Survey of Healthcare-Associated Infections and Antimicrobial Use in U.S. Nursing Homes for use in Exploring the Development of a National Prevalence Model

New Information Collection Request

Part A

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- The goal is to conduct a multi-state prevalence survey to estimate the burden and describe the epidemiology of healthcare-associated infections (HAI) and antimicrobial use in a sample of nursing homes in ten states.
- The results will be used to 1) explore the development of an approach to modeling the national burden of HAI. Such estimates may be used to inform state and federal priority

setting for public health initiatives to improve HAI prevention, 2) inform development of the CDCs National Healthcare Safety Network, 3) evaluate uptake of antibiotic stewardship activities in nursing homes in 10 states.

- The application of the prevalence survey method, in which data are collected in healthcare facilities during a short, specified time period, will be used to develop an approach to modeling estimated national burden of HAI. This is an efficient, resource- and cost-effective alternative to prospective, studies of HAI and antimicrobial use incidence.
- The survey will be performed by the CDC through the Emerging Infections Program (EIP), a collaboration with CDC and 10 state health departments with experience in HAI surveillance and data collection. Respondents are nursing homes certified by the Centers for Medicare & Medicare Services (CMS) in EIP states. Nursing home participation is voluntary.
- Variables will be compared in residents with and without HAIs and antimicrobials using chi-square tests and Wilcoxon rank-sum or median tests. Associations between resident and facility-level characteristics and HAIs and antimicrobial use will be explored using univariate and multivariable log binomial regression modeling or other appropriate methods.

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

This is a new information collection request from the Centers for Disease Control and Prevention (CDC) for a Prevalence Survey of Healthcare-Associated Infections (HAI) and Antimicrobial Use in US Nursing Homes. Approval is requested for a period of 3 years.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Elimination of HAIs is a priority of the U.S. Department of Health and Human Services (HHS) (see www.hhs.gov/ash/initiatives/hai/) and a CDC "Winnable Battle" (see /www.cdc.gov/winnablebattles/healthcareassociatedinfections/index.html). Understanding the scope and magnitude of all types of HAIs in patient populations across the spectrum of U.S. healthcare facilities is essential to the development of effective prevention and control strategies and policies. HAI prevalence and antimicrobial use estimates can be obtained through prevalence surveys, in which data are collected in healthcare facilities during a short, specified time period. Since 2009, the CDC has conducted surveys to evaluate the prevalence of HAIs and antimicrobial use in acute care hospitals (1, 2, 3), with the most recent performed in 2015 [2015 survey OMB Control No. 0920-0852, expiration date 12/31/2016]. Providing a snapshot of the frequency and nature of HAI and antimicrobial use, prevalence surveys represent an efficient and cost-effective alternative to prospective, facility-wide incidence studies.

CDC conducts HAI surveillance through The National Healthcare Safety Network (NHSN www.cdc.gov/nhsn/) [OMB Control No. 0920-0666, expiration date 12/31/2018]. The Long-

term Care Facility (LTCF) Component of NHSN (www.cdc.gov/nhsn/ltc/index.html), provides infrastructure and methods to enable nursing homes to perform prospective surveillance for incident HAIs. The NHSN LTCF Component, available since September 2012, enables nursing homes (and other types of LTCF) to report data on selected HAIs known to be of importance in this healthcare setting, including urinary tract infections (UTIs) and *Clostridium difficile* infections and multi-drug resistance organisms via a laboratory-based infection proxy measure. Due to the limited HAI surveillance options for nursing homes in NHSN, CDC cannot use the data from NHSN to estimate the scope and magnitude of all HAIs affecting residents of US nursing homes. Furthermore, while NHSN includes reporting for antimicrobial use in acute care hospitals, this surveillance, which relies exclusively on automated reporting using electronic data, is not available to nursing homes. CDC, therefore, does not currently collect data on antimicrobial use in nursing homes. 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 (www.cdc.gov/mmwr/preview/mmwrhtml/mm6309a4.htm?s_cid=mm6309a4_w).

The methods to be used for this survey will be similar to those used for the CDC hospital surveys, with changes informed by prevalence surveys conducted in long-term care facilities by the European CDC (ECDC) (4,5), and a CDC pilot prevalence survey (6,7). The pilot, a small survey with less than 10 respondents, was completed in 2014 (6,7) in collaboration with four states (CO, CT, NM and NY) from the CDC's Emerging Infections Program (EIP). In this pilot involving 1,272 nursing home residents, the HAI and antimicrobial use prevalence was 5.5% and 11.0%, respectively. The strongest predictor of prevalence was resident type (as defined by CMS, short- or long-stay), with short-stay residents having HAI and antimicrobial use prevalences of 9% and 21%, respectively. Collection of this information from a larger sample of U.S. nursing homes in 10 states is necessary to understand the potential scope and type of infections and antimicrobial use that should be targeted for more intensive surveillance or prevention and improvement efforts.

The national burden of HAIs in U.S. nursing homes has not been estimated in over 20 years, and is currently unknown. Therefore, the results from this CDC prevalence survey will be combined with nursing home data from the CMS Nursing Home Compare (www.medicare.gov/NursingHomeCompare/About/Nursing-Home-Info.html) to model national burden estimates of HAI in nursing homes. The CMS Nursing Home Compare includes datasets with facility-level data derived from administrative data routinely collected by CMS from all active nursing homes (currently 15,691 nursing homes) in the United States.

We plan to explore adapting a process similar to the modeling approach used for the CDC 2011 hospital prevalence survey data (2). First, data from the approximately 200 NHs (or 15,000 nursing home residents) in the survey will be used to determine HAI prevalence and identify predictors of HAI prevalence in those locations. Second, we will explore development of a model that incorporates the relevant HAI predictors for nursing homes (see part B for additional detail), HAI prevalence data from the survey will be used to calculate an estimated national HAI incidence. Finally, the number of nursing home residents with HAI nationally will be estimated-

by multiplying incidence by the number of U.S. nursing home residents obtained from CMS Nursing Home Compare.

As with the prior healthcare prevalence surveys conducted by CDC (1,2,3,6,7), this survey will be performed by CDC through the EIP (www.cdc.gov/ncezid/dpei/eip/). EIP is a collaboration between CDC and 10 state health departments and their academic partners, funded and organized by CDC, with the goal of conducting enhanced public health surveillance and applied research to detect, prevent, and control emerging infectious diseases (8).

CDC will solicit expert advice at several stages of the development of this model. Of particular interest is obtaining advice from survey statisticians on how to characterize the potential representativeness of the 10 state health departments given that the risk factors are not being identified a priori. That input can be gathered before data collection has been completed. Specialists in healthcare related infection and nursing homes should be queried regarding the risk factors identified from the analysis of the nursing homes in these 10 states. Finally, before disseminating the estimate, CDC will have the final estimate and underlying methodology subject to independent expert peer review consistent with OMB's Information Quality Bulletin for Peer Review, including charge questions that elicit opinions on the strengths and weakness of the final model, thus informing CDC's characterization of the uses of the resulting estimates.

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

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 the prevalence of resistant pathogens are to estimate the burden, types, and causative organisms of HAIs and assess the nature and extent of antimicrobial use in U.S. healthcare facilities, and assess the nature and extent of antimicrobial use. The current national burden of HAIs and antimicrobial use in nursing homes in the United States is unknown. HAI burden was last estimated in a 2000 publication and based on data collected between 1978 and 1998 (9). The estimate of between 1.64 and 3.83 million infections per year (and causing 21,880 to 388,370 deaths), has continued to be cited for many years by scientists, public health officials, and policy makers. To illustrate, this estimate was used in the HHS National Action Plan to prevent HAIs: Chapter 8 Long Term Care Facilities (http://health.gov/hcq/pdfs/hai-action-plan-ltcf.pdf), despite the acknowledged limitations, due to an absence of more robust or contemporary national HAI data for nursing homes. New HAI national burden estimates are needed for public health priority setting, for policy-making purposes, and for communications with the public and other stakeholders. Understanding of the current HAI and antimicrobial use epidemiology are necessary for collaborations with partners in other parts of the world (the European Union, for example) and internally for state health departments and the CDC to identify surveillance and prevention priorities.

The results from this survey and the developmental work associated with modeling national HAI prevalence can be used in the following ways:

1) State health departments of participating EIP sites can share survey data with their HAI Committees to inform priority setting for public health initiatives to improve HAI prevention and antimicrobial use;
2) The CDC can use the survey results to inform further development of HAI and antimicrobial use surveillance for nursing homes in the NHSN Long-Term Care Facility Component
3) The CDC can use the survey results from the Healthcare Facility Assessment to evaluate uptake of CDC The Core Elements of Antibiotic Stewardship for Nursing Homes, a set of antibiotic stewardship activities designed for nursing homes, (see www.cdc.gov/longtermcare/prevention/antibiotic-stewardship.html)
4) 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) National HAI burden estimates generated using survey data can be used to update the estimates included in the Department of HHS National Action Plan to Prevent HAIs – Chapter 8: Long-term Care

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 the use of prevalence surveys. Without these surveys, knowledge of the entire spectrum of HAIs and antimicrobial use will not be gained. There are no other surveillance systems currently in the United States that can provide this information. In addition, the proposed data collection will be CDC's first large-scale attempt to evaluate antimicrobial use quality in the nursing home setting, and will contribute greatly toward understanding those agents or infections that should be the focus of local, state or national stewardship programs. No other large-scale, resident-level assessment of antimicrobial use is underway in US nursing homes.

3. Use of Improved Information Technology and Burden Reduction

The proposed data collection will be performed using either paper forms or a mobile tablet device. It is necessary to permit data collection using paper forms because survey personnel may not have reliable or timely access to computers or the internet, as information technology resources vary widely among nursing homes.

As part of the proposed data collection, nursing home staff will complete a Healthcare Facility Assessment (HFA) (Attachment C), a questionnaire that will be completed on a one-time basis by staff from participating nursing homes. EIP personnel will provide the HFA and written instructions to nursing home staff either in person or via electronic communication (e-mail). 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 nursing home 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 data management system for sharing with CDC.

Selected nursing home staff (referred to as the NH Team) may additionally complete the Residents by Location Form (see Attachment D), a data collection instrument in a table format where each row represents a nursing home resident and each column representing the data element (variable) to be collected. EIP personnel will provide a sufficient number of Resident by Location Forms to ensure every licensed bed in each nursing home is included, and written instructions to the NH team either in person or via e-mail. The form format, previously used by European CDC for their long-term care surveys and for the CDC pilot nursing home survey, enables efficient collection of resident-level demographic and basic clinical information while participants of the NH team are completing their routine resident-care duties (e.g., nursing rounds). Provided a suitable WiFi internet connection is available at the nursing home, the data for this form can be collected with a CDC-developed database, such as REDCAP, loaded onto a mobile tablet device. EIP personnel will provide tablet devices for temporary use by nursing home staff for survey data collection activates and will be returned upon completion of data collection. Data collected via a tablet device will be entered directly into the database, and enable the use of data entry edits, checks and skip patterns to reduce errors and make data entry more efficient. The option for NH team data collection using a paper form is also available.
All data collected on paper forms will be entered by EIP site personnel into a CDC-developed database such as REDCAP or a CDC-developed, web-based, electronic data management system. No personal identifiers such as resident 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.

4. Efforts to Identify Duplication and Use of Similar Information

CDC's NHSN [OMB Control No. 0920-0666] Long-term Care Facility Component, released in September 2012, is not designed to estimate the scope and magnitude of all types of HAI that occur in nursing home residents; rather, it focuses on specific types of infections, such as urinary tract infections (http://www.cdc.gov/nhsn/about.html), and infections due to specific types of organisms (e.g., *Clostridium difficile* infection, methicillin resistant *staphylococcus aureus*). Reporting of antimicrobial use data to NHSN is available for hospitals (www.cdc.gov/nhsn/acute-care-hospital/aur/index.html), but not for nursing homes, as this surveillance requires the use of electronic medication administration record (eMAR) and/or bar coding medication record (BCMA) and submission of data using Clinical Document Architecture. In its current form NHSN cannot provide estimates of all types of HAI nor antimicrobial use for nursing homes.

Measurements of the magnitude and types of HAIs and nature and extent of antimicrobial use occurring across all healthcare settings 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 can be obtained in prevalence surveys. Prevalence surveys have been conducted in long-term care

facilities or nursing homes in several European countries (4, 5) and in U.S. Veterans Affairs facilities in recent years (10,11,12). There are currently no duplicate efforts in general (e.g., non-VA facilities) nursing homes underway in the United States.

Other CDC systems that have the capability of collecting information on infections in nursing homes include the National Nursing Home Survey (NNHS), run by the National Center for Health Statistics (NCHS). However, the NNSH was last conducted in 2004 (www.cdc.gov/nchs/nnhs.htm). We in the Division of Healthcare Quality Promotion (DHQP) collaborated with NCHS staff to generate and publish in the peer reviewed literature estimates of infection prevalence in various U.S. long-term care settings, including nursing homes (13). While useful, these estimates were of all infections, not those that are "healthcare-associated," because the data collected did not permit us to distinguish between infections that had their on-set in the nursing home from those present at the time of nursing home admission (e.g., after discharge from hospital). In 2012, the NNHS was replaced by the biennial National Study of Long-Term Care Providers (NSLTCP, www.cdc.gov/nchs/nsltcp/about_nsltcp.htm). However, in order to meet the goal of monitoring continual changes occurring in the long-term care field in a time of increasingly limited resources, the NSLTCP does not perform any primary data collection in nursing homes, and relies on existing administrative data obtained from other federal agencies (i.e., the Centers for Medicare & Medicaid Services (CMS)). This was confirmed in consultation with Dr. Lauren Harris-Kojetin, Chief of the Long-term Care Statistics branch (LTCSB) at NCHS, and prompted discussion on identifying future opportunities for collaboration NCHS (Attachment I). We will continue to work with staff of the LTCSB to explore opportunities to share data collection platforms in the future, as well as to understand the sample of nursing home for the current prevalence survey.

CMS, the federal agency responsible for oversight and regulation of U.S. nursing homes, routinely collects large amounts of nursing home resident and facility-level data for programs such as the Nursing Home Prospective Payment System and the Nursing Home Quality Initiative. All persons (regardless of payer) who reside in a Medicare or Medicaid-certified nursing facility must have a resident assessment, via the Minimum Data Set (MDS), completed. The MDS uses a variety of data sources, including resident interviews and medical records, to capture information on clinical diagnoses, medication, physical and cognitive functioning, mood, and resident preferences in diet and activities. Electronic MDS assessment data are available from approximately 16,000 nursing homes for approximately 3 million individuals who reside in nursing homes each year. The MDS collects substantial resident-level data, including (in Section I of the MDS 3.0: Active diagnoses) information on selected infections, including urinary tract infection, pneumonia, septicemia, tuberculosis, viral hepatitis, and also if the resident used antibiotics in the seven days prior to the assessment. However, the MDS was not designed for the collection of data for HAI surveillance purposes, with the major limitation being that no standardized infection definitions are used. Additionally, some MDS measures may apply only to long-stay or short-stay NH residents, and not all residents; the look back periods for the measures differ, and the time between resident MDS assessments varies. These points are illustrated with the MDS urinary tract infection and urinary catheter use measure in the HHS National Action Plan to prevent HAIs: Chapter 8 Long Term Care Facilities (http://health.gov/hcq/pdfs/hai-action-plan-ltcf.pdf). Collectively, these

factors make the MDS unsuitable to describe epidemiology and estimate the prevalence of HAIs and antimicrobial use among US nursing home residents.

Importantly, to reduce the public burden of data collection, we will make use of publicly available CMS data. The CMS Nursing Home Compare website (www.medicare.gov/NursingHomeCompare/About/Nursing-Home-Info.html) includes datasets with all active nursing homes containing information including nursing home state and county, ownership type (e.g., For profit, not-for profit, Government), number of certified beds, occupancy, staff-to-resident ratios for nursing staff and other para-professionals, and various healthcare quality measure scores derived by CMS. EIP staff will, therefore, be able to use data available from the CMS Nursing Home Compare to obtain descriptive characteristics about NHs included in the sample would otherwise need to be collected from NH staff as part of survey process.

5. Impact on Small Businesses or Other Small Entities

Small nursing homes 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 assist with or perform most 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 3/11/2016, volume 81, No. 48, page 12900-12901. (Attachment B). No comments were received.

B. Efforts to consult outside the agency include contact with the following individuals:

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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 the Privacy and Confidentiality of Information Provided by Respondents

This information collection request has been reviewed by NCEZID who has determined that the Privacy Act does not apply. Patient (i.e., nursing home resident) and healthcare facility data will be collected on either paper forms or mobile tablet devices from existing sources of information, including electronic and paper medical records, healthcare facility information systems in use at the nursing home, or from existing publically available datasets. Data collected will be entered into a data management system, such as REDCap, or a CDC-developed, web-based, electronic data management system. Data collection and data entry partners will include local healthcare facility staff (e.g., Director of Nursing, Infection Prevention and Control Officer, and other staff working in their own facilities) and EIP site personnel (local and state public health professionals, and their academic collaborators). Data will be transferred between each EIP site and CDC securely, for example, through a CDC-established, Secure Access Management System (SAMS) or encrypted File Transfer Protocol (FTP) site. CDC staff will download site-specific databases from the SAMS or FTP site and merge them for analysis purposes. EIP sites will have access to data submitted from facilities within their catchment areas. The information in the CDC database will be maintained indefinitely for comparison purposes, since this data collection will be repeated at regular intervals. Information in identifiable form (potentially including name, 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. 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 (i.e. nursing home resident) data.

Healthcare facility information will be collected using the “Healthcare Facility Assessment” (HFA) (Attachment C1). It includes information regarding the numbers of facility beds, services provided, types of selected staff members in the facility, and information about facility infection control and antimicrobial stewardship resources, policies and practices. EIP personnel will also obtain publicly available healthcare facility information from CMS Nursing Home Compare datasets (available at https://data.medicare.gov/data/nursing-home-compare), as outlined on the EIP HFA (Attachment C2). Attachment C2 is provided as supplemental information only; the EIP data collection is not part of the public burden (see Section 14).

Patient-level data will be collected through review of medical records and nursing home documentation and by direct observation, for example to confirm the presence of medical devices (e.g., ventilator use). Residents will not be interviewed. If resident data is collected by the EIP team instead of NH team, EIP team members will not directly observe residents but may consult with NH team members on nursing units to confirm information (such as the presence of medical devices). Three forms will be used collect resident-level data including the “Residents

by Location Form" (RLF), 'Resident Antimicrobial Use Form (RAU)" and the "Resident Infection Form" (RIF). Most of the data collection will be completed by EIP personnel and is not part of the public burden.

The NH Team may participate in collection of data on the RLF (see Attachment D; example of draft instructions provided in Attachment E). Information from the RLF that is transmitted to CDC includes: state, data collection date, resident care location, unique resident identification code, nursing home admission date, resident demographic information (age, gender, race, ethnicity), presence of selected clinical conditions or medical care (diabetes, receiving dialysis, mobility, pressure ulcers, and receiving wound care), presence of medical devices (urinary catheter, central line, ventilator), and whether the resident was on antimicrobial therapy or had signs or symptoms suggested of an infection.

The EIP Team is responsible for completing the RAU and RI forms (Attachments F1 and F2). Data collection pertaining to HAIs includes specific signs and symptoms related to the presence of HAIs, onset dates, microbiology, diagnostic and laboratory testing performed and the results, including causative pathogens and antimicrobial susceptibility of those pathogens. Data collection pertaining to antimicrobial use includes drug names, route of administration, dose information, start dates, indication or rationale for use, and therapeutic sites. Attachments F1 and F2 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 Attachments C2, F1 and F2 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 admission date, survey 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 (or resident) identifiers, such as name or medical record number, will not be transmitted to CDC. Each resident will be assigned a unique identification code that will not contain identifying information. CDC will know the names of the nursing homes that agree and do not agree to participate in the information collection. EIP personnel will be able to link facility identification codes with facility names, but CDC will not have these linkages. Local data collectors in participating nursing homes and EIP personnel will need to collect information in identifiable form (IIF) for nursing home residents within their own facility or catchment area, such as room number and name or medical record number. This information will not be transmitted to CDC.

Data will be treated in a secure manner, and will not be disclosed, unless otherwise compelled by law. A unique identification code will be assigned to each resident included in the survey. These codes will not include patient (i.e., nursing home resident) identifiers. The codes will be linked at the facility level and EIP site level to the individual resident 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 nursing homes within EIP 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 the resident 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 (e.g., bed size, etc.) or resident characteristics (e.g., presence of devices) are associated with aspects of HAI prevalence or antimicrobial use. 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 collected during the survey 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 and reducing infection caused by antibiotic resistance organisms is a priority of CDC and other federal agencies (see the 2015 Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (CARB) initiative www.hhs.gov/ash/carb/. This prevalence survey will provide estimates of the magnitude and burden of HAIs in a large sample of U.S. nursing homes, 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. Sensitive information being collected includes information race and ethnicity, information on the presence of HAIs and appropriateness of antimicrobial use. Data will be entered into the electronic data management system and retrieved by CDC using identification codes that do not contain patient (resident) identifiers. CDC will analyze and report aggregated data obtained during the data collection. The 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. Individual healthcare facilities may also request their own results from EIP sites and use the data to inform institution-level practice and policy.

Nursing homes selected to participate in the data collection are informed that participation is voluntary. Individual nursing home residents are not the respondents for this data collection, and are not informed of their inclusion in the data collection. There is no interaction between EIP or CDC personnel and individual nursing home residents. 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. 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.

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

Institutional Review Board (IRB)
The protocols and tools used to conduct this information collection request have been reviewed and approved by NCEZID's Human Subjects Advisor, who determined that this data collection

does not meet the definition of research under 45 CFR 46.102(d). IRB review is not required (Attachment G).

Justification for Sensitive Questions
Information on criminal behavior, sexual behavior and attitudes, alcohol or drug use, and religious beliefs, will not be collected. Race and ethnicity will be collected, in accordance with federal standards, by nursing home staff or 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.

The reporting of adverse events occurring in nursing home residents, including infections, could be considered sensitive unless participating 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. The Director of Nursing, Infection Control and Prevention Officer, 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 2017, 2) participate in training for the 2017 survey, and 3) collect survey data on nursing home residents, limited to basic demographic and clinical information on the Residents by Location Form.

   For the Healthcare Facility Assessment (Table A), respondents will be Director of Nursing or Infection Control and Prevention Officer (or other designated healthcare facility staff). We anticipate up to a total of 200 respondents, one for each participating facility, who will complete the assessment one time for the survey. Based on knowledge gained from the CDC hospital survey and the CDC pilot nursing home survey, the time required to complete the assessment is estimated to be 45 minutes.

   For the training and Residents by Location Form completion burden on nursing home staff in participating facilities (Table A), we incorporated knowledge gained from the conduct of the CDC pilot nursing home survey. Please note: throughout this Information Collection Request, any reference to number of residents surveyed or included in the survey should be interpreted to mean the number of residents' medical records that are reviewed/included in the survey; it does *not* mean that residents are actually being interviewed or interacted with directly. This is made clear in Section 1.1, "Resident data will be collected through review of medical records. Residents will not be interviewed." Therefore, the total number of records reviewed was estimated as follows: [(200 facilities)* (2 respondents per facility)*(38 resident records) = 15,000 resident records], which translated to an average of 75 responses per respondent. The time required to participate in training and data collection to complete the RLF is estimated to be 20 minutes.

Table A: Estimated Annualized Burden Hours

Type of	**Form**	**Number of**	**Number of**	**Average**	**Total**

Respondent	Name	Respondents	Responses per Respondent	Burden per Response (in hours)	Burden Hours
Director of Nursing, Registered Nurse, Infection Control and Prevention Officer	Healthcare Facility Assessment	200	1	45/60	150
Registered Nurse	Residents by Location Form	200	38	20/60	2,533
Licensed Practical or Licensed Vocational Nurses		200	38	20/60	2,533
Total					**5,217**

B. The total cost burden in participating nursing homes is estimated as follows: With a total annual burden of 5,217 hours, the total cost of the time to respond to the proposed survey is estimated to be $136,430.24 (Table B). We have utilized the mean hourly wage for a Medical Health Services Manager in the Nursing Care Facilities (Skilled Nursing Facility) industry, $41.22, obtained from the Bureau of Labor Statistics, National Industry-Specific Occupational Employment and Wage Estimates (accessed February 08, 2015 at http://www.bls.gov/oes/current/oes119111.htm). We utilized this wage because: 1) the Director of Nursing or Infection Control and Prevention Officer are Registered Nurses with additional program and/or staff management and administrative duties; and 2) there is no wage information specifically for Director of Nursing or Infection Control and Prevention Officer available in the Bureau of Labor Statistics database cited above. The collection of data for the Resident by Location Form is expected to be shared among Registered Nurses and Licensed Practical or Licensed Vocational Nurses within the nursing home. We utilized the mean hourly wage for Registered Nurse, $30.02, and in the Nursing Care Facilities (Skilled Nursing Facility) industry, $30.02 and for Licensed Practical and Licensed Vocational Nurses, $21.39 obtained from the Bureau of Labor Statistics, National Industry-Specific Occupational Employment and Wage Estimates (accessed February 08, 2015 at http://www.bls.gov/oes/current/oes119111.htm and http://www.bls.gov/oes/current/oes292061.htm).

Table B: Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent

				Cost
Director of Nursing, Infection Control and Prevention Officer	Healthcare Facility Assessment	150	$41.22	$6,183.00
Registered Nurse	Residents by Location Form	2533.5	$30.02	$76,055.67
Licensed Practical or Licensed Vocational Nurses		2533.5	$21.39	$54,191.57
Total				$136,430.24

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, and costs for photocopying survey materials.

CDC personnel working on the data collection are estimated to include a 0.5 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 $35.63 (obtained from the Bureau of Labor Statistics, Occupational and Employment Statistics data, available at http://www.bls.gov/oes/current/oes191041.htm), for a total cost of $37,055.20. The mean hourly wage for a database administrator is $39.56 (obtained from the Bureau of Labor Statistics, Occupational and Employment Statistics data, available at: http://www.bls.gov/oes/current/oes151141.htm), for a total cost of $16,456.96 for a database developer and $16,456.96 for a database manager.

EIP sites (see Row #4 of Table C) are supported through a Cooperative Agreement with CDC. For the prior CDC prevalence surveys in hospitals [2015 survey OMB Control No. 0920-0852, expiration date 12/31/2016], EIP personnel (and therefore, the forms included in Attachments C2, F1 and F2) were not included in the annualized public burden estimate, but 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 $35.63 (obtained from the Bureau of Labor Statistics, Occupational and Employment Statistics Section 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 $1,111,656.12

Review time for each record on average (including time to fill out the RAUF and RIF for a limited number of records (approximately 25%)) is estimated to be 30 minutes, including time to account for training and other survey-related activities. Based on experience from previous surveys, 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 $187,500. We estimate an additional $100,000 for coordination and travel- and supply-related expenses. The total estimated cost of this contract is therefore $287,500. If one data collection is conducted during the 3-year approval period, the annualized cost of the contract is therefore $287,500 divided by 3, or $95,833.33.

There will also be costs related to photocopying of forms and instructions. The cost is estimated to be $5,000 ($0.05 to copy each page, estimated 100,000 copies made to support survey activities in 200 facilities in 10 EIP sites). If one data collection is conducted during the 3-year approval period, the annualized cost is $5,000 divided by 3, or $1,666.67.

The total annualized cost to the federal government for personnel and photocopying is therefore estimated to be $1,183,291.79.

Table C: Annualized cost to the federal government

Government Employee Title	Total Number of Hours Dedicated per Year	Hourly Rate	Total
CDC epidemiologist	1,040	$35.63	$37,055.20
Database developer	416	$39.56	$16,456.96
Database manager	416	$39.56	$16,456.96
EIP epidemiologists (1.5 FTE in each of 10 sites)	31,200	$35.63	$1,111,656.00
Photocopying	--	--	$1,666.67
Total			**$1,183,291.79**

15. Explanation for Program Changes or Adjustments

None. This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

A resident-level surveillance dataset will continue to be maintained at CDC. This dataset will be used to determine HAI 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 3.01 (or newer versions as they become available). This survey will use the most up-to-date infection surveillance definitions used in the nursing homes, and by the European CDC for the surveys in long-term care facilities, “Surveillance Definitions for Infections in Long-Term Care Facilities” (also known as the revised McGeer

criteria) published in 2012 by The Society for Healthcare Epidemiology of America and endorsed by CDC (14). Categorical and continuous variables will be compared in residents with and without HAIs and in residents receiving and not receiving antimicrobials using chi-square tests and Wilcoxon rank-sum or median tests, respectively. Associations between resident 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 based on that from Rhame and Sudderth (15), as outlined in Section A1 and Statement B. HAI and antimicrobial use burden estimates will be generated using prevalence survey data and data from the Minimum Dataset (MDS), Nursing Home Compare database, and the Certification and Survey Provider Enhanced Reporting (CASPER) from the CMS.

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**
Training of staff in participating nursing homes	Within 1-4 months after OMB approval
Conduct of survey	Within 4-9 months after OMB approval
Data collection by EIP personnel	Within 6-15 months after OMB approval
Transmission of all survey data to CDC	Within 18 months after OMB approval
Analysis and presentation of results	Within 18-30 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
B. 60-day Federal Register Notice
C. Healthcare Facility Assessment (HFA)
    1. HFA - Nursing Home
    2. Supplemental Information: HFA Variables - EIP
D. Residents by Location Form
E. Instructions for Residents by Location data collection (draft example)
F. Supplemental Information: Data collection performed by EIP personnel, but not part of the public burden
    1. Resident Infection Form
    2. Resident Antimicrobial Use Form
G. IRB determination letter
H. Informational document for Nursing Homes
I. Correspondence between National Center for Health Statistics Long-Term Care Branch Chief and Division of Healthcare Quality Promotion Branch Chief