above will be recorded on paper forms and in the electronic data management system, and will be submitted to CDC.

As part of the proposed survey, healthcare facility staff will complete a HFA (see Section A.1.1 and Attachment D). The HFA is a questionnaire that will be completed on a one-time basis by a staff member in each participating facility. EIP personnel will provide the HFA and instructions to healthcare facility staff either in person or via electronic communication. The HFA will be completed in paper form, due to the wide array of electronic communication capabilities across healthcare facilities and because it is anticipated that the healthcare facility staff member completing the HFA may need to consult with other colleagues in the facility to answer some of the HFA questions. EIP personnel will enter HFA data into the electronic data management system for transmission to the CDC.

4. Efforts to Identify Duplication and Use of Similar Information

CDC's first large-scale HAI prevalence survey was conducted in the 1970s (Study on the Efficacy of Nosocomial Infection Control, SENIC), using a team of trained abstractors to collect comprehensive HAI data from a probability sample of 338 hospitals [3]. The SENIC project found that approximately 5% of hospitalized patients acquired an infection not present or incubating at the time of admission [4]. At a cost of $27 million, the SENIC project has not been repeated. In the 1980s and 1990s CDC conducted voluntary, hospital-wide infection surveillance through the National Nosocomial Infections Surveillance (NNIS) system (OMB Control Number 0920-0012); in NNIS, data were reported from local hospital personnel rather than a common team of CDC-trained data collectors (http://www.cdc.gov/ncidod/dhqp/nnis.html). As demands on infection control grew, voluntary NNIS hospitals began to perform targeted surveillance in high-risk hospital areas (such as intensive care units) that were most useful in calculating risk-adjusted HAI incidence rates. The NNIS system's hospital-wide HAI surveillance component was eliminated in 1996. CDC's successor to the NNIS system, the National Healthcare Safety Network (NHSN) (OMB Control No. 0920-0666), is not designed to estimate the scope and magnitude of HAIs hospital-wide; rather, it focuses on device-associated and procedure-associated infections (e.g., central-line associated bloodstream infections, catheter-associated urinary tract infections, surgical site infections, etc.) (http://www.cdc.gov/nhsn/about.html). Healthcare facility participation in the NHSN is in many cases driven by state legislative HAI reporting mandates and by requirements of the Centers for Medicare and Medicaid Services' (CMS) Hospital Inpatient Quality Reporting (IQR) Program, which includes selected HAIs. In its current form, the NHSN cannot provide estimates of HAI for all types of HAIs or antimicrobial use throughout an entire hospital. Measurements of the magnitude and types of HAIs and nature and extent of antimicrobial use occurring across all acute care patient populations 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, measures to encourage appropriate antimicrobial use, and/or justification to focus efforts at specific antimicrobial resistant infections. Such measurements, while not directly obtainable within the current NHSN

infrastructure, can be obtained in prevalence surveys. Prevalence surveys have been conducted in several countries around the world in recent years [5-29]. The first large-scale U.S. prevalence survey since the 1970s was conducted in 2011. There are no duplicate efforts underway within the United States.

While the information collected in the prevalence survey is broader in scope than the data collected in the NHSN, there may be some minimal overlap. Most hospitals in the United States are participating in central line-associated bloodstream infection (CLABSI) surveillance and catheter-associated urinary tract infection (CAUTI) surveillance in intensive care units through the NHSN as part of required reporting for the CMS IQR program. Most hospitals are also reporting deep incisional and organ/space SSI data from colon surgeries and abdominal hysterectomies to the NHSN because of CMS requirements. Other, more recent additions to the CMS IQR program requirements include reporting of facility-wide MRSA bacteremia and *C. difficile* infection through the NHSN. We estimate that these infections account for approximately 24% of all HAIs, based on 2011 Phase 3 survey results. It is important to note that while we estimate that approximately 24% of the HAIs identified in the prevalence survey in a given hospital will have to be entered in to the NHSN system, each facility will conduct the prevalence survey over a very short period of time (one day) and will only be collecting data on a sample of patients in the facility during that short time period. For example, a hospital with 500 acute care beds may be asked to review 100 patient medical records for the purposes of the prevalence survey. If 4% of these patients have HAIs (4 patients) and we estimate that 24% of HAIs detected will also need to be entered into NHSN, that represents a burden of approximately one patient record for that facility.

Other CDC systems that have the capability of collecting information on HAIs in acute care inpatients include the National Health Care Survey (NHCS), run by the National Center for Health Statistics (NCHS). The NHCS integrates three surveys: the National Hospital Discharge Survey (NHDS), the National Hospital Ambulatory Medical Care Survey, and the Drug Abuse Warning Network. The NHCS collects data on inpatients and visits to emergency departments and outpatients departments including ambulatory surgery. We in the Division of Healthcare Quality Promotion (DHQP) previously worked with NCHS staff to incorporate a CLABSI event detection component into the redesigned NHDS, precursor to the NHCS, in 2007-2008. The conclusion of a 9-facility pilot of this event detection component (presented by Ms. Nancy Sonnenfeld in June 2008 to DHQP) was that the required sampling of charts to enhance the likelihood of detecting a CLABSI was successful in only half of the pilot hospitals. The required data elements to detect CLABSI events (which represent less than 10% of all HAIs) more than doubled the chart abstraction time compared to the typical redesigned NHDS review, rendering this component impractical for inclusion in the NHDS.

With the implementation of the NHCS in 2011, a new sample of approximately 500 hospitals is being recruited to participate. Hospital recruitment is anticipated to be completed in the next 1-2 years. Hospitals participating in the NHCS submit their inpatient and ambulatory UB-04 administrative claims data to the NHCS. Questionnaires are also completed to gather facility-level information. While studies have shown that administrative claims data are not acceptable for identifying HAIs [30-33], we understand that in future years, it will be possible to conduct special projects within the NHCS, such as projects involving detailed medical record abstraction

and collection of clinical data. We have begun discussions with NCHS colleagues (Clarice Brown, Paul Beatty and Carol DeFrances) to explore the possibility of using the NHCS infrastructure in future years to conduct or enhance the HAI and antimicrobial use prevalence survey, recognizing the potential limitations, such as loss of comparability with data collected using the EIP infrastructure in 2011 and 2014.

5. Impact on Small Businesses or Other Small Entities

Small healthcare facilities may participate in the prevalence survey. Participation is voluntary, but we anticipate that most facilities selected for participation will agree to participate. Elimination of HAIs is a major goal of all U.S. healthcare institutions, large and small, and we expect that facilities will be highly motivated to participate. The data collection and management burden for participating healthcare facilities will be minimized as much as possible. This will be accomplished by having EIP personnel perform most of the data collection. In hospitals that agree to participate but that have insufficient resources to perform any data collection, EIP personnel may perform all of the data collection.

6. Consequences of Collecting the Information Less Frequently

The survey was developed with the goal of repeating it at regular but infrequent intervals (e.g., once every 3 years). Repeating the survey will provide information on changes in HAI prevalence over time as well as changes in the burden and distribution of infection types and causative organisms. There are no technical or legal obstacles to reducing the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances that require the information to be collected in any of the formats identified, and the request fully complies with regulations.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. A Federal Register Notice was published on 12/04/2012, volume 77, No. 233, page 71798-71899. No public comments were received. (Attachment B)

A. As required in the Notice of Action for the Phase 2 survey, on June 14, 2010 we consulted with colleagues in the National Center for Health Statistics (Dr. Jane Sisk, former Director of the Division of Health Care Statistics, Attachment H). In the process of developing and conducting Phases 2 and 3 of the prevalence survey we also consulted with experts in the ECDC, where our primary point of contact is Dr. Carl Suetens, Senior Expert. We have continued our communications with ECDC experts, participating in conference calls (such as a call of the Transatlantic Task Force on Antimicrobial Resistance on June 13, 2013) and attending meetings (including a meeting of the European Antimicrobial Resistance and HAI Networks in Berlin, Germany in November 2012), and expect to maintain this collaboration in the years to come.

9. Explanation of Any Payment or Gift to Respondents

Participating healthcare facilities may receive a certificate or letter of appreciation. EIP sites or state health departments may choose to provide education and/or training resources to participating facilities.

10. Assurance of Confidentiality Provided to Respondents

Data will be treated in a secure manner, and will not be disclosed, unless otherwise compelled by law. As in previous survey phases, a unique code will be assigned to each patient included in the survey. These codes will not include patient identifiers. The codes will be linked at the facility level and EIP site level to the individual patient from whose record the data were collected; however, those links and patient identifiers other than certain dates will not be shared with CDC. CDC will know the identities of healthcare facilities within EIP catchment areas, those facilities within the catchment areas that are eligible for participation, those facilities that are selected to participate, and those facilities that agreed or did not agree to participate. EIP sites will use codes to identify specific facilities. Data collection forms will be filled out using patient and facility codes. Links between facility codes and names will be maintained by EIPs and will not be shared with CDC. Participating facilities' data will be aggregated by CDC to provide HAI and antimicrobial use prevalence estimates. An individual participating facility may have access to its own data (e.g., provided in a report prepared by the EIP site staff). Individual states and/or CDC may choose to present or publish state-specific survey data. Individual states, in consultation with participating facilities in that state, may elect to present or publish facility-specific information.

The data management system for Phases 2 and 3 was certified and accredited as a Level 1 system. The same data management system will be used for the proposed surveys, with some minor modifications to reflect changes to the data collection forms. These modifications will also undergo the appropriate approval processes prior to implementation.

<u>IRB Approval</u>

The 2011 Phase 3 survey was determined not to be human subjects research. A formal determination has not yet been sought for the proposed surveys, but we do not anticipate it to differ from the Phase 3 survey determination since the objectives, methods and the nature of the data collection have not changed substantially.

10.1 Privacy Impact Assessment

Healthcare facilities selected to participate in the survey are informed that participation is voluntary. Individual patients are not the respondents for these surveys, and are not informed of their inclusion in the survey. There is no interaction of EIP or CDC personnel with individual patients. Participating facilities are provided with their individual results by the EIP sites, upon request. Information received by CDC will be stored in a secure, password-protected database. Information received by CDC will be provided only to those individuals at CDC with a need to

know. Data will be treated in a secure manner, and will not be disclosed, unless otherwise compelled by law. This information collection request has been reviewed by CDC/Information Collection Review Office who has determined that the Privacy Act does not apply.

11. Justification for Sensitive Questions

Information on criminal behavior, sexual behavior and attitudes, alcohol or drug use, and religious beliefs, will not be collected, although we will collect information on patient location within healthcare facilities, and one type of location is a jail unit. Race and ethnicity will be collected by healthcare facility staff and EIP personnel. We believe it is important to collect data on race and ethnicity because studies have indicated that there is a higher burden of some types of HAIs in minority patients. For example, a study published in 2010 showed that post-operative infections were significantly more common among black patients than white patients [34]. Similarly, data from the Emerging Infections Program's invasive MRSA surveillance have shown that the incidence of healthcare-associated invasive MRSA infections was significantly higher in black persons than in white persons [35]. Data on race and ethnicity will be collected in accordance with federal standards, except that a classification of "other race" will be provided. This category is present in the Nationwide Inpatient Sample database (see http://www.hcup-us.ahrq.gov/db/vars/race/nisnote.jsp), and where possible we have sought to align prevalence survey patient demographic variables with those in the Nationwide Inpatient Sample. The reporting of adverse events occurring in hospitalized patients, including infections, could be considered sensitive unless healthcare facilities are assured that the data-aggregating organization will provide security for the data and maintain the institution's confidentiality. Data security will be assured as described above.

12. Estimates of Annualized Burden Hours and Costs

A. Infection preventionists (or other designated staff) in participating healthcare facilities will be asked to do the following: 1) complete the HFA on a one-time basis in advance of the survey, 2) participate in survey training, and 3) collect patient data, limited to basic demographic and clinical information on the PIF.

   For the HFA (Table A), respondents will be infection preventionists (or other designated healthcare facility staff). We anticipate a total of 500 respondents, one for each participating facility, who will complete the assessment one time prior to the survey. The time required to complete the assessment is estimated to be 45 minutes.

   For the training and PIF completion burden on infection preventionists in participating facilities (Table A), we incorporated knowledge gained from the conduct of the Phase 2 and 3 surveys. Please note: throughout this Information Collection Request, any reference to number of patients surveyed or included in the survey should be interpreted to mean the number of patients' medical records that are reviewed/included in the survey; it does *not* mean that patients are actually being interviewed or interacted with directly. This is made clear in Section 1.1, above: "Patient data will be collected through review of medical records. Patients will not be interviewed." In Phase 3, EIP sites asked each participating facility to survey a fixed number of patient records, 75-100 randomly-selected acute care inpatients,

depending upon hospital size. Small and medium facilities were asked to survey 75 patients each (or, if the hospital has <75 beds, the facility surveyed all patients), while large hospitals were asked to survey 100 patients each. Small hospitals accounted for 51% of facilities in the survey (and not all of these hospitals had 75 patients to survey), medium hospitals accounted for approximately 37% of facilities in the survey, and large hospitals accounted for 12% of facilities in the survey. With an estimated 500 facilities participating in the survey, 255 of these would be small hospitals, 185 would be medium hospitals, and 60 would be large hospitals. Of the 255 small hospitals, we estimate that 20% of these (51 hospitals) would be able to review 75 patients, while in the other 80% (204 hospitals), we estimate that 37 patients would be available for review. Therefore, the total number of records reviewed was estimated as follows: [(51 small facilities)*(75 records)] + [(204 small facilities)*(35 records)] + [(185 medium facilities)*(75 records)] + [60 large facilities)*(100 records)] = 30,840 records, which translated to an average of 62 responses per respondent. The time required to participate in training and data collection to complete the PIF is estimated to be 17 minutes.

If 2 surveys are conducted during the requested 3-year approval period, the estimated annualized burden associated with the HFA (with 2 responses from 500 respondents over 3 three years) is the burden associated with 0.67 responses per year (rounded to 1 response per year), for each of the 500 respondents, or 375 annual burden hours.

If 2 surveys are conducted during the requested 3-year approval period, the estimated annualized burden associated with the training and completion of PIFs (with 62 responses for each of 2 surveys from 500 respondents annualized over 3 years) is the burden associated with 41.33 responses per year, rounded to 42 responses per year, for each of the 500 respondents, or 5950 hours.

Table A: Estimated Annualized Burden Hours

Type of Respondent	**Form Name**	**Number of Respondents**	**Number of Responses per Respondent**	**Average Burden per Responses (in hours)**	**Total Burden Hours**
Infection preventionist	Healthcare Facility Assessment (HFA)	500	1	45/60	375
Infection preventionist	Patient Information Form (PIF)	500	42	17/60	5950
Total					**6325**

Although 17 minutes represents a 2-minute increase in the estimated data collection time from the approved burden for Phases 2 and 3 (and is related to the addition of data collection items), the overall burden to the public (i.e., infection preventionists or other designated

healthcare facility staff) for the HFA and PIF combined is 6325 hours when annualized over the 3 year approval period period.

B. The total cost burden for the infection preventionist respondents in healthcare facilities is estimated as follows: With a total annual burden of 6325 hours, the total cost of the time to respond to the proposed survey is estimated to be $206,574.50 ([6325 hours]*[$32.66], Table B). We have utilized the mean hourly wage for a Registered Nurse, $32.66, obtained from the Bureau of Labor Statistics, Occupational and Employment Statistics Section May 2012 data (accessed June 14, 2013 at http://www.bls.gov/oes/current/oes291141.htm). We utilized this wage because: 1) infection preventionists are in many cases Registered Nurses; and 2) there is no wage information specifically for infection preventionists available in the Bureau of Labor Statistics database cited above. There will be no direct costs to facilities and local data collectors other than their time to participate in the study.

Table B: Estimated Annualized Burden Costs

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Avg. Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Registered Nurse	HFA	500	1	45/60	375	$32.66	$12,247,50
Registered Nurse	PIF	500	42	17/60	5950	$32.66	$194,327.00
Total							**$206,574.50**

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

None.

14. Annualized Cost to the Government

Costs to the government include costs for CDC and EIP site personnel to develop and coordinate survey activities, EIP site personnel to perform local survey coordination and data collection and entry activities, costs for a database manager, costs for photocopying survey materials, and costs for an external Contractor to perform data validation activities.

CDC personnel working on the survey are estimated to include a 0.3 full-time-equivalent (FTE) public health analyst or epidemiologist (see Row #1 of Table C) and a 0.2 FTE database developer and a 0.2 FTE data database manager (see Row #2 of Table C). The mean hourly wage for an epidemiologist is $34.33 (obtained from the Bureau of Labor Statistics, Occupational and Employment Statistics Section May 2012 data, available at http://www.bls.gov/oes/current/oes191041.htm), for a total cost of $21,421. The mean hourly wage for a database administrator is $38.04 (obtained from the Bureau of Labor Statistics,

Occupational and Employment Statistics Section May 2012 data, available at: http://www.bls.gov/oes/current/oes151141.htm), for a total cost of $15,825 for a database developer and $15,825 for a database manager.

EIP sites (see Row #4 of Table C) are supported through a Cooperative Agreement with CDC. During a May 7, 2010 teleconference with Dr. Margo Schwab and Ms. Julie Wise from OMB, Dr. Schwab informed CDC prevalence survey personnel that because the EIP is a CDC-run program under a Cooperative Agreement, EIP personnel (and therefore, the forms included in Attachment G) should not be included in the annualized public burden estimate, but rather in the estimate of annualized cost to the government. We estimate that on an annualized basis, 1.5 FTE employees are needed in each site to conduct survey activities. These employees are epidemiologists, with an estimated hourly wage of $34.33 (obtained from the Bureau of Labor Statistics, Occupational and Employment Statistics Section May 2012 data, available at: http://www.bls.gov/oes/current/oes191041.htm). Therefore, in each EIP site, the estimated annual cost is $107,096. The estimated cost across the 10 EIP sites is $1,070,960.

If resources are available, CDC will work with a Contractor (see Rows #4 and #5 of Table C) to identify external expert infection preventionists to perform data validation in Phase 3. These expert infection preventionists will comprise the Evaluation Team, or EVALT. We estimate that the EVALT will review approximately 6168 medical records (20% sample of all records). Review time for each record on average (including time to fill out the AUF and HAIF for a limited number of records) is estimated to be 27 minutes, including time to account for training and other survey-related activities. Based on previous experience, the hourly cost for these medical record reviews is estimated to be $100.00. The total cost for record review alone is therefore estimated to be $273,750. We estimate an additional $100,000 for coordination and travel- and supply-related expenses. The total estimated cost of this contract is therefore $377,600. If 2 surveys are conducted during the 3-year approval period, the annualized cost of the contract is therefore (2 surveys)*($377,600), divided by 3, or $251,733.33.

There will also be costs related to photocopying of survey forms and instructions. The cost is estimated to be $10,452 ($0.05 to copy each page, estimated 209,040 copies made to support survey activities in 500 facilities in 10 EIP sites). If 2 surveys are conducted during the 3-year approval period, the annualized cost is (2 surveys)*($10,452) divided by 3, or $6968.00.

The total annualized cost to the federal government for personnel and photocopying is therefore estimated to be $1,382,732.

Table C: Annualized cost to the federal government

Government Employee Title	Total Number of Hours Dedicated to Survey per Year	Hourly Rate	Totals
CDC epidemiologist	624	$34.33	$21,421
Database developer	416	$38.04	$15,825
Database manager	416	$38.04	$15,825
EIP epidemiologists (1.5 FTE in each of 10 sites)	31,200	$34.33	$1,070,960

Photocopying	--	--	$6,968
Contractor—data validation	2,776	$100	$251,733
Contractor—data validation travel, coordination and supply–related costs	--	--	$100,000
Total			**$1,382,,732**

15. Explanation for Program Changes or Adjustments

The burden for each individual respondent in this survey, per survey conducted, has increased by 47 minutes over the burden for the OMB-approved Phase 3 survey. This increase is due to a program change (the addition of data collection items) and an adjustment (reduction in the average number of responses per respondent based on actual experience conducting the Phase 3 survey). Note that the annualized burden for the current reinstatement request is 6325 hours, which is less than the previously approved burden of 9158 hours for the Phase 3 survey. This difference is because the current burden estimate has been developed with the anticipation of performing 2 surveys during a 3-year approval period (one in year 1 of the approval period, and one in year 3 of the approval period), and dividing that total burden over the 3 years of the approval period. In the previously approved ICR, the total burden approved represented the burden for performing the survey during the single year in which it was conducted; the burden was not divided into equal parts over the 3-year approval period.

Changes to the public data collection (i.e., the data collection performed by healthcare facility personnel) have been made in response to experience and knowledge gained during the performance of previous surveys in 2010 and 2011. These changes consist of: 1) minor changes (modifications, additions and deletions) to the data collection form (the PIF, Attachment E) and 2) addition of the HFA (Attachment D, a questionnaire that collects information regarding the characteristics and infection control and antimicrobial stewardship policies and practices in place in healthcare facilities participating in the survey).

Changes to the data collection performed by agents of the government (i.e., data collection performed by EIP site personnel) have also been made. These consist of: 1) minor changes (modifications, additions and deletions) to the AUF and HAIF, and 2) addition of a limited EIP HFA, and 3) addition of assessments of the appropriateness of antimicrobial use. These appropriateness assessments are made using antimicrobial use assessment/audit forms. See Attachment G.

16. Plans for Tabulation and Publication and Project Time Schedule

A patient-level surveillance dataset will continue to be maintained at CDC. This dataset will be used to determine HAI prevalence and antimicrobial use prevalence, the distribution of HAI types and causative organisms, and the distribution of types of antimicrobials and rationale for their use. Analysis will occur in SAS version 9.3 or newer versions as they become available (SAS Institute, Carey, NC) and OpenEpi versions 2.3.1 and 3.01 (or newer versions as they

become available). Categorical and continuous variables will be compared in patients with and without HAIs (and receiving and not receiving antimicrobials) using chi-square tests and Wilcoxon rank-sum tests, respectively. Associations between patient and facility-level characteristics and HAIs and antimicrobial use will be explored using univariate and multivariable log binomial regression modeling. HAI and antimicrobial use prevalence will be converted to incidence using the formula of Rhame and Sudderth [36]. HAI and antimicrobial use burden estimates will be generated using prevalence survey data and data from the Nationwide Inpatient Sample, Healthcare Cost and Utilization Project, Agency for Healthcare Research and Quality.

Results from this survey will be presented at national meetings and published in a manuscript format in a peer-reviewed scientific journal. Publications will include a discussion of potential biases and other limitations of the project.

Because of planning and funding considerations, we will conduct the 2014 survey as soon as possible following OMB approval of this Information Collection Request.

Table A.16.1: Project time schedule

Activity	**Time Schedule**
Training of infection preventionists in participating hospitals	Immediately, or within 1-2 months after OMB approval (April 2014)
Conduct of survey	Within 2-6 months after OMB approval (April-August 2014)
Data collection by EIP personnel	Within 3-12 months after OMB approval (May 2014-April 2015)
Transmission of all survey data to CDC	Within 15 months after OMB approval (July 2015)
Analysis and presentation of results	Within 15-20 months after OMB approval (July 2015-November 2015)
Repeat of survey (2017)	Approximately 36 months after OMB approval

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

The display of the OMB expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

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List of Attachments

A: United States Code, Title 42, Chapter 6A Part 241 (referenced in Part A)

B: 60-day Federal Register Notice (referenced in Part A)

C: American Recovery and Reinvestment Act of 2009 (referenced in Part A)

D: Healthcare-Associated Infections and Antimicrobial Use Prevalence Survey Healthcare Facility Assessment (HFA) (referenced in Part A)

E: Healthcare-Associated Infections and Antimicrobial Use Prevalence Survey Patient Information Form (PIF) (referenced in Part A)

F: Primary Team instructions for data collection (draft example) (referenced in Part A)

G: Supplemental information: data collection forms utilized by EIP personnel and the Contractor, but NOT completed by infection preventionists in participating healthcare facilities, and not part of the public burden (referenced in Part A)

H: Email correspondence from Dr. Jane Sisk, Director, Division of Healthcare Statistics, National Center for Health Statistics (referenced in Part A)

I: Example of informational document distributed to healthcare facilities in EIP catchment areas (referenced in Part B)