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

(OMB Control No. 0920-0852, Expiration 12/31/2016)

Revision ICR

Supporting Statement A

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- **Goals of project**: Determine the prevalence of healthcare-associated infections (HAIs) in hospital patients; types of HAIs and causative pathogens; nature and extent of antimicrobial use in hospitals; prevalence of inappropriate antimicrobial use and opportunities for improvement in antimicrobial use in hospitals; and prevalence of antimicrobial resistance among pathogens causing HAIs.
- **Intended use of the resulting data**: Provide current, national estimates of the HAI and antimicrobial use burden in U.S. acute care hospitals, and assess progress made in preventing HAIs, controlling antimicrobial resistance, and improving the quality of hospital antimicrobial prescribing.
- **Method to be used to collect**: Cross-sectional approach via point-prevalence surveys in participating U.S. short-term, acute care hospitals.
- **Subpopulation to be studied**: Patients of all ages in U.S. short-term, acute care hospitals.
- **How data will be analyzed**: The proportions of patients with HAIs and on antimicrobials drugs will be calculated. Factors associated with HAIs and antimicrobial use will be analyzed using log binomial regression modeling. Prevalence will be converted to incidence using the formula of Rhame and Sudderth (see reference 36).

This is a request for OMB approval of a revision of an 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). The reasons for requesting the revision are to: 1) extend the approval for another three years; and 2) reduce the estimated data collection burden.

This data collection was initially funded with the American Recovery and Reinvestment Act of 2009 (ARRA), and was approved through May 2013.

A request for reinstatement with change was approved in October 2013, and a request for a non-substantive change was approved in September 2014, with an expiration date of 12/31/2016. Emerging Infections Program staff are now in the process of completing data collection and entry for the full-scale prevalence survey hospitals conducted between May and September 2015.

The CDC is requesting a three-year extension of the approval for 0920-0852. Another full-scale survey to assess changes in hospital inpatient antimicrobial drug use and healthcare-associated infections is anticipated to be conducted in 2019. The CDC is requesting approval of a revision because the estimated burden to the public has been reduced.

Because a survey was conducted in 2011 and the same methods were used in 2015 and will be used again in 2019, it will be possible to assess changes in the above over time.

Based on the experience conducting surveys in 2011 and 2015, the burden to the public is lower than we previously estimated. We have therefore reduced the estimated burden in this revision request.

1. Circumstances Making the Collection of Information Necessary

This is a request for revision of an approved data collection (0920-0852), to extend the expiration date by three years and to reduce the estimated public burden. The most recent prevalence survey was conducted in hospitals between May and September 2015. Emerging Infections Program (EIP) sites are currently completing data collection and data entry for the 2015 survey. 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. An extension of the existing approval is requested to allow another full-scale prevalence survey to occur in 2019.

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 12/31/2018). Most healthcare facilities participating in the NHSN report incident device-associated HAIs occurring in high-risk patient locations (such as intensive care units, ICU), infections related to selected types of surgeries, *Clostridium difficile* infections, and bacteremia due to methicillin-resistant *Staphylococcus aureus* (MRSA); 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.

Improving antimicrobial prescribing is a critical component of strategies to reduce antimicrobial resistance, and is a priority for CDC and other government agencies (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6309a4.htm?s_cid=mm6309a4_w). The President's National Strategy for Combating Antibiotic Resistant Bacteria (CARB), published in September 2014, calls for "inappropriate inpatient antibiotic use for monitored conditions/agents" to be "reduced 20% from 2014 levels" (page 9, https://www.whitehouse.gov/sites/default/files/docs/carb_national_strategy.pdf). Currently, the EIP HAI and Antimicrobial Use Prevalence Survey is the only large-scale CDC project designed to assess the quality of inpatient antimicrobial prescribing for selected clinical conditions. The quality assessment currently being performed as part of the 2015 survey data collection will be used as a baseline to evaluate whether progress has been made in improving antimicrobial prescribing quality in 2019.

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 2015 survey (with data collection and entry to be finalized in 2016) included 200 healthcare facilities in the 10 EIP sites. More than 75% of these facilities previously participated in the 2011 survey. Data were collected from medical records and healthcare facility information systems. Patients were not interviewed. In addition to the individual patient-level data collection, a healthcare facility assessment was also administered in 2015. The assessment 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. In 2019, at the time of the next prevalence survey, the healthcare facility assessment will again be administered to participating hospitals.

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).

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. Until the 2011 prevalence survey was performed, 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), continued to be cited for many years by scientists, public health officials, and policy makers. New estimates were needed for public health priority setting, for policy-making purposes, and for communications with the public and other stakeholders. New estimates were also needed for public health priority setting, for policy-making purposes, and for communications with the public and other stakeholders. Updated estimates, and a current understanding of HAI and antimicrobial use epidemiology, continue to be necessary 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). Results of the 2015 survey are anticipated to be available in 2017, once data collection, entry, and cleaning are complete. Updated HAI burden estimates were last 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 published in *The New England Journal of Medicine* on March 27, 2014 [37]. We estimated that approximately 722,000 HAIs occurred in 648,000 acute care hospital patients in 2011. Approximately 75,000 patients with HAIs died during their hospitalizations (http://www.cdc.gov/HAI/surveillance/).

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 used the survey results to inform development of forms to assess antimicrobial prescribing quality. The current forms are based on the most common scenarios encountered in the 2011 survey, including use of antimicrobial agents for urinary tract infection and community-onset pneumonia, and use of vancomycin (the most commonly-used antimicrobial agent overall) and fluoroquinolones (the most commonly prescribed class of antimicrobial agents).
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 proposed data collection on antimicrobial prescribing quality is the CDC's first large-scale attempt to evaluate prescribing quality 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. Data collected in the prevalence survey will also allow for an assessment of progress in meeting CARB and other national targets for improving antimicrobial use and preventing HAIs. To our knowledge, no other large-scale, patient-level assessment of inpatient antimicrobial prescribing quality use is underway in the United States.

3. Use of Improved Information Technology and Burden Reduction

The survey uses primarily 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, access, and information technology resources vary widely among healthcare facilities and EIP sites. If resources and capabilities allow, we will explore options for electronic data collection. Data will be entered by EIP site personnel into a web-based, CDC-developed database. No 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 data management system, and will be submitted to CDC.

As part of the proposed data collection, healthcare facility staff will complete a Healthcare Facility Assessment (HFA, Attachment D). The HFA is a questionnaire that will be completed on a one-time basis by participating facilities. EIP personnel will provide the HFA and instructions to healthcare facility staff either in person or via electronic communication. The HFA is anticipated to be completed in paper form in most facilities, 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. Some facilities may elect to complete the form electronically (e.g, fillable PDF, REDCap, etc.). EIP or healthcare facility personnel will enter HFA data into the data management system for sharing with 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, which took several years to complete, found that approximately 5% of hospitalized patients acquired an infection not present or incubating at the time of admission [4]. 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), and selected infections due to resistant organisms. A new reporting module also allows healthcare facilities to submit location-specific antimicrobial consumption data to the NHSN; data submission must be done electronically (i.e., no manual data entry), and facility-wide data submission is not required. Patient-level data are not submitted to the antimicrobial use reporting option. Healthcare facility participation in the NHSN is in many cases driven by state 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 currently no duplicate efforts underway within the United States, although it is our understanding that a global prevalence survey focusing on antimicrobial use (not HAIs) has been supported by a biotechnology company (http://www.biomerieux.com/en/4th-world-hai-forum-antimicrobial-resistance). The extent to which U.S. hospitals have been included in this effort is uncertain, although a report presented at the European Conference on Clinical Microbiology and Infectious Diseases in 2016 indicated that 15 U.S. hospitals (all part of the Healthcare Corporation of America) had participated (http://www.global-pps.com/wp-content/uploads/ECCMID-2016_USA.pdf).

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 Hospital 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, there may be future opportunities to conduct prevalence surveys outside of the EIP infrastructure. Approximately 120 hospitals participated in the NHCS in 2015, and it is anticipated that more will participate in 2016 (Carol DeFrances, personal communication). 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 as hospitals participating in the NHCS also begin submitting electronic health record data, it may be possible to conduct special projects within the NHCS. We have previously had communications 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, and we will continue to explore these possibilities as full implementation of the NHCS progresses. Currently it is necessary to use the EIP infrastructure to be able to assess changes over time.

5. Impact on Small Businesses or Other Small Entities

Small healthcare facilities may participate in the data collection. Participation is voluntary, but we anticipate that most facilities selected for participation will agree to participate. Elimination of HAIs and improving antimicrobial prescribing are major goals 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 07/12/2016, volume 81, No. 133, page 45164-45166. No public comments were received. (Attachment B)

B. 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. Protection of Privacy and Confidentiality of Information Provided by Respondents

This information collection request has been reviewed by NCEZID's Information Systems Security Officer who has determined that the Privacy Act does not apply. Healthcare facilities selected to participate in the data collection are informed that participation is voluntary. Individual patients are not the respondents for this data collection, and are not informed of their inclusion in the data collection. 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 database. Access to the CDC database will be provided only to those individuals at CDC (employees, trainees/fellows, and contractors) with a need to know. Data will be treated in a secure manner, and will not be disclosed, unless otherwise compelled by law.

As in the previous surveys, conducted in 2010, 2011, and 2015, patient and healthcare facility data in the 2019 survey will be collected from existing sources of information, including electronic and paper medical records and healthcare facility information systems, and entered used for the 2011 and 2015 surveys, and is anticipated to be used for the 2019 survey. Data collection and data entry partners outside of CDC will include local healthcare facility staff (e.g., infection preventionists and other staff working in their own healthcare facilities), EIP site personnel (employees and contractors), academic collaborators, and local and state public health professionals. CDC staff with access to prevalence survey data in the CDC database include employees, trainees/fellows, and contractors. 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, address, birthdate, medical record numbers, and medical information) will be maintained by local facilities and/or EIP sites until completion of all survey activities, and according to local and/or state requirements and regulations, but names, specific addresses, 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 (hospital) data and patient data:

- Healthcare facility information will be collected using the "Healthcare Facility Assessment" (HFA) (Attachment D). The HFA will be completed as part of the survey in 2019. 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 J). Attachment G, J and K are 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 prescribing quality assessment 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 PIFs. EIP site personnel are responsible for completing an EIP HFA, the AUF, the HAIF, and the antimicrobial prescribing quality assessment forms (Attachments G, J and K). 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 quality of antimicrobial prescribing will include detailed information on antimicrobial treatment, patient allergies or other adverse events, underlying conditions and diagnoses, clinical signs and symptoms of infection, and results of laboratory and microbiological testing. Prescribing quality will be assessed for several different prescribing events: adult and pediatric pneumonia, adult and pediatric urinary tract infection, adult and pediatric intravenous vancomycin prescribing, and adult fluoroquinolone prescribing. Attachments G, J and K are provided as supplemental information only; the EIP data collection is not part of the public burden (see Section 14).

Although medical information and hospital admission and discharge dates, survey dates and data collection 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 specific street address, will not be transmitted to CDC. 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. Data may be analyzed to determine whether certain facility characteristics

(e.g., bed size, etc.) or patient characteristics are associated with aspects of HAI prevalence or antimicrobial prescribing. 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. Survey results 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.

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.

The survey data management system will comply with applicable information technology and information security standards at CDC. The system will undergo the applicable evaluation and approval processes prior to deployment.

If resources are available, data validation of patient-level data will be performed as part of the survey through a contractor, or by the EIP site staff. If validation is performed by 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.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

Institutional Review Board (IRB)

The 2011 Phase 3 survey and the 2015 survey were determined not to be human subjects research (Attachment L). A formal determination has not yet been sought for the 2019 survey, but we do not anticipate it to differ from previous survey determinations, since the objectives, methods and the nature of the data collection have not changed substantially.

Justification for Sensitive Questions

Information on criminal behavior, sexual behavior and attitudes, and religious beliefs, will not be collected, with the exception of collection of drug use (which impacts the need for vancomycin treatment in patients with skin and soft tissue infections). We will collect information on patient location within healthcare facilities (one type of location is a jail unit), and we will collect information on locations of patients prior to admission and upon discharge from the hospital (such as a correctional facility).

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 (now National) Inpatient Sample. Also, some medical records allow race to be reported as "other," and this is a data collection based on medical records.

We will collect information on the presence of underlying conditions, including alcoholism, drug use and HIV/AIDS, because these conditions are risk factors for certain types of infections and may warrant modifications to antimicrobial treatment in certain circumstances. 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 protected 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, 2) participate in survey training, and 3) collect survey patient data, limited to information on the PIF.

   For the HFA (Table A), respondents will be infection preventionists (or other designated healthcare facility staff). Based on the numbers of hospitals participating in previous surveys, we anticipate up to a total of no more than 300 respondents, one for each participating facility, who will complete the assessment around the time of the survey (ideally during the month before the survey date). 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; patients are *not* interviewed or interacted with directly. 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 maximum of 300 facilities participating in the survey, 153 of these would be small hospitals, 111 would be medium hospitals, and 36 would be large hospitals. Of the 153 small hospitals, we estimate that 20% of these (31 hospitals) would be able to review 75 patients, while in the other 80% (122 hospitals), we estimate that 37 patients would be available for review. Therefore, the total number of records reviewed was estimated as follows: [(31 small facilities)*(75 records)] + [(122 small facilities)*(37 records)] + [(111 medium facilities)*(75 records)] + [36 large facilities)*(100 records)] = 18,764 records, which translated to an average of 63 responses per respondent.

The time required to participate in training and data collection to complete the PIF is estimated to be 17 minutes.

One full-scale survey is planned for the three-year approval period. In total, 300 respondents will complete the HFA once and the PIF, on average, 63 times. To annualize the burden over a three-year period in Table A below, the number of respondents has been set at 100 per year.

Table A: Estimated Annualized Burden Hours

Type of Respondents	**Form Name**	**No. of Respondents**	**No. of Responses per Respondent**	**Avg. Burden per Response (in hours)**	**Total Burden Hours**
Infection preventionist	Healthcare Facility Assessment (HFA)	100	1	45/60	75
	Patient Information Form (PIF)	100	63	17/60	1,785
Total					**1,860**

The overall burden to the public (i.e., infection preventionists, hospital computer systems analysts or other designated healthcare facility staff) is 2,010 hours when annualized over the 3 year approval period.

B. The total cost burden for the infection preventionist respondents in healthcare facilities is estimated as follows: With an annualized burden of 1,860 hours, the annualized cost of the time to respond to the proposed survey is estimated to be $63,500.40 (Table B). We have utilized the mean hourly wage for a Registered Nurse (RN), $34.14, obtained from the Bureau of Labor Statistics, Occupational and Employment Statistics Section May 2015 data (accessed June 20, 2016 at http://www.bls.gov/news.release/ocwage.t01.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 project.

Table B: Estimated Annualized Burden Costs

Type of Respondents	Form Name	No. of Respondents	No. Responses per Respondent	Avg. Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
RN	HFA	100	1	45/60	75	$34.14	$2,560.50
	PIF	100	63	17/60	1,785	$34.14	$60,939.90
Total							**$63,500.40**

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 data collection activities, EIP site personnel to perform local 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 data collection are estimated to include 1 full-time-equivalent (FTE) public health analyst or epidemiologist (see Table C), 0.5 FTE business analyst, 1 FTE database developer and a 0.5 FTE database manager (see Table C). The mean hourly wage for an epidemiologist is $36.97, for a total annual cost of $76,900. The mean hourly wage for business analyst is $43.56, for a software developer is $49.12 ($102,160 annually), and for a database administrator is $40.51 (obtained from the Bureau of Labor Statistics, Occupational and Employment Statistics Section May 2015 data, accessed June 20, 2016 at http://www.bls.gov/news.release/ocwage.t01.htm).

EIP sites (see 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, J and K) 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 $36.97 (obtained from the Bureau of Labor Statistics, Occupational and Employment Statistics Section May 2015 data). The estimated cost across the 10 EIP sites is $1,153,464.

If resources are available, CDC will work with a Contractor (see Table C) to identify external expert infection preventionists to perform data validation. These expert infection preventionists will comprise the Evaluation Team, or EVALT. We estimate that the EVALT will review

approximately 3753 medical records (20% sample of all records; annualized, 1251 records per year). 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 45 minutes, including time to account for training and other survey-related activities, or a total of 2815 hours. 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 $281,500, or $93,833 per year. We estimate an additional $100,000 for coordination and travel- and supply-related expenses, or $33,333 per year. The total estimated cost of this contract (over 3 years) is $381,500; the annualized cost of the contract is therefore $381,500 divided by 3, or $127,166.

There will also be costs related to photocopying of forms and instructions. The cost is estimated to be $8,382 ($0.05 to copy each page, estimated 167,648 copies made to support survey activities in 300 facilities in 10 EIP sites). The annualized cost is $8,382 divided by 3, or $2,794.

The total annualized cost to the federal government for personnel and photocopying is therefore estimated to be $1,549,916.00.

Table C: Annualized cost to the federal government

Government Employee Title	**Total Number of Hours Dedicated per Year**	**Hourly Rate**	**Total Annualized Cost**
CDC epidemiologist	2080	$36.97	$76,900
Business analyst	1040	$43.56	$45,302
Database developer	2080	$49.12	$102,160
Database administrator	1040	$40.51	$42,130
EIP epidemiologists (1.5 FTE in each of 10 sites)	31,200	$36.97	$1,153,464
Photocopying	--	--	$2,794
Contractor—data validation	938	$100	$93,833
Contractor—data validation travel, coordination and supply–related costs	--	--	$33,333
Total			**$1,549,916.00**

15. Explanation for Program Changes or Adjustments

The annualized public burden for this revision request is 2010 hours, less than the burden of 5350 hours approved in September 2014. This difference is because the current burden estimate has been developed with the anticipation of performing one survey during a 3-year approval period, and dividing that total burden over the 3 years of the approval period. In the most recent approval (September 2014), the burden reflected two data collections over a 3-year approval period. In addition, we have reduced the number of hospitals we expect to participate in the 2019 survey from 500 to 300, based on our prior experience and anticipated funding. This has reduced the annualized public burden as well as the annualized cost to the public.

The estimated annualized cost to the government has increased when compared to the prior approval in September 2014. This increase is largely due to increases in anticipated personnel costs, particularly costs to support the prevalence survey database and information technology staff.

16. Plans for Tabulation and Publication and Project Time Schedule

A patient-level survey dataset and a hospital-level survey dataset will continue to be maintained at CDC. These datasets 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. They will be used to describe hospitals participating in the survey, assess factors associated with HAIs and antimicrobial use, and describe antimicrobial use prescribing quality. 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 or median 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 or other appropriate methods. 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 National Inpatient Sample, Healthcare Cost and Utilization Project, Agency for Healthcare Research and Quality.

Results from this data collection 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.

Table A.16.1: Project time schedule

Activity	**Time Schedule**
Data cleaning activities for 2015 survey by EIP personnel	December 2016-March 2017
Analysis and presentation of preliminary 2015 survey results	6 months after OMB approval (May 2017)
Publication of final 2015 survey results	12-18 months after OMB approval (December 2017-May 2018)
Training of infection preventionists in participating hospitals for 2019 survey activities	24-27 months after OMB approval (December 2018-March 2019)
Conduct of survey by EIP and hospital staff	29-31 months after OMB approval (May-September 2019)
Data collection by EIP personnel	Beginning as early as 29 months after OMB approval (anticipate extension request submission)
Transmission of all survey data to CDC	Beginning as early as 29 months after

	OMB approval
Analysis and presentation of results	Beginning in 2020-2021 (anticipate extension request submission)

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.

References

1) Magill SS, Hellinger W, Cohen J, et al. Prevalence of healthcare-associated infections in acute care hospitals in Jacksonville, Florida. Infect Control Hosp Epidemiol 2012;33:283-91.
2) Klevens RM, Edwards JR, Richards CL, et al. Estimating health care-associated infections and deaths in U.S. hospitals, 2002. Public Health Reports 2007;122:160-6.

3) Haley RW, Culver DH, White JW, et al. Study on the Efficacy of Nosocomial Infection Control (SENIC project): summary of study design. Am J Epidemiol 1980;111:472-85.
4) Haley RW, Hooton TM, Culver DH, et al. Nosocomial infections in U.S. hospitals, 1975-1976: estimated frequency by selected characteristics of patients. Am J Med 1981;70:947-59.
5) Lanini S, Jarvis WR, Nicastri E, et al. Healthcare-associated infection in Italy: annual point-prevalence surveys, 2002-2004. *Infect Control Hosp Epidemiol* 2009;30:659-65.
6) Smyth ETM, McIlvenny G, Enstone JE, et al. Four Country Healthcare Associated Infection Prevalence Survey 2006: overview of the results. *J Hosp Infect* 2008;69:230-48.
7) Reilly J, Stewart S, Allardice GA, et al. Results from the Scottish National HAI Prevalence Survey. *J Hosp Infect* 2008;69:62-68.
8) Kanerva M, Ollgren J, Virtanen MJ, Lyytikäinen O, for the Prevalence Survey Study Group. Estimating the annual burden of healthcare-associated infections in Finnish adult acute care hospitals. *Am J Infect Control* 2009;37:227-30.
9) Gastmeier P, Kampf G, Wischnewsky N, et al. Prevalence of nosocomial infections in representative German hospitals. J Hosp Infect 1998;38:37-49.
10) Scheel O, Stormark M. National prevalence survey on hospital infections in Norway. J Hosp Infect 1999;41:331-5.
11) Vaque J, Rossello J, Arribas JL, et al. Prevalence of nosocomial infections in Spain. J Hosp Infect 1999;43:105-11.
12) The French Prevalence Survey Study Group. Prevalence of nosocomial infections in France: results of the nationwide survey in 1996. J Hosp Infect 2000;46:186-193.
13) Azzam R, Dramaix M. A one day prevalence survey of hospital-acquired infections in Lebanon. J Hosp Infect 2001;49:74-8.
14) Zotti CM, Messori G, Charrier L, et al. Hospital-acquired infections in Italy: a region wide prevalence study. J Hosp Infect 2003;56:142-9.
15) Gikas A, Pediaditis J, Papadakis JA, et al. Prevalence study of hospital-acquired infections in 14 Greek hospitals. J Hosp Infect 2002;50:269-75.
16) Plowman R, Graves N, Griffin MA, et al. The rate and cost of hospital-acquired infections occurring in patients admitted to selected specialities of a district general hospital in England and the national burden imposed. J Hosp Infect 2001;47:198-209.
17) Emmerson AM, Enstone JE, Griffin MA, et al. The Second National Prevalence Survey of infection in hospitals—overview of the results. J Hosp Infect 1996;32:175-90.
18) Pittet D, Harbarth S, Ruef C, et al. Prevalence and risk factors for nosocomial infection in four university hospitals in Switzerland. Infect Control Hosp Epidemiol 1997;20:37-42.
19) Faria S, Sodano L, Gjata A, et al. The first prevalence survey of nosocomial infections in the University Hospital Centre Mother Teresa of Tirana, Albania. J Hosp Infect 2007;65:244-50.

20) Hajdu A, Samodova OV, Carlsson TR, et al. A point prevalence survey of hospital-acquired infections and antimicrobial use in a pediatric hospital in north-western Russia. J Hosp Infect 2007;66:378-84.
21) Lee MK, Chiu CS, Chow VC, et al. Prevalence of hospital infection and antibiotic use at a university medical Center in Hong Kong. J Hosp Infect 2007;65:341-74.
22) Duerink DO, Roeshadi D, Wahjono H, et al. Surveillance of healthcare-associated infections in Indonesian hospitals. J Hosp Infect 2006;62:219-29.
23) Klavs I, Luznik TB, Skerl M, et al. Prevalence of and risk factors for hospital-acquired infections in Slovenia—results of the first national survey, 2001. J Hosp Infect 2003;54:149-57.
24) Kallel H, Bahoul M, Ksibi H, et al. Prevalence of hospital-acquired infection in a Tunisian hospital. J Hosp Infect 2005;59:343-7.
25) Metintas S, Akgun Y, Durmaz G, et al. Prevalence and characteristics of nosocomial infections in a Turkish university hospital. Am J Infect Control 2004;32:409-13.
26) Danchaivijitr S, Judaeng T, Sripalakij S, Naksawas K, Plipat T. Prevalence of nosocomial infection in Thailand 2006. J Med Assoc Thai 2007;90:1524-9.
27) Gravel D, Matlow A, Ofner-Agostini M, et al. A point prevalence survey of healthcare-associated infections in pediatric populations in major Canadian acute care hospitals. Am J Infect Control 2007;35:157-62.
28) Gravel D, Taylor G, Ofner M, et al. Point prevalence survey for healthcare-associated infections within Canadian adult acute-care hospitals. J Hosp Infect 2007;66:243-8.
29) Ansari F, Erntell M, Goossens H, et al. The European Surveillance of Antimicrobial Consumption (ESAC) point-prevalence survey of antibacterial use in 20 European hospitals in 2006. Clin Infect Dis 2009;49:1496-1504.
30) Sherman ER, Heydon KH, St John KH, et al. Administrative data fail to accurately identify cases of healthcare-associated infection. Infect Control Hosp Epidemiol 2006;27:332-7.
31) Jhung MA, Banerjee SN. Administrative coding data and health care-associated infections. Clin Infect Dis 2009;49:949-55.
32) Cass AL, Kelly JW, Probst JC, et al. Identification of device-associated infections utilizing administrative data. Am J Infect Control 2013 Jun 12 (Epub ahead of print).
33) Moehring R, Staheli R, Miller BA, et al. Central line-associated infections as defined by the Centers for Medicare and Medicaid Services' Hospital-acquired Condition versus standard infection control surveillance: why Hospital Compare seems conflicted. Infect Control Hosp Epidemiol 2013;34:238-44.
34) Mayr FB, Yende S, Linde-Zwirble WT, et al. Infection rate and acute organ dysfunction risk as explanations for racial differences in severe sepsis. JAMA 2010;303:2495-2503.
35) Klevens RM, Morrison MA, Nadle J, et al. Invasive methicillin-resistant *Staphylococcus aureus* infections in the United States. JAMA 2007;298:1763-71.
36) Rhame FS, Sudderth WD. Incidence and prevalence as used in the analysis of the occurrence of nosocomial infections Am J Epidemiol 1981;113:1-11.

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: Antimicrobial Use Form and Healthcare-Associated Infection Form: 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)

J: EIP Healthcare Facility Assessment Form: supplemental information, not part of the public burden (referenced in Part A)

K: Antimicrobial Prescribing Quality Assessment Forms: draft, supplemental information, not part of public burden (referenced in Part A)

L: Non-research determination