Emerging Infections Program (0920-0978)

Revision

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SUPPORTING STATEMENT PART A: Justification

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- Emerging Infection Program (EIP): Population-based surveillance via active, laboratory case finding is used for detecting, identifying, and monitoring emerging pathogens. The estimates of the infection incidence generated by this collection provide the foundation for a variety of epidemiologic studies to explore risk factors, spectrum of disease, and prevention strategies.
- This ICR includes four collections:
  - Active Bacterial Core surveillance (ABCs): active population-based laboratory surveillance for invasive bacterial diseases;
  - Foodborne Diseases Active Surveillance Network

A. Justification

1. Circumstances Making the Collection of Information Necessary

A three-year OMB clearance revision is requested for "Emerging Infections Program (EIP) OMB No. 0920-0978."

A revision is being submitted to make existing forms clearer and to add several new forms: ABCs Semi-CAS Infection Supplemental Form, HAIC Multi-site Gram-Negative Bacilli Case Report Form for Carbapenem-resistant Pseudomonas aeruginosa (CR-PA), HAIC Multi-site Gram-Negative Surveillance Initiative – Extended-Spectrum Beta-Lactamase-Producing Enterobacteriaceae (MuGSI-ESBL), HAIC Invasive Methicillin-sensitive Staphylococcus aureus (MSSA), and HAIC Candidemia Case Report Form. These forms will allow the EIP to better detect, identify, and monitor emerging pathogens. The estimates of the infection incidence generated by this collection provide the foundation for a variety of epidemiologic studies to explore risk factors, spectrum of disease, and prevention strategies.

The Emerging Infections Programs (EIPs) are population-based centers of excellence established through a network of state health departments collaborating with academic institutions; local health departments; public health and clinical laboratories; infection control professionals; and healthcare providers. EIPs assist in local, state, and national efforts to prevent, control, and monitor the public health impact of infectious diseases. Clearance approval for 3 years is sought under this request.

Activities of the EIPs fall into the following general categories: (1) active surveillance; (2) applied public health epidemiologic and laboratory activities; (3) implementation and evaluation of pilot prevention/intervention projects; and (4) flexible response to public health emergencies.

Activities of the EIPs are designed to: (1) address issues that the EIP network is particularly suited to investigate; (2) maintain sufficient flexibility for emergency response and new problems as they arise; (3) develop and evaluate public health interventions to inform public health policy and treatment guidelines; (4) incorporate training as a key function; and (5) prioritize projects that lead directly to the prevention of disease.

Activities in the EIP Network to which all applicants must participate are:

- Active Bacterial Core surveillance (ABCs): active population-based laboratory surveillance for invasive bacterial diseases.
- Foodborne Diseases Active Surveillance Network (FoodNet): active population-based laboratory surveillance to monitor the incidence of select enteric diseases.
- Influenza: active population-based surveillance for laboratory confirmed influenza-related hospitalizations.
- Healthcare-Associated Infections-Community Interface (HAIC) surveillance: active population-based surveillance for healthcare-associated pathogens and infections.

Table A.1 Listing of all Activities and subprojects included in this ICR package

Activity	Surveillances/Projects
ABCs	ABCs Surveillance
	ABCs H. Influenzae Neonatal Sepsis Expanded Surveillance (HiNSES)
	ABCs Invasive Pneumococcal Disease in Children Surveillance
	ABCs Neonatal Infection Expanded Tracking
	ABCs Surveillance Non-Invasive Pneumococcal Pneumonia Surveillance (SNiPP)
	ABCs Severe GAS Infection Form
FoodNet	FoodNet Active Surveillance
	Hemolytic Uremic Syndrome (HUS) Surveillance
Influenza	Influenza Hospitalization Surveillance Network (FluSurv-NET)
HAIC	*C. difficile* Infection (CDI) Surveillance
	Invasive *Candida* Infections Surveillance
	Invasive Methicillin-resistant Staphylococcus aureus (MRSA) Surveillance
	Invasive Methicillin-sensitive Staphylococcus aureus (MSSA)
	Multi-site Gram-Negative Surveillance Initiative (MuGSI-CRE/CRAB)
	Multi-site Gram-Negative Surveillance Initiative – Carbapenem-resistant *Pseudomonas aeruginosa* (MuGSI-CR-PA)
	Multi-site Gram-Negative Surveillance Initiative – Extended-Spectrum Beta-Lactamase-Producing Enterobacteriaceae (MuGSI-ESBL)

Information in Identifiable Form (IIF) will be collected by each EIP site, and selected identifiers (such as name or medical record number) will be removed prior to its transmission of data to CDC. Please refer to section A.10 for further description of the process for removing selected identifiers from data. Other information that may be collected could include hospitalization history, lab test results and culture information, symptoms, discharge diagnosis, antimicrobial treatments, ICD-9 or ICD-10 codes, healthcare worker status, influenza vaccination status, and underlying medical conditions. Information transmission occurs via a secure CDC website. The case report form does not involve web-based data collection methods, although case report form data are entered into a CDC-developed, approved web-based data management system for some activities, and does not refer respondents to websites.

This program is authorized under the Public Health Service Act Sections 301(a)[42 U.S.C. 241(a)], 317(k)(1)[42 U.S.C. 247b(k)(1)], and 317(k)(2)[42 U.S.C. 247b(k)(2)], as amended (Attachment 1).

2. Purpose and Use of Information Collection

ABCs data is critical for documenting disease burden, describing the epidemiology of these bacterial pathogens, detecting emerging infections and epidemics, tracking trends in antimicrobial resistance, contributing to the development and evaluation of new vaccines, developing and assessing public health prevention measures, and improving overall public health practice. ABCs is currently being used to evaluate the effectiveness of meningococcal and pneumococcal vaccines. ABCs data is also used to develop ACIP recommendations for use of bacterial vaccines in children, adolescents and adults. Surveillance data from ABCs is also used to evaluate non-vaccine interventions for invasive bacterial disease. Continuation of these activities is essential to reduce the burden of invasive disease due to these pathogens.

The Foodborne Diseases Active Surveillance Network (FoodNet) is the principal foodborne disease component of the Centers for Disease Control and Prevention's (CDC) Emerging Infections Program. FoodNet is a collaborative project among CDC, ten state health departments, the Food Safety and Inspection Service of the United States Department of Agriculture (USDA), and the Center for Food Safety and Applied Nutrition and Center for Veterinary Medicine of the United States Food and Drug Administration (FDA).

The objectives of FoodNet are to determine the burden of foodborne diseases in the United States; monitor trends in the burden of specific foodborne illnesses over time; attribute the burden of foodborne illnesses to specific foods and settings; and disseminate information that can lead to improvements in public health practice and the development of interventions to reduce the burden of foodborne illness. FoodNet was established in 1996 in five sites: Minnesota, Oregon, and selected counties in California, Connecticut, and Georgia. By 2004, the FoodNet surveillance area had expanded to include 10 sites; Connecticut, Georgia, Maryland, Minnesota, New Mexico, Oregon, and Tennessee, and selected counties in California, Colorado, and New York. In 2017, the surveillance area included 49 million persons (15% of the U.S. population).

FoodNet conducts population-based active surveillance for laboratory-confirmed infections of 9 pathogens and 1 condition commonly transmitted through food: including *Campylobacter*, *Cryptosporidium*, *Cyclospora*, *Listeria monocytogenes*, *Salmonella*, Shiga toxin-producing *Escherichia coli* (STEC), *Shigella*, *Vibrio*, *Yersinia* and hemolytic uremic syndrome (HUS) in residents of the FoodNet surveillance area. FoodNet collects standardized data elements from Connecticut, Georgia, Maryland, Minnesota, New Mexico, Oregon, and Tennessee and selected counties within California, Colorado, and New York. All of the pathogens included in FoodNet surveillance are notifiable conditions within the states and/or counties covered in the FoodNet surveillance area. The majority of data elements that are transmitted to the FoodNet program at CDC are collected as part of routine public health follow up at the state. Information is collected through chart review, patient interview, or directly from providers. FoodNet collects standard data elements for the 9 pathogens and has a case report form for HUS. All information is housed at the state level in state-specific data systems. An extract of the data is made monthly and transmitted to CDC. No individually identifiable information is collected at CDC, data are only identifiable at the state level.

The Centers for Disease Control (CDC), National Center for Immunization and Respiratory Diseases (NCIRD) is committed to achieving the "Healthy People 2020" goals of increasing immunization rates and reducing preventable infectious diseases. The Influenza Hospitalization Surveillance Network (FluSurv-NET) aligns with these goals and plays an integral role in protecting America's health. FluSurv-NET is used to obtain population-based surveillance data about laboratory-confirmed influenza-associated hospitalizations in children and adults. These data are used to characterize the burden of and risk factors for influenza-associated hospitalizations in several geographic locations in the United States. The results from this data collection assist the Influenza Division and the CDC in determining which groups are at increased risk for severe outcomes of influenza and in guiding public health interventions and vaccine recommendations.

The need for data on influenza impact in children was first highlighted during the 2003-2004 season when anecdotal reports of influenza-associated pediatric deaths and severe complications in otherwise healthy children emerged. When CDC launched an emergency response in December 2003, no systems were in place that could substantiate these anecdotal reports in a timely manner. To address this need, the available surveillance infrastructure of the Emerging Infections Program (EIP) was used to commence FluSurv-NET. In 2005, adult influenza surveillance was added to this platform. In 2006, data from FluSurv-NET were used by the Advisory Committee on Immunization Practices (ACIP) in its decision to expand the ages for which it recommended influenza vaccination from 6-23 month olds to 6- 59 month olds, and to evaluate influenza vaccine effectiveness based on these recommendations. FluSurv-NET data were used by the ACIP in its decision to expand influenza vaccination recommendations for all persons aged 6 months or older. The utility of these data was further underscored during the 2009 H1N1 pandemic. FluSurv-NET data were used to identify groups at highest risk for influenza-associated hospitalizations (e.g., pregnant women during the 2009 H1N1 pandemic), mathematically model the morbidity and mortality burden of the influenza pandemic, and provide data for several peer-reviewed journal articles describing seasonal and pandemic influenza among high risk groups in the population. The data collection network is part of the Emerging Infections Program (EIP), an established CDC-state-academic institution collaborative network which includes the states of California, Colorado, Connecticut, Georgia, Maryland, Minnesota, New Mexico, New York, Oregon, and Tennessee. Upon verification of an influenza positive laboratory result and confirmation of residence within the pre-defined FluSurv-NET catchment area, each FluSurv-NET site conducts data abstraction of the medical chart and laboratory report to complete the project's standardized case report form. Influenza vaccination status is an important piece of information that is used to evaluate the influenza vaccine program. To obtain as complete an influenza vaccine history as possible sites will use the following sources to collect this information: 1) review the patient's medical chart, 2) consult the state vaccination registry, 3) contact the patient's provider via fax or telephone and/or 4) contact the patient or their proxy. If providers and/or patients or proxies need to be contacted, a Consent Form and Provider Vaccination History Fax Form will be used to obtain influenza vaccination history.

The Healthcare-Associated Infections/Community Interface (HAIC) activity was launched in 2009. The HAIC projects include large-scale projects involving all 10 EIP sites that have their own OMB numbers as well as smaller-scale projects involving fewer than 10 EIP sites. The

HAIC activity is a collaboration between CDC and the 10 state health departments and academic partners of the EIP network, in California, Colorado, Connecticut, Georgia, Maryland, Minnesota, New Mexico, New York, Oregon, and Tennessee. Healthcare-associated infections (HAIs) are major threats to patient safety and public health in the United States. Elimination of HAIs is a U.S. public health priority. The HAIC activity contributes to the goal of eliminating HAIs through its mission to promote patient safety and healthcare quality by critically evaluating the epidemiology and public health impact of HAIs to understand emerging pathogens and populations-at-risk and to inform prevention interventions. The HAIC activity conducts population-based surveillance for urgent threats to patient safety, including *Clostridium difficile* infection (CDI), antibiotic-resistant Gram-negative bacilli, invasive *Candida* infections, and invasive *Staphylococcus aureus* infections.

The HAIC activity also conducts periodic HAI and antimicrobial use prevalence surveys under 0920-0852 (hospital survey, expiration 12/31/2019) and 0920-1165 (nursing home survey, expiration 02/29/2020)—these projects are not population-based surveillance, are methodologically distinct from 0920-0978, and were therefore not incorporated into 0920-0978 and will maintain their own OMB control numbers.

For HAIC activities included in 0920-0978, upon verification of a positive laboratory result, each EIP site conducts data abstraction of the medical chart and laboratory report to complete the standardized case report forms. HAIC data collection forms are used by sites during review of medical records to collect demographic and clinical information on laboratory-confirmed cases of CDI, resistant Gram-negative bacilli, invasive *S. aureus* infection, and invasive *Candida* infections. Each participating EIP site will destroy identifiers at the earliest opportunity, unless there is a public health or research justification for retaining the identifiers or they are required to by law.

Data collected through HAIC population-based surveillance have utility for the government, public health officials, healthcare facilities, and the public. The original purpose for reporting communicable diseases was to determine the prevalence of diseases dangerous to public health. However, collecting these data also provided the basis for planning and evaluating effective programs for prevention and control of infectious diseases. Current information on disease incidence is needed to study present and emerging disease problems. These data have served as the foundation for several important public health reports, including the major national CDC report entitled "Antibiotic Resistance Threats in the United States, 2013" (http://www.cdc.gov/drugresistance/threat-report-2013/index.html) and CDC Vital Signs reports on CDI and *Candida* (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6109a3.htm) and on carbapenem-resistant Enterobacteriaceae (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6209a3.htm). HAIC surveillance is unique in that it collects detailed data on all cases in the population under surveillance, including cases not associated with hospitalizations or other healthcare exposures, and because isolates of the pathogens under surveillance are submitted to CDC for molecular characterization that contributes to enhanced understanding of resistance and transmission.

3. Use of Improved Information Technology and Burden Reduction

For ABCs case report forms will be entered and maintained at each surveillance area. CDC will provide to each EIP site a Microsoft Access database that mirrors the data collection forms. Surveillance staff at each participating EIP site will enter data from the data collection form into the database. The computerized databases, with personal identifiers removed, will be transmitted to CDC by the fifth of every month. All of the forms included in this package will be submitted to CDC electronically. All data transfers to CDC take place via a secure CDC SAMS (secure access management services).

For FoodNet, data are housed in an electronic database at each site and an extract is transmitted to CDC once a month through PHIN messaging. In 2017, FoodNet developed a standardized message mapping guide and began transitioning data collection to an HL7 format. This will allow for more automated and timely data transmission while reducing staff burden at the sites. FoodNet data elements are incorporated into state case report forms. FoodNet collects standard data elements. FoodNet does not require states to administer a separate standardized questionnaires for routine surveillance data. It is up to the states to decide how best to collect the information required. Sites do complete a standardized case report form for HUS surveillance (Attachment 10).

For all laboratory-confirmed influenza cases, a standardized case report form is completed by surveillance officers using data obtained from medical record review. Due to the varied sizes of site catchment areas and differences in health care facilities' electronic reporting capabilities, it is not feasible to have an electronic reporting form at each site under surveillance. Therefore, data are often obtained from manually reviewing medical and laboratory charts. If influenza vaccine history is not noted in the medical chart or state vaccination registry, telephone and facsimile equipment will be used to contact primary care providers, and if necessary, the patient and/or proxy, to obtain vaccination information.

CDC provides each FluSurv-NET site a Microsoft Access database that mirrors the case report form. Surveillance staff at each participating EIP site enters data from the case report form into the database and submit the complete database, stripped of identifiers, to CDC weekly. Sites that do not use the CDC Access database use local systems which are modeled after the CDC Access database or adapted to meet CDC requirements for data collection and delivery. All data transfers to CDC take place via a secure CDC SAMS or CDC FTP site. At CDC, data from all sites will be concatenated and exported into SAS.

HAIC data for CDI, resistant Gram-negative bacilli, invasive *Candida* infections, and invasive *S. aureus* infections are collected by EIP site personnel on paper case report forms (Attachments 16-22). Case tracking information is entered into secure locally-housed case tracking systems for CDI and resistant Gram-negative bacilli; identifiable data (such as name, street address, medical record number) entered into these local systems are not shared with CDC. Case information (without identifiers such as name, medical record number, street address, etc.) from these local systems is then imported or transmitted via a secure web service into CDC-approved, web-based data management systems (including .NET and REDCap systems). Other case report form data for CDI, resistant Gram-negative bacilli, and invasive *Candida* infections are entered directly by EIP site personnel into these secure web-based systems. The databases used by EIP site personnel for capturing these surveillance data (including ESBLs) have Certification and

Accreditation by the Office of the CDC Chief Information Security Officer (OCISO) for compliance with current information technology security policies and procedures. Data on case patient census tracts are uploaded by EIP site personnel to site-specific, encrypted, secure CDC Secure Access Management Services (SAMS) or CDC File Transfer Protocol (FTP) sites for analysis by CDC project staff. For invasive *S. aureus*, case report forms are entered and maintained in each EIP site. CDC provides each EIP site with a Microsoft Access database that mirrors the data collection forms. Surveillance staff at each participating EIP site enter data from the data collection forms into the Access database. The databases, with personal identifiers such as name and medical record number removed, are transmitted to CDC by sites on a regular basis. All data from forms included in this package are submitted to CDC electronically. All data transfers to CDC take place via a secure CDC SAMS or CDC FTP site.

4. Efforts to Identify Duplication and Use of Similar Information

ABCs is the gold standard for the collection of population- and laboratory-based invasive bacterial disease data in the U.S. No other nationwide surveillance systems which monitor these diseases exist. While similar information may be collected on a sample basis or from a particular area of the country, for most diseases, sampling would not be sufficient for the states' need of conducting prevention or control programs. ABCs collect data from EIP sites in a uniform manner.

ABCs staff routinely attends local, national, and international conferences relevant to the pathogens of interest and communicates frequently with non-federal colleagues at universities and health departments, as well as colleagues within the government in order to prevent duplication of effort.

Much of the information collected by FoodNet (e.g. patient demographics and laboratory data) is already being collected as part of routine public health surveillance at the state level. FoodNet assembles this information in order to describe it on a national level and to assess changes in incidence over time. We allow sites to use their existing structure and databases to avoid duplicate data entry. All analyses of multi-site data must be proposed and approved by the FoodNet steering committee to avoid duplication of publications.

CDC epidemiologists conduct literature reviews continually to stay informed of the current knowledge-base of influenza. CDC staff also attends local, national, and international conferences relevant to the topic, and communicate frequently with non-federal colleagues at universities and health departments as well as colleagues within the government.

FluSurv-NET provides a unique information collection mechanism. No other system exists in which the breadth of demographic, medical, laboratory and epidemiologic are collected for hospitalized patients with laboratory-confirmed influenza. FluSurv-NET provides a critical set of data that are used to make influenza vaccination recommendations, mathematically model the overall burden of influenza morbidity and mortality, and enhance the understanding of severe influenza.

Due to the uniqueness of this system, the questions contained in the standardized case report form have not been taken directly from another survey. The demographic, clinical and

epidemiologic information is characteristic of the data routinely collected through public health surveillance.

HAIC surveillance for CDI, resistant Gram-negative bacilli, invasive *Candida* infections, and invasive *S. aureus* infections provides unique information not available through other systems, including detailed clinical and demographic data on all cases of infection, not limited to healthcare or hospital-associated cases, and isolates of the pathogens under surveillance for testing and molecular characterization. The National Healthcare Safety Network (NHSN, 0920-0666) receives data from U.S. healthcare facilities on CDI, and on selected infections due to *S. aureus*, *Candida*, and resistant Gram-negative bacilli. Data received by the NHSN are collected by healthcare facility staff rather than trained epidemiologists and are limited to healthcare-associated cases (i.e., community-associated infections and other infections not requiring hospitalization are generally not included). Unlike HAIC, NHSN does not have an isolate submission component, and patient-level data reported to NHSN are limited (e.g., no information on underlying conditions).

The EIP HAI and antimicrobial use prevalence surveys (0920-0852, 0920-1165) are cross-sectional "snapshots" of all HAIs attributable to acute care hospitals or nursing homes (not limited to specific types of infections reported to NHSN through prospective HAI surveillance or specific laboratory-identified pathogens reported through HAIC population-based surveillance). The surveys are conducted intermittently (e.g., approximately every 4 years in a specific healthcare setting). The survey is conducted throughout the entire facility in all eligible units, rather than being limited to specific unit types within the facility (as in NHSN), with a goal of defining the overall burden of HAIs as well as antimicrobial drug use in that specific healthcare setting.

5. Impact on Small Businesses or Other Small Entities

For all activities, the data collection itself will not impact small businesses because the burden of completing the case report form rests with the surveillance officers appointed by the states, not the hospitals where the cases are identified. However, in some sites, data collection is performed in cooperation with on-site medical personnel (e.g., Infection Control Practitioners or Medical Records Personnel). The impact on these facilities should be minimal, since the hospital has entered into an agreement with the State health department.

The data collection itself will not impact small businesses because the burden of completing the case report form rests with the surveillance officers appointed by the states, not the hospitals where the cases are identified. However, in some sites, data collection is performed in cooperation with on-site medical personnel (e.g., Infection Control Practitioners or Medical Records Personnel). The impact on these facilities should be minimal, since the hospital has entered into an agreement with the State health department.

6. Consequences of Collecting the Information Less Frequently

For ABCs and FoodNet, partnering state health departments submit data collection forms or standardized data elements to CDC on a monthly basis. Prompt notification to CDC allows for timely data analysis, tracking of the effects of prevention measures, and policy development.

Collecting data less frequently would result in a delay in analysis and subsequent reports and publications.

Respondents are required to submit FluSurv-NET data to the CDC on a weekly basis during influenza season (October 1-April 30). However, reporting frequency may vary, as some weeks during the seven-month influenza season might not include any influenza cases. It would not be appropriate to collect influenza surveillance data less frequently than weekly because the first step in the control of a given disease is its rapid identification followed by notification to the local health authority that a case of disease exists within a particular jurisdiction. In general, case reports are submitted as soon as possible after the investigation of a case. Prompt notification to CDC allows for identification of epidemics and outbreaks, so that immediate prevention measures can be taken. In order to lessen the burden of weekly reporting, respondents are required to submit as soon as possible data for only five variables on the case report form during influenza season. CDC requests the remaining variables to be completed and submitted by September 30.

HAIC EIP personnel will complete data collection on cases as they are identified from laboratory reports on an ongoing basis. Performing data collection on cases as they are identified (versus on a quarterly or annual basis) will allow for rapid classification of cases into epidemiologic categories (e.g. community-associated) and identification of epidemiologic changes, including rates and severity of disease in geographically diverse patient population segments over time. Linking these epidemiological changes to several important determinants of disease, including host susceptibility, practices in prescribing antimicrobials, infection control practices, or the emergence of more virulent strains, requires timely and consistent data collection.

There are no legal obstacles to reduce the burden.

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

For the reasons described in A.6 above, respondents are required to report information more often than quarterly (monthly). FluSurv-NET requires weekly reporting during the influenza season (October 1- April 30); however, reporting frequency will vary as some weeks during the influenza season might not include influenza cases. Surveillance reports are requested on a periodic basis to permit timely data analysis and prompt initiation of prevention and control measures.

As stated in A.6., delays in reporting could result in serious public health consequences. There are no other special circumstances relating to the guidelines of CFR 1320.5.

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

A. A 60-day Federal Register Notice was published in the Federal Register on December 21, 2017, Volume 82, No. 244, p. 60608. No comments were received.

B. ABCs and FoodNet are the gold standards for the collection of population- and laboratory-based bacterial disease data in the U.S. CDC conducts a conference call with site surveillance

officers to discuss surveillance-related issues monthly. CDC conducts conference calls with ABCs and FoodNet Principle Investigators to discuss bi-monthly and quarterly, respectively. . CDC also organizes the annual ABCs and FoodNet Steering Committee meetings with each site's Principle Investigators in attendance and an annual Site coordinator meeting which includes representatives from all sites. These meetings offer the opportunity to discuss ongoing projects and plan for future priorities.

Since FluSurv-NET's inception, consultation with sites has taken place at an annual meeting to address information collection activities. Additionally, monthly conference calls are held with site personnel to ensure that data collection is standardized, efficient and relevant.

CDC staff involved in the HAIC activity conducts quarterly conference calls with EIP site HAIC principal investigators and hold an annual in-person meeting at CDC with the principal investigators and other key participants to discuss progress and scientific direction for the activity. Regular calls are also held with EIP site and CDC project leads and coordinators to discuss progress and challenges for individual projects.

9. Explanation of Any Payment or Gift to Respondents

No payments or gifts will be provided to respondents. EIP sites, at their discretion, may provide resources to catchment area laboratories or healthcare facilities, for example, to enable or enhance isolate collection and submission.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

This submission has been reviewed by NCEZID who determined that the Privacy Act does not apply.

As a measure of EIP's data protection plan, the ABCs, FoodNet, Influenza, and HAIC activity utilizes data transfer methods that are password protected in order to protect the data. In addition to using the CDC FTP platform to transmit data, CDC and EIP sites also have the option to utilize the CDC SAMS platform to transmit data, if they prefer. CDC SAMS is a federal information technology system that gives authorized personnel secure access to non-public CDC applications through a highly secure and password protected and encrypted portal. The SAMS partner portal is a website designed to provide centralized access to public health information and computer applications operated by the CDC. Through this portal EIP sites and CDC are able to transfer data in a secure portal to keep data protected.

Names or other personal identifying information are not routinely collected by CDC on case report forms. There are no personal identifiers in the database submitted to CDC for any of the forms included in this package. Thus, the subjects whose charts are reviewed will not be able to be identified through data submitted to CDC; only the EIP site collecting the case information will be able to link personal identifiers with case information.

Each participating EIP site will destroy identifiers at the earliest opportunity, unless there is a public health or research justification for retaining the identifiers or are required to by law. Project paperwork maintained by each participating site will never be submitted to CDC and will remain in a locked, secure location, available only to a minimum number of local project staff,

and will not be reused or disclosed to any other person or entity except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted.

FoodNet surveillance is conducted by state health departments as part of routine public health surveillance and, as such, personnel at the state health departments collect personal identifiers (name, address, phone number) in order to conduct appropriate public health follow up of cases. Date of birth and a coded FoodNet ID field are transmitted to CDC; however, names, addresses and phone numbers are not. The code linking the FoodNet ID field to other personal identifier is maintained confidentially and securely with the state health department that reported the case; it is not shared with CDC. When surveillance data are requested for analysis by persons at CDC, state or federal partners (e.g. FDA or USDA), or others (e.g. students) an analytic dataset is provided that includes only the minimum number of variables required for the specified analysis; it does not include the FoodNet ID field.

There are no personal identifiers in the database submitted to CDC in the data collected for FluSurv-NET. Thus, the patients whose charts are reviewed will not be able to be identified through data submitted to CDC; only the FluSurv-NET site collecting the case information will be able to link personal identifiers with case information. Additionally, CDC will not have identifying information on patient health care providers. Each hospital where charts are abstracted will be given a numerical ID that can be linked to hospital name only by staff within individual surveillance areas.

Each participating FluSurv-NET site will destroy identifiers at the earliest opportunity, unless there is a public health or research justification for retaining the identifiers or they are required to by law. Project paperwork maintained by each participating site will never be submitted to CDC and will remain in a locked, secure location, available only to a minimum number of local project staff, and will not be reused or disclosed to any other person or entity except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted.

The HAIC activity conducts population-based surveillance for urgent threats to patient safety, including CDI, resistant Gram-negative bacilli, invasive *Candida* infections, and invasive *S. aureus* infections. As with ABCs surveillance described above, upon verification of a positive laboratory result and confirmation of residence within the pre-defined EIP catchment area, each EIP site conducts data abstraction of the medical chart and laboratory report to complete the standardized case report forms. HAIC data collection forms (Attachments 17, 19, 21, 22) are used by sites to review medical records and collect demographic and clinical information on laboratory-confirmed cases.

Each participating EIP site will destroy identifiers at the earliest opportunity, unless there is a public health or research justification for retaining the identifiers or they are required to by law.

Information in Identifiable Form (IIF) will be collected by each EIP site, and de-identified prior to its transmission to CDC. Other information that may be collected could include hospitalization history, lab test results and culture information, symptoms, discharge diagnosis, antimicrobial

treatments, ICD-9 and/or ICD-10 codes, healthcare worker status, influenza vaccination status, and underlying medical conditions. Information transmission occurs via a secure CDC website. The case report form does not involve web-based data collection methods, although case report form data are entered into a CDC-developed, approved web-based data management system for some activities, and does not refer respondents to websites.

For HAIC projects, personally identifying information such as names and addresses are not shared with CDC. Date of birth, race, gender, hospitalization dates and census tract information are shared with CDC. Only the EIP site collecting the case information will be able to link personal identifiers with case information. Each participating EIP site will destroy identifiers at the earliest opportunity, unless there is a public health or research justification for retaining the identifiers or are required to by law. Project paperwork maintained by each participating site will not be submitted to CDC and will remain in a locked, secure location, available only to a minimum number of local project staff, and will not be reused or disclosed to any other person or entity except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted.

Data collection for HAIC CDI cases (Attachment 16) includes state and county of residence, age, gender, date of birth, race/ethnicity, date of stool collection positive for *C. difficile*, location of stool collection (i.e. hospital inpatient, long term acute care hospital, long term care/skilled nursing facility, emergency room, or outpatient setting), hospitalization and date of admission, residency prior to stool collection (i.e. hospital inpatient, long term acute care hospital, long term care/skilled nursing facility, emergency room, or outpatient setting), hospital admission due to CDI, presence of other enteric pathogens in stool tested for CDI, exposures to healthcare (i.e. chronic hemodialysis, surgical procedure in the 12 weeks prior to stool collection, or emergency room visit in the 12 weeks prior to stool collection), patient outcome (patient survived and date of discharge or patient died and date of death), colectomy and date of procedure, intensive care unit (ICU) admission and date, CDI recurrence, radiographic findings (including toxic megacolon and ileus), presence of pseudomembranous colitis, clinical findings (including diarrhea and white blood cell counts), Charlson co-morbidity index components, medication used in the 14 days prior to illness onset (including antimicrobial therapy use, immunosuppressive therapy use, and use of proton pump inhibitors or H2 blockers), and CDI treatment information (Attachment 16). Healthcare facilities are identified by facility identification codes. These facility identification codes are assigned by EIP sites. Local data collectors at 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, address, telephone number, date of birth, and medical record number. With the exception of date of birth, this information will not be transmitted to CDC. CDI cases are also geocoded and census tract numbers are assigned; EIP site personnel strip out geocoded data (e.g., address, latitude, longitude), and the census tract number is shared with CDC. Unique identification codes not containing any patient identifiers are assigned by EIP sites to patients; CDC does not have access to linkages between patient name and patient identification code.

Data collected for the HAIC resistant Gram-negative bacilli surveillance (Attachment 20-22) are similar to those collected for CDI cases, and include variables such as state, county of residence, age, gender, date of birth, race/ethnicity, weight and height or body mass index, date of

collection of specimens positive for resistant Gram-negative bacilli, types of specimens, location of specimen collection, results of testing performed on the specimen (including pathogens isolated and antimicrobial susceptibility test results), residency prior to specimen collection, hospitalization data (including dates), underlying conditions, healthcare exposures and other risk factors for infection, signs and symptoms of infection, and patient outcome. For patients with the CR-PA and ESBLs selected resistant organisms, data collection, prior medications are also collected. As with CDI surveillance, healthcare facilities are identified by facility identification codes in the data collection forms. Local data collectors and EIP personnel will need to collect information in identifiable form (including information such as patient name, address, telephone numbers, date of birth, and medical record number), but this information (with the exception of date of birth) is not transmitted to CDC. Cases may also be geocoded and census tract numbers assigned; EIP sites will strip other data (e.g., address, latitude, longitude), and the census tract number will be shared with CDC. Unique identification codes not containing identifiers are assigned by EIP sites to patients; CDC does not have access to any linkages between patient name and patient identification code.as described above for CDI.

Data collected for the HAIC invasive S. aureus surveillance (Attachments 18, 19) are similar to those collected for CDI cases, and include variables such as state, county of residence, age, gender, date of birth, race/ethnicity, weight and height or body mass index, date of collection of specimens positive for S. aureus, types of positive specimens, location of initial specimen collection, results of antimicrobial susceptibility testing performed on the specimen (including pathogens isolated and antimicrobial susceptibility test results), residency prior to specimen collection, hospitalization and ICU admission data (including date of hospital admissions), underlying conditions, type of infection associated with the culture, healthcare exposures and other risk factors for infection, signs and symptoms of infection, and patient outcome. As with CDI surveillance, healthcare facilities are identified in the data collection forms by facility identification codes. Local data collectors and EIP personnel will need to collect information in identifiable form (including information such as patient name, address, telephone numbers, date of birth, and medical record number), but this information (with the exception of date of birth) is not transmitted to CDC. Cases may also be geocoded as described above for CDI. Cases may also be geocoded and census tract numbers assigned; EIP sites will strip other data (e.g., address, latitude, longitude), and the census tract number will be shared with CDC. Unique identification codes not containing identifiers are assigned by EIP sites to patients; CDC does not have access to any linkages between patient name and patient identification code.

Data collected for the HAIC Candidemia program (Attachment 17) are similar to those collected for CDI cases, and include variables such as state, county of residence, age, gender, date of birth, race/ethnicity, date of collection of specimens positive for resistant Gram-negative bacilli, types of specimens, location of specimen collection, results of testing performed on the specimen (including *Candida* species and antimicrobial susceptibility test results), residency prior to specimen collection, hospitalization data (including dates), underlying conditions, healthcare exposures and other risk factors for infection, signs and symptoms of infection, and patient outcome. As with CDI surveillance, healthcare facilities are identified in the data collection forms by facility identification codes. Local data collectors and EIP personnel will need to collect information in identifiable form (including information such as patient name, address, telephone numbers, date of birth, and medical record number), but this information (with the exception of date of birth) is not transmitted to CDC. Cases may also be geocoded and census

tract numbers assigned; EIP sites will strip other data (e.g., address, latitude, longitude), and the census tract number will be shared with CDC. Unique identification codes not containing identifiers are assigned by EIP sites to patients; CDC does not have access to any linkages between patient name and patient identification code.

Privacy Impact Assessment Information

1. Respondents are informed about the voluntary nature of their response.

2. For FluSurv-NET, consent forms are obtained from patients undergoing telephone interview for influenza vaccination history. Copies of the consent form will be retained at the participating site and will not be submitted to CDC. CDC only receives vaccine status information and does not receive any personally identifiable information.
   For the medical review component of HAIC, consent is not applicable as EIP personnel perform review of existing medical record data in participating facilities or via remote access and submit these data to CDC in a secure manner, as described previously, without having any interaction with individual patients. Information received by CDC are stored in secure databases (certification and accreditation at appropriate level according to current information security procedures and standards) or will be uploaded by EIP site personnel to site-specific encrypted, secure CDC FTP sites or other secure sites meeting current information security requirements. Case-specific information received by CDC will be provided only to those individuals at CDC with a need to know.

3. Project case report forms maintained by each participating site will not be submitted to CDC, and will remain in a locked, secure location, available only to a minimum number of local project staff, and will not be reused or disclosed to any other person or entity except as required by law, for authorized oversight of the surveillance project, or for other research for which the use or disclosure of protected health information would be permitted. Each participating EIP site will destroy identifiers at the earliest opportunity, unless there is a public health justification for retaining the identifiers or are required to by law.

4. This submission has been reviewed by NCEZID who determined that the Privacy Act does not apply.

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

IRB Approval

The data collection forms included in this package constitute public health surveillance and are not considered human subjects research. Therefore the protocols associated with the forms included in this package are not subject to IRB review.

Justification for Sensitive Questions

For ABCs, epidemiological characteristics such as age, race, sex, geographic location, etc., are collected only when these factors may produce health problems. Clinical and laboratory data are collected and analyzed with the purpose of contributing valuable knowledge to the field of public health.

For FoodNet, clinical and laboratory data are collected and analyzed with the purpose of contributing valuable knowledge to the field of public health. Data collected for FoodNet surveillance are not considered sensitive. However, persons can refuse to provide any information that they consider to be sensitive.

In FluSurv-NET, age and variables related to documentation of laboratory-confirmed influenza-associated hospitalization are of central importance to this study. Additional clinical and, underlying health conditions, influenza vaccination status, diagnosis with secondary bacterial co-infections, and ICU admission are necessary for determining rates of influenza-associated complications and factors associated with these complications. Questions about pregnancy, past medical history or chronic conditions are asked to clarify any risk factors for influenza or assess confounding factors of illness. Questions about race and ethnicity are asked in order to clarify risk factors for influenza and evaluate race and ethnicity in the context of influenza infection. All race and ethnicity questions meet OMB's minimum standards for collecting race and ethnicity information.

For HAIC surveillance, demographic and clinical data (including information on the presence of HIV/AIDS and other chronic conditions, smoking drug and alcohol use, and incarceration) are collected from medical records and analyzed with the purpose of contributing valuable knowledge to the field of public health. These data are collected to clarify risk factors for infection with important healthcare-associated pathogens.

12. Estimates of Annualized Burden Hours and Costs

For this revision, the total estimated burden is 40,347 hours. The previous approval (non-substantive change request approved 1/29/2018) was for an estimated annual burden of 22,090 hours.

A. **ABCs:** The total burden estimate for the ABCs collection activity is 3,528 hours and is shown in Table A.12-A1. ABCs Severe GAS Infection Supplemental Form is a new form with 453 hours of total burden. This form collects clinical and laboratory data to further characterize the severity of invasive group A *streptococcus* cases. The other ABC forms have minor changes, but no change to burden.

B. **FoodNet:** The total burden estimate for the FoodNet collection activity is 7,443 hours and is shown in Table A.12-A1. The changes made for this collection helps further characterize and determine the burden of foodborne illness. These changes are minor and do not impact the overall burden greatly.

C. **Influenza:** The total burden estimate for the Influenza FluSurv-NET collection activity is 5,001 hours and is shown in Table A.12-A1. The number of responses varies by influenza season and the current burden estimates are based on previous experience and feedback from stakeholders using these instruments. Burden changes include an increase in the number of responses from 400 to 1,000 on the Case Report Form to more accurately reflect the number of cases during the 2014-15 through 2016-17 influenza seasons. Influenza Hospitalization Surveillance Project Vaccination Phone Script Consent Form (English/Spanish) and the Influenza Hospitalization Surveillance Project Vaccination Phone Script (English/Spanish) have increases to the number of responses per respondent

from 100 to 333 to reflect the increase in the number of cases. The Influenza Hospitalization Surveillance Project Provider Vaccination History Fax Form (Children/Adults) is a new form with a total of 278 burden hours.

D. HAIC: In this revision package we wish to add four new collection tools associated with the HAIC portion of the EIP. Two new collection forms are being added as part of the Resistant Gram-negative Bacilli Surveillance: Surveillance for Extended-Spectrum Beta-Lactamase-Producing Enterobacteriaceae Multi-site Gram-Negative Bacilli Surveillance (MuGSI) and 2017-2018 Carbapenem-resistant *Pseudomonas aeruginosa* Multi-Site Gram-Negative Surveillance (MuGSI) Case Report. One new collection tool is being added for the invasive *Staphylococcus aureus* infection surveillance activity: Invasive Methicillin-Sensitive *Staphylococcus aureus* (MSSA) Healthcare-Associated Infections Community Interface (HAIC) Case Report-2018. The fourth new collection tool being added is the case report form for Invasive Candida Infections Surveillance. The total burden estimate for collection of all data elements for HAIC is 24,377 hours. Burden estimates are based on previous experience with collection of these data elements.

Table A.12-A1. Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of respondents	No. of responses per respondent	Avg. burden per response (in hours)	Total burden (in hours)
State Health Department	ABCs Case Report Form	10	809	20/60	2697
	ABCs Invasive Pneumococcal Disease in Children Case Report Form	10	22	10/60	37
	ABCs Surveillance for Non-Invasive Pneumococcal Pneumonia (SNiPP) Case Report Form	10	125	10/60	208
	ABCs *H.influenzae* Neonatal Sepsis Expanded Surveillance Form	10	6	10/60	10
	ABCs Severe GAS Infection Supplemental Form – NEW FORM	10	136	20/60	453
	ABCs Neonatal Infection Expanded Tracking Form	10	37	20/60	123
	FoodNet Campylobacter	10	850	21/60	2975
	FoodNet Cryptosporidium	10	130	10/60	217

	FoodNet Cyclospora	10	3	10/60	5
	FoodNet Listeria monocytogenes	10	13	20/60	43
	FoodNet Salmonella	10	827	21/60	2895
	FoodNet Shiga toxin producing E. coli	10	190	20/60	633
	FoodNet Shigella	10	290	10/60	483
	FoodNet Vibrio	10	25	10/60	42
	FoodNet Yersinia	10	30	10/60	50
	FoodNet Hemolytic Uremic Syndrome	10	10	1	100
	Influenza Hospitalization Surveillance Network Case Report Form	10	1000	25/60	4167
	Influenza Hospitalization Surveillance Project Vaccination Phone Script Consent Form (English)	10	333	5/60	278
	Influenza Hospitalization Surveillance Project Vaccination Phone Script Consent Form (Spanish)	10	333	5/60	278
	Influenza Hospitalization Surveillance Project Provider Vaccination History Fax Form (Children/Adults)	10	333	5/60	278
	HAIC CDI Case Report Form	10	1650	30/60	8250
	HAIC Multi-site Gram-Negative Bacilli Case Report Form *(MuGSI-CRE/CRAB)*	10	500	20/60	1667
	HAIC Multi-site Gram-Negative Bacilli Case Report Form for Carbapenem-resistant *Pseudomonas aeruginosa*(CR-PA) – NEW FORM	10	344	45/60	2580
	HAIC Multi-site Gram-Negative Surveillance Initiative – Extended-Spectrum Beta-Lactamase-Producing Enterobacteriaceae (MuGSI-ESBL) – NEW FORM	10	1200	20/60	4000
	HAIC Invasive Methicillin-resistant *Staphylococcus aureus* (MRSA)—previously listed under ABCs, now included in the HAIC activity	10	609	20/60	2030

	HAIC Invasive Methicillin-sensitive *Staphylococcus aureus* (MSSA) – NEW FORM	10	1,035	20/60	3450
	HAIC Candidemia Case Report Form – NEW FORM	9	800	20/60	2400
Total					40,347

B. The following table shows estimated burden costs associated with each instrument. The mean hourly wage for epidemiologists was used (https://www.bls.gov/oes/current/oes191041.htm).

Type of Respondent	**Form Name**	**Total burden hours**	**Hourly wage rate**	**Total respondent costs**
State Health Department	ABCs Case Report Form	2697	$37.37	$100,774.43
	ABCs Invasive Pneumococcal Disease in Children Case Report Form	37	$37.37	$1,370.23
	ABCs Surveillance for Non-Invasive Pneumococcal Pneumonia (SNiPP) Case Report Form	208	$37.37	$7,785.42
	ABCs *H.influenzae* Neonatal Sepsis Expanded Surveillance Form	10	$37.37	$373.70
	ABCs Severe GAS Infection Supplemental Form – NEW FORM	453	$37.37	$16,941.07
	ABCs Neonatal Infection Expanded Tracking Form	123	$37.37	$4,608.97
	FoodNet Campylobacter	2975	$37.37	$111,175.75
	FoodNet Cryptosporidium	217	$37.37	$8,096.83
	FoodNet Cyclospora	5	$37.37	$186.85
	FoodNet Listeria monocytogenes	43	$37.37	$1,619.37
	FoodNet Salmonella	2895	$37.37	$108,167.47
	FoodNet Shiga toxin producing E. coli	633	$37.37	$23,667.67
	FoodNet Shigella	483	$37.37	$18,062.17
	FoodNet Vibrio	42	$37.37	$1,557.08
	FoodNet Yersinia	50	$37.37	$1,868.50
	FoodNet Hemolytic Uremic Syndrome	100	$37.37	$3,737.00

	Influenza Hospitalization Surveillance Network Case Report Form	4167	$37.37	$155,708.33
	Influenza Hospitalization Surveillance Project Vaccination Phone Script Consent Form (English)	278	$37.37	$10,370.18
	Influenza Hospitalization Surveillance Project Vaccination Phone Script Consent Form (Spanish)	278	$37.37	$10,370.18
	Influenza Hospitalization Surveillance Project Provider Vaccination History Fax Form (Children/Adults)	278	$37.37	$10,370.18
	HAIC CDI Case Report Form	8250	$37.37	$308,302.50
	HAIC Multi-site Gram-Negative Bacilli Case Report Form for Carbapenem-resistant Enterobacteriacaea and *Acinetobactoer baumannii (MuGSI-CRE/CRAB)*	1667	$37.37	$62,283.33
	HAIC Multi-site Gram-Negative Bacilli Case Report Form for Carbapenem-resistant *Pseudomonas aeruginosa*(CR-PA) – NEW FORM	2580	$37.37	$96,414.60
	HAIC Multi-site Gram-Negative Surveillance Initiative – Extended-Spectrum Beta-Lactamase-Producing Enterobacteriaceae (MuGSI-ESBL) – NEW FORM	4000	$37.37	$149,480.00
	HAIC Invasive Methicillin-resistant *Staphylococcus aureus* (MRSA)	2030	$37.37	$75,861.10
	HAIC Invasive Methicillin-sensitive *Staphylococcus aureus* (MSSA) – NEW FORM	3450	$37.37	$128,926.50
	HAIC Candidemia Case Report Form – NEW FORM	2400	$37.37	$89,688.00

Total		$1,507,767.39

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

There are not costs to respondents other than their time.

14. Annualized Cost to the Federal Government

Estimated cost based on 2017 figures

Active Bacterial Core surveillance (ABCs) - Active population-based laboratory surveillance for invasive bacterial diseases

Table 14-1: Estimates of Annualized Costs to the Federal Government

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government	CDC Principal Investigator (0.8 FTE); CDC Surveillance Coordinator (0.8 FTE); Program Analyst (1.0 FTE), Data Manager (1.0 FTE)	350,000
	Subtotal, Direct Costs to the Government	350,000
Cooperative Agreement Expenses	California Site Cost and Fees	638,409
	Colorado Site Cost and Fees	629,781
	Connecticut Site Cost and Fees	711,556
	Georgia Site Cost and Fees	1,112,959
	Maryland Site Cost and Fees	1,226,107
	Minnesota Site Cost and Fees	1,384,433
	New Mexico Site Cost and Fees	751,779
	New York Site Cost and Fees	1,069,299
	Oregon Site Cost and Fees	793,550
	Tennessee Site Cost and Fees	1,092,127
	Subtotal, Contracted Services	9,410,000
	TOTAL COST TO THE GOVERNMENT	9,760,000

Foodborne Diseases Active Surveillance Network (FoodNet)

Table 14-2: Estimates of Annualized Costs to the Federal Government

Expense Type	Expense Explanation	

		Annual Costs (dollars)
Direct Costs to the Federal Government	CDC Principle Investigator (1.0 FTE); CDC Doctoral staff (2.0 FTE); CDC project Coordinator (1.0 FTE); CDC surveillance officers (5.0 FTE); CDC Technical research assistant (1.0 contractor); CDC Programmer (1.0 FTE contractor)	850,000
	Subtotal, Direct Costs to the Government	850,000
Cooperative Agreement Expenses	California Site Cost and Fees	582,048
	Colorado Site Cost and Fees	543,900
	Connecticut Site Cost and Fees	483,861
	Georgia Site Cost and Fees	738,442
	Maryland Site Cost and Fees	310,893
	Minnesota Site Cost and Fees	645,087
	New Mexico Site Cost and Fees	332,463
	New York Site Cost and Fees	549,537
	Oregon Site Cost and Fees	532,946
	Tennessee Site Cost and Fees	491,605
	Subtotal, Contracted Services	5,210,782
	TOTAL COST TO THE GOVERNMENT	6,060,782

Influenza - All Age Influenza Hospitalization Surveillance Project

Table 14-3: Estimates of Annualized Costs to the Federal Government

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government	CDC Project Officer (1.0 FTE); CDC Principle Investigator (0.8 FTE)	214,500
	Subtotal, Direct Costs to the Government	155,500
Cooperative Agreement Expenses	California Site Cost and Fees	601,046
	Colorado Site Cost and Fees	307,163
	Connecticut Site Cost and Fees	428,671

	Georgia Site Cost and Fees	373,245
	Maryland Site Cost and Fees	404,000
	Minnesota Site Cost and Fees	396,754
	New Mexico Site Cost and Fees	374,850
	New York Site Cost and Fees	696,142
	Oregon Site Cost and Fees	550,673
	Tennessee Site Cost and Fees	536,368
	Subtotal, Contracted Services	4,668,912
	TOTAL COST TO THE GOVERNMENT	4,824,412

Healthcare Associated Infections-Community Interface (HAIC)

Table 14-4: Estimates of Annualized Costs to the Federal Government

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government	CDC HAIC Director (1.5 FTE), Principal Investigators (3.48 FTE); CDC Surveillance Coordinators (3.37 FTE); Laboratory Scientists (6.3FTE); Data Manager (0.75 FTE); Business Analyst (0.5 FTE)	2,124,107
	Subtotal, Direct Costs to the Government	2,124,107
Cooperative Agreement Expenses	California Site Cost and Fees	693,421
	Colorado Site Cost and Fees	695,678
	Connecticut Site Cost and Fees	1,100,944
	Georgia Site Cost and Fees	908,109
	Maryland Site Cost and Fees	961,446
	Minnesota Site Cost and Fees	1,076,459
	New Mexico Site Cost and Fees	362,214
	New York Site Cost and Fees	786,703
	Oregon Site Cost and Fees	515,751
	Tennessee Site Cost and Fees	1,221,964
	Subtotal, Contracted Services	8,322,689
	TOTAL COST TO THE GOVERNMENT	10,446,796

Annualized Total Cost to the Federal Government	31,091,990

15. Explanation for Program Changes or Adjustments

This is a request for a revision. The majority of the collection activities remain the same, however, there are multiple proposed revisions including form consolidation, minor revised language and rewording to improve clarity and readability of the data collection forms and the discontinuation of the previously approved Legionellosis Expanded Case Report Form.

CDC is also requesting the use of 5 new forms: ABCs Severe GAS Infection Supplemental Form, HAIC Multi-site Gram-Negative Bacilli Case Report Form for Carbapenem-resistant *Pseudomonas aeruginosa* (CR-PA), HAIC Multi-site Gram-Negative Surveillance Initiative – Extended-Spectrum Beta-Lactamase-Producing Enterobacteriaceae (MuGSI-ESBL), HAIC Invasive Methicillin-sensitive Staphylococcus aureus (MSSA), and HAIC Candidemia Case Report Form. These forms will allow the EIP to better detect, identify, and monitor emerging pathogens. Details of each collection instrument for the revision is as follows:

ABCs Case Report Form

A non-substantive change request was OMB approved on 05/05/2017. In summary, that non-substantive change request included the addition of questions to capture information on cases with positive culture independent diagnostic tests (CIDTs), underlying conditions, and unknown checkboxes for several existing questions. This information is important to understand the changing diagnostic landscape for ABCs pathogens.

For this revision, the addition of response options to type of culture-independent diagnostic test used (for a positive test only), questions on whether an isolate was available for the case and if not available, why. Questions to collect additional information on substance abuse were added. These questions are important to understand the impact of the opioid epidemic on the disease burden for ABCs pathogens. These are minor changes and do not change the time expected to complete the case report form. There is not change to burden for this revision.

ABCs Invasive Pneumococcal Disease in Children Case Report Form

In May 2017, OMB approved a non-substantive change request that included updates to wording for vaccine history information being collected. For this revision, no change to content or burden.

ABCs Surveillance for Non-Invasive Pneumococcal Pneumonia (SNiPP) Case Report Form

In February 2016, OMB approved a non-substantive change request that included a title change for this form from “ABCs Non-Bacteremic Pneumococcal Disease Case Report Form” to “Non-invasive Pneumococcal Pneumonia (SNiPP) Case Report Form”. An increase in the number of responses per respondent changed from 100 to 125 was also approved at that time.

For this revision, no change to content or burden.

ABCs H. influenzae Neonatal Sepsis Expanded Surveillance Form (HiNSES)

A non-substantive change request was OMB approved on 05/05/2017. In summary, that non-substantive change request included addition to options for pregnancy outcome and unknown checkboxes for several date fields, addition of ICD9/10 codes. For this revision, changes were made to clarify wording on questions relating to culture collection to ensure clarity in collection of information for the group of interest. These are minor changes and do not change the time expected to complete the expanded surveillance form. There is not change to burden for this revision.

ABCs Neonatal Infection Expanded Tracking Form

A non-substantive change request was OMB approved on 05/05/2017. In summary, that non-substantive change request included addition of ICD10 codes to include capture of any streptococcal infection. For this revision, the only change is the addition of a question to capture the number of prior pregnancies. This is important to assess risk of mothers for acquiring this infection. This change is minor and does not change the time expected to complete the case report form. There is not change to burden for this revision.

ABCs Severe GAS Infection Supplemental Form

This is a new form. This form collects clinical and laboratory data to further characterize the severity of invasive group A *streptococcus* cases in addition to the data collected on the core ABCs case report form. The increase in burden represents an estimated total of 453 hours.

Legionellosis Expanded Case Report Form

In May 2017, OMB approved a non-substantive change request that included the discontinuation of the Legionellosis Expanded Case Report Form. Total burden was reduced by 333 total burden hours.

FoodNet Active Surveillance Case Report Form

A non-substantive change request was OMB approved on 05/05/2017. In summary, in this revision 3 variables were added to further characterize and capture antibiotic resistance in foodborne illness. The increase in burden represents an estimated total of 1,517 hours.

Hemolytic Uremic Syndrome Case Report Form

A non-substantive change request was OMB approved on 05/05/2017. In summary, that non-substantive change request added 3 new site-transmitted variables to our HUS case report form. In this revision no changes were made and there is no change to burden.

FluSurv-NET – Case Report Form

Multiple non-substantive change requests have been approved for the FluSurv-NET Case Report Form during 2015 and 2016. On 2/17/2015, OMB approved a non-substantive change that included additional data elements to be collected on patient residence, influenza test type, signs/symptoms, underlying medical conditions, and type of influenza vaccination.

On 3/2/2016, OMB approved a non-substantive change that included minor changes to better capture information regarding signs/symptoms at the time of admission, additional sign/symptoms commonly noted in the medical chart such as Fatigue/weakness and URI/ILI and an underlying medical condition variable Atrial Fibrillation. Burden hours remained the same for these non-substantive change requests.

For this revision, proposed revisions include minor revised language and rewording to improve clarity of the data collection form and additional of variables such as test type, substance abuse, disease, treatment and diagnosis. There is an increase in the number of responses per respondent from 400 to 1,000 to more accurately reflect the number of cases during the 2014-15 through 2016-17 influenza seasons. The number of responses vary by influenza season. It has been communicated to program by the EIP sites that the time it takes to complete the case report form is more accurately reflected at 25 minutes versus 15, therefore there is an increase in the average burden per response (in hours). The total burden in hours for the FluSurv-NET Case Report Form has increased from 1000 to 4167.

FluSurv- NET – Vaccination Phone Script Consent Form (English/Spanish)

For this revision, overall burden has increased in the number of responses per respondent from 100 to 333 due to the increased number of responses for the Case Report Form, resulting in an increase to 278 in the total burden. There isn't any content change for this revision.

FluSurv-NET – Vaccination Phone Script (English/Spanish)

On 2/7/2015, OMB approved a non-substantive change request to include influenza vaccine type on the phone interview.

For this revision overall burden has increased in the number of responses per respondent from 100 to 333 due to the increased number of responses for the Case Report Form, resulting in an increase to 278 in the total burden. The name of this form was previously titled FluSurv-Net Vaccination Telephone Surveys. There isn't any content change for this revision.

FluSurv-NET Provider Vaccination History Fax Form (Children/Adults)

This is a new form with a total of 278 burden hours.

C. difficile infection (CDI) Surveillance Case Report Form

A non-substantive change request was OMB approved on 1/29/2018. There is no change to the burden for this revision.

Multi-site Gram-Negative Surveillance Initiative – (MuGSI-CRE/CRAB)

A non-substantive change request was OMB approved on 1/29/2018. There is no change to the burden for this revision.

Multi-site Gram-Negative Surveillance Initiative – Carbapenem-resistant Pseudomonas aeruginosa (MuGSI-CR-PA)

This is a new form with a total of 2580 burden hours.

Multi-site Gram-Negative Surveillance Initiative – Extended-Spectrum Beta-Lactamase-Producing Enterobacteriaceae (ESBL)

This is a new form with a total of 4000 burden hours.

Methicillin-resistant Staphylococcus aureus (MRSA) Case Report Form

A non-substantive change request was OMB approved on 1/29/2018. For administrative purposes, this collection tool has been moved from the ABCs activity to the HAIC activity. There is no change to the burden for this revision.

Methicillin-sensitive Staphylococcus aureus (MSSA) Case Report Form

This is a new form with a total of 3450 burden hours.

Candidemia Case Report Form

This is a new form with a total of 2400 burden hours.

16. Plans for Tabulation and Publication and Project Time Schedule

For ABCs, CDC will provide each surveillance area with several forms of feedback including data integrity checks and summary tables. Specifically, data from multiple sites will be concatenated approximately 3 weeks after receipt at CDC. Feedback from sites to local hospitals, laboratories, and other constituents is at the discretion of each site.

CDC generates pathogen-specific ABCs surveillance reports annually in October (http://www.cdc.gov/ncidod/dbmd/abcs/survreports.htm). CDC also summarizes data for presentation in written manuscripts for peer-reviewed journals, and at national and local scientific meetings. These analyses are on-going throughout the calendar year.

For FoodNet, surveillance data are reviewed monthly at CDC, shared quarterly with the FoodNet steering committee and published yearly in an MMWR an annual report, and online through a web-based interface (https://wwwn.cdc.gov/foodnetfast/).

For FluSurv-NET, prospective surveillance will be conducted for hospital admissions occurring each influenza season between October 1 and April 30.

Activity	Time Schedule
Begin prospective case finding and chart review	October 1
Weekly: sites send data to CDC	October 1- April 30
End prospective case finding	April 30
Sites submit finalized prospective data to	September 30

CDC	
Data Analysis	Continuous throughout and following data collection
Presentation of findings	Continuous throughout and following data collection
Manuscript Preparation	Continuous throughout and following data collection

For HAIC, CDC provides each EIP site with several forms of feedback including data integrity checks. HAIC staff members at CDC and in the sites are engaged in an ongoing fashion in data analysis, and it is routine each year (throughout the year) for several abstracts and papers to be presented at national meetings and published in peer-reviewed journals. Feedback from sites to local hospitals, laboratories, and other constituents is at the discretion of each site. CDC also produces an annual report for CDI (https://www.cdc.gov/hai/eip/clostridium-difficile.html) and MRSA (https://www.cdc.gov/hai/eip/saureus.html).

EIP will be developing an approach to (or guidance for) making EIP datasets publicly available, in accordance with recently issued requirements. The policy at CDC (SDAP – Scientific Data Access Project) is still new and precisely what is required and by when appears to be still under discussion. A plan will be forthcoming.

17. Reasons Display of OMB Expiration Date is Inappropriate

Data collections for ABCs and HAIC forms remain constant from one expiration date to the next. In order to make the most efficient use of the forms that have already been distributed to state health department personnel we request that the OMB expiration date not be printed on these forms. Therefore, the display of the OMB expiration date is not appropriate. For FoodNet and the Flu Hosp project the expiration date will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the Paperwork Reduction Act Submission certification.