Emerging Infections Program (0920-0978)

Revision

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SUPPORTING STATEMENT PART A: Justification

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TABLE OF CONTENTS

16. Influenza - Nonresearch Determination (Attachment 16)
17. Influenza - Vaccination Telephone Surveys (Attachment 17)
17a Influenza – Vaccination Telephone Surveys Spanish (Attachment 17a)
18. Influenza - Consent Form (Attachment 18)
18a Influenza – Consent Form Spanish (Attachment 18a)
19. ABCs - ABCs 2012 Surveillance Catchment (Attachment 19)
20. Influenza - Flu Hosp Project Flow Chart (Attachment 20)

21. Foodborne - FoodNet PS_clean 03072012 (Attachment 21)
22. HAIC-A – 2015 CDI Case Report Form (Attachment 22
23. HAIC-A – 2015 CDI Treatment Form (Attachment 23)
24. HAIC-A – Adult Verbal Consent/Assent (16-17)/Parental Permission, CDI Interview (Attachment 24)
25. HAIC-A – Child Assent (13-15), CDI Interview (Attachment 25)
26. HAIC-A – Screening Questions for CDI Telephone Interview (Attachment 26)
27. HAIC-A – CDI Telephone Interview (Attachment 27)
28. HAIC-A – 2015 Resistant Gram-negative Bacilli Case Report Form (Attachment 28)

- 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 (FoodNet): active population-based laboratory surveillance to monitor the incidence of select enteric diseases .
  - Healthcare-Associated Infections-Community Interface (HAIC) surveillance: active population-based surveillance for healthcare-associated pathogens and infections. Active population-based HAIC surveillance conducted or anticipated to be conducted in more than 9 sites includes the following:
    - *Clostridium difficile* surveillance (currently 0920-0892, 10 sites, expiration 2/28/2017)
    - Antibiotic-resistant Gram-negative bacilli surveillance (currently conducted in 8 sites, no OMB number, with potential to expand in future years)

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

Activity	Surveillances/Projects
ABCs	ABCs Surveillance
	Invasive Methicillin-resistant Staphylococcus aureus (MRSA) Surveillance

A. Justification

1. Circumstances Making the Collection of Information Necessary

Background

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 [originally 0920-0802].
- 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 [originally 0920-0806].
- Healthcare-Associated Infections-Community Interface (HAIC) surveillance: active population-based surveillance for healthcare-associated pathogens and infections. Active population-based HAIC surveillance conducted or anticipated to be conducted in more than 9 sites includes the following:
  - *Clostridium difficile* surveillance (currently 0920-0892, 10 sites, expiration 2/28/2017)
  - Antibiotic-resistant Gram-negative bacilli surveillance (currently conducted in 8 sites, no OMB number, with potential to expand in future years)

	ABCs Invasive Pneumococcal Disease in Children Surveillance
	ABCs Non-Bacteremic Pneumococcal Disease Surveillance
	Neonatal Infection Expanded Surveillance
	ABCs Legionellosis Surveillance
FoodNet	FoodNet Active Surveillance
Influenza	Influenza Hospitalization Surveillance Project
HAIC	*C. difficile* Infection (CDI) Surveillance
	Resistant Gram-Negative Bacilli Surveillance

In this revision package we wish to add Healthcare Associated Infections-Community Interface (HAIC) active population-based surveillance for healthcare-associated pathogens and infections. The HAIC population-based surveillance projects are very similar methodologically to other projects included within 0920-0978. Inclusion of HAIC population-based surveillance within 0920-0978 will consolidate all larger-scale EIP population-based surveillance projects into a single Information Collection Request and OMB number. There are no other changes included in this revision request; therefore, no changes are being made to the ABC, FoodNet and Influenza portions of the EIP.

Note that both the FoodNet and HAIC collections include projects that already have their own, separate OMB numbers. Specifically, there is a separate FoodNet related collection for the STEC non-O157 study that CDC conducts, which has a separate OMB number, 0920-0905 and for the FoodNet population survey seeking separate clearance, which is now in review. Given the very different study protocols and associated burdens, these projects were not included in this package and are separate. Within the EIP HAIC activity, there are also projects that already have their own OMB numbers. The already-approved HAIC project that is now being incorporated into 0920-0978 is population-based surveillance for *Clostridium difficile* infection surveillance (currently 0920-0892, expiration 2/28/2017). Note that there are two other HAIC projects with their own OMB number: the HAI and antimicrobial use prevalence survey (0920-0852, expiration 12/31/2016), and the community-associated CDI risk factor study (0920-1013, expiration 4/30/2017). The survey, 0920-0852, is NOT being incorporated into 0920-0978 because it is an intermittently-performed, cross-sectional project that is methodologically entirely distinct from the population-based surveillance activities described herein. The risk factor study, 0920-1013, is NOT being incorporated into 0920-0978, because it is a one-time project which utilizes a case-control approach that is also methodologically distinct from the ongoing population-based surveillance activities described herein. The differences among the HAIC collections are described later in this Supporting Statement (see Section A.4).

Information in Identifiable Form (IIF) will be collected by each EIP site, and de-identified prior to its transmission to CDC. Please refer to section A.10 for further description of the process for de-identifying 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

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 2011, the surveillance area included 47 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 information 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 All Age Influenza Hospitalization Surveillance (Flu Hosp) project aligns with these goals and plays an integral role in protecting America's health. The Flu Hosp project 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 the Flu Hosp project. In 2005, adult influenza surveillance was added to his platform. In 2006, data from the Flu Hosp project 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. The Flu Hosp 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. The Flu Hosp 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. Currently EIP is the only national surveillance system in place that collects the type of information needed to estimate the burden of laboratory-confirmed influenza-associated hospitalizations. Approval is sought for Flu Hosp project's All Age Case Report Form (Attachment 8). This form is used by sites to collect demographic and clinical information about children and adults with laboratory-confirmed influenza hospitalizations who reside in a geographic- and population-defined area of the United States. 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 EIP catchment area, each EIP 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, in order of priority, 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 standardized interview will be used to obtain influenza vaccination history.

The Healthcare-Associated Infections/Community Interface (HAIC) activity is the newest of the EIP's major activities, and was launched in 2009 with support from American Recovery and Reinvestment Act funds. 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 priority of the Department of Health and Human Services and a CDC Winnable Battle. 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—currently conducted under 0920-0892) and antibiotic-resistant Gram-negative bacilli (currently conducted in 8 sites, no OMB control number, with the potential to expand).

These two projects—CDI and Gram-negative bacilli surveillance—are being incorporated into 0920-0978, to consolidate all 10-site EIP population-based surveillance under a single OMB control number. The HAIC activity also conducts periodic HAI and antimicrobial use prevalence surveys under 0920-0852 (expiration 12/31/2016)—this project is not population-based surveillance, is methodologically distinct from 0920-0978, and is therefore not being incorporated into 0920-0978 (it will maintain its own OMB control number). The HAIC activity also includes a CDI case-control study under 0920-1013 (expiration 4/30/2017)—this project is a one-time project nearing completion, is not population-based surveillance, and is methodologically distinct from 0920-0978, and is therefore not being incorporated into 0920-0978.

This new request seeks to bring these HAIC population-based surveillance projects (CDI and Gram-negative bacilli surveillance) under the EIP OMB clearance order, which also covers ABCs, FoodNet and Influenza. 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 are used by sites to review medical records and collect demographic and clinical information on laboratory-confirmed cases of CDI and resistant Gram-negative bacilli. Additional information for putative community-associated CDI cases (for example, food history, exposures to outpatient healthcare settings and selected medications) is collected through patient interview. 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 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 the CDC Vital Signs reports on CDI ("deadly diarrhea," http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6109a3.htm) and on carbapenem-resistant Enterobacteriaceae ("nightmare bacteria," http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6209a3.htm). The 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.

No changes are being made to the ABC, FoodNet and Influenza portions of the EIP OMB clearance order.

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. 100% 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) or CDC FTP (file transfer protocol) site.

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. FoodNet collects standard data elements. FoodNet does not require states to administer 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 13).

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 EIP 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. 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.

To ease the burden on respondents, the separate OMB-approved pediatric and adult case report forms have been consolidated into one instrument (OMB# 0920-0806). This minimizes paperwork at each site and decreases the likelihood of errors in information collection and entry, and improves the timeliness of data transmission to CDC.

HAIC CDI and resistant Gram-negative bacilli data are collected by EIP site personnel on paper case report forms (Attachments 22, 23, 28). Burden associated with consent for CDI patient interviews is included with the burden associated with the information collection instruments (Attachments 22, 23, 26, 27, 28). Case tracking information is entered into locally-housed case tracking systems; identifiable data entered into these secure, local systems are not shared with CDC. Case information (without identifiers, save for date of birth) from these local systems is then imported or transmitted via a secure web service into CDC-developed, approved, web-based data management systems. These online, enterprise SQL-supported databases have secure web and data servers at the CDC. The databases used by EIP sites for capturing these surveillance data 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 will be uploaded by EIP site personnel to site-specific, encrypted, secure CDC SAMS or CDC FTP sites for analysis by CDC project staff.

No changes are being made to the ABC, FoodNet and Influenza portions of the EIP OMB clearance order.

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. We allow sites to use their existing structure and databases to avoid duplicate data entry. Data analyses are 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.

The Flu Hosp project 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. The Flu Hosp projects 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 CDI surveillance and surveillance for resistant Gram-negative bacilli provide unique information not available through other surveillance 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 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 not captured at this time). Unlike HAIC, NHSN does not have an isolate submission component, and data reported to NHSN on patients with CDI or infections due to resistant Gram-negative bacilli are very limited (e.g., no information on underlying conditions).

The EIP HAI and antimicrobial use prevalence survey (0920-0852) is a cross-sectional "snapshot" of all HAIs attributable to acute care hospitals (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 survey is conducted intermittently (e.g., approximately every 4 years) and focuses on a specific healthcare setting—acute care hospitals—rather than the broad spectrum of facilities in the United States in which healthcare is provided. The survey is conducted throughout the entire hospital 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.

The EIP CDI risk factor study (0920-1013) is a one-time project nearing completion; it is a case-control study aimed at identifying potentially modifiable risk factors for community-associated CDI. It is not itself an ongoing surveillance activity.

No changes are being made to the ABC, FoodNet and Influenza portions of the EIP OMB clearance order.

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.

No changes are being made to the ABC, FoodNet and Influenza portions of the EIP OMB clearance order.

6. Consequences of Collecting the Information Less Frequently

For ABCs and FoodNet, partnering state health departments submit data collection forms 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 Flu Hosp project data to the CDC on a weekly basis during flu season (October 1- April 30). However, reporting frequency may vary, as some weeks during the seven-month flu season might not include any flu 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.

No changes are being made to the ABC, FoodNet and Influenza portions of the EIP OMB clearance order.

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

For all Activities, this request fully complies with the regulation 5 CFR 1320.5. For the reasons described in A.6 above, respondents are required to report information more often than quarterly (monthly). 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.

No changes are being made to the ABC, FoodNet and Influenza portions of the EIP OMB clearance order.

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 05/06/2015, Volume 80, 87, p. 26051. No comments were received.

B. ABCs is the gold standard for the collection of population- and laboratory-based invasive bacterial disease data in the U.S. CDC conducts a conference call with ABCs Principle Investigators to discuss ABCs-related issues quarterly. CDC also organizes the annual ABCs Steering Committee meeting with each site's ABCs Principle Investigators in attendance.

CDC conducts a conference call with site surveillance officers to discuss surveillance-related issues monthly. CDC also organizes an annual FoodNet Vision Meeting and Site Coordinator meeting which include representatives from all site and federal partners. These meetings offer the opportunity to discuss ongoing projects and plan for future priorities.

Since the Flu Hosp project 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.

No changes are being made to the ABC, FoodNet and Influenza portions of the EIP OMB clearance order.

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.

No changes are being made to the ABC, FoodNet and Influenza portions of the EIP OMB clearance order.

10. Assurance of Confidentiality Provided to Respondents

As a measure of EIP's data protection plan, the ABCs, Influenza, and HAIC activity utilizes data transfer method that are encrypted and 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.

For ABCs, 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 the Flu Hosp project. Thus, the patients 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. 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 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. 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 is the newest of the EIP's major activities, and was launched with support from American Recovery and Reinvestment Act funds. The HAIC activity is a collaboration between CDC and in the 10 state health departments and academic partners of the EIP network. Healthcare-associated infections (HAIs) are major threats to patient safety and public health in the United States. Elimination of HAIs is a priority of the Department of Health and Human Services and a CDC Winnable Battle. 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 CDI and antibiotic-resistant Gram-negative bacilli. This new request seeks to bring these population-based surveillance projects under the EIP OMB clearance order. 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 22, 232, 28) are used by sites to review medical records and collect demographic and clinical information on laboratory-confirmed cases of CDI and resistant Gram-negative bacilli. Additional information for putative community-associated CDI cases is collected through patient interview (Attachments 24-27).

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.

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.

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 includes information gathered from medical records and for selected cases (putative community-associated cases), information gathered from case patient (or when the patient is a young child, parent) interview. Information collected 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 (i.e. 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 ilues), 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 (Attachments 22 and 23). For patients who are interviewed, data collected include information about the patient's illness, household contacts, healthcare exposures, food intake, medical history and medication exposures, animal and other community exposures, and demographics (Attachment 27). Healthcare facilities are identified by facility identification codes. These facility identification codes are assigned codes that EIP sites use currently in the course of their surveillance activities, and although EIP personnel are able to link facility codes with facility names, CDC will not have these linkages. 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 assigned; EIP sites strip other data (e.g., address, latitude, longitude), and the census

tract number is 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 resistant Gram-negative bacilli surveillance (Attachment 28) 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. As with CDI surveillance, healthcare facilities are identified in the data collection forms by facility identification codes. These are codes that EIP sites assign; EIP personnel are able to link facility codes with facility names, but CDC does not have these linkages. 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.

IRB Approval

For ABCs, FoodNet, and HAIC- CDI and resistant Gram-negative bacilli surveillance, the data collection forms included in this package constitute public health surveillance and are not considered research. Therefore the protocols associated with the forms included in this package are not subject to IRB review. The primary objective of the Flu Hosp project is to conduct surveillance and evaluation of the magnitude of severe influenza during yearly influenza seasons and to assess the impact of the influenza vaccination program. The National Center for Immunization and Respiratory Diseases has determined that these activities are not research, but rather a combination of surveillance and program evaluation. As such, they do not need to be reviewed or approved by CDC's Institutional Review Board (Attachment 16).

Privacy Impact Assessment Information

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

2. For persons whose influenza vaccination is documented in the medical chart, and would not be contacted by telephone, a request for waiver of consent is requested. Similar to vaccination status information, this project and data collection could not practically be carried out without the waiver.

   For HAIC CDI surveillance, verbal consent will be obtained from patients undergoing telephone interview (Attachment 24). For persons 18 years of age or older, verbal consent will be obtained from all eligible participants. Because this study requires that

participants be interviewed in a timely manner, all participants will be interviewed over the telephone. The consent will be read to participants who agree to health interview. For persons aged 13-17 years, verbal assent will be obtained (Attachments 24 and 25). Parents or guardians will be interviewed for children 1-12 years of age (Attachment 24). A copy of the consent form read to those study participants aged 13-17 and the parent/guardian, with responses noted and signed by the interviewer, will be retained with each completed questionnaire (Attachments 24-27).

For the medical review component of HAIC CDI surveillance and resistant Gram-negative bacilli surveillance, consent is not applicable as EIP personnel will perform review of existing medical record data in participating facilities and submit these data to CDC without having any interaction with individual patients. Information received by CDC will be stored in a secure, password-protected database (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. Information received by CDC will be provided only to those individuals at CDC with a need to know.

3. Project case report formsmaintained 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.

No changes are being made to the ABC, FoodNet and Influenza portions of the EIP OMB clearance order.

11. 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. With the possible exception of underlying conditions (which are only collected for Listeria cases), data collected for FoodNet surveillance are not considered sensitive. However, persons can refuse to provide any information that they consider to be sensitive.

In the Flu Hosp project, 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, healthcare worker 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, intravenous drug use, and alcohol abuse, and incarceration prior to specimen collected) are collected and analyzed with the purpose of contributing valuable knowledge to the field of public health. These questions are asked to clarify risk factors for infection with important healthcare-associated pathogens. The reporting of adverse events associated with healthcare can be sensitive unless the institution is assured that the data aggregating organization will provide security for the data and maintain the institution's security. As stated above, the individual's and institution's security will be assured.

No changes are being made to the ABC, FoodNet and Influenza portions of the EIP OMB clearance order

12. Estimates of Annualized Burden Hours and Costs

A. The total burden estimate for collection of all data elements for HAIC 10,300 hours which is shown in Tables A12-A1 in the highlighted area. Burden estimates are based on previous experience with collection of these data elements. The number of respondents varies by year; numbers used are based on recent data from CDI surveillance in 10 sites and resistant Gram-negative bacilli surveillance in 8 EIP sites.

Table A.12-A1. Estimated Annualized Burden Hours
(New forms added to this revision have been highlighted)

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
	Invasive Methicillin-resistant *Staphylococcus aureus* ABCs Case Report Form	10	609	20/60	2030
	ABCs Invasive Pneumococcal Disease in Children Case	10	22	10/60	37

	Report Form				
	ABCs Non-Bacteremic Pneumococcal Disease Case Report Form	10	100	10/60	167
	Neonatal Infection Expanded Tracking Form	10	37	20/60	123
	ABCs Legionellosis Case Report Form	10	100	20/60	333
	Campylobacter	10	637	20/60	2123
	Cryptosporidium	10	130	10/60	217
	Cyclospora	10	3	10/60	5
	Listeria monocytogenes	10	13	20/60	43
	Salmonella	10	827	20/60	2757
	Shiga toxin producing E. coli	10	90	20/60	300
	Shigella	10	178	10/60	297
	Vibrio	10	20	10/60	33
	Yersinia	10	16	10/60	27
	Hemolytic Uremic Syndrome	10	10	1	100
	Influenza Hospitalization Surveillance Project Case Report Form	10	400	15/60	1000
	Influenza Hospitalization Surveillance Project Vaccination Telephone Survey	10	100	5/60	83
	Influenza Hospitalization Surveillance Project Vaccination Telephone Survey Consent Form	10	100	5/60	83
EIP site	CDI Case Report Form	10	1650	20/60	5500
	CDI Treatment Form	10	1650	10/60	2750
	Resistant Gram-Negative Bacilli Case Report Form	10	500	20/60	1667
Person(s) in the community infected with *C. difficile* (CDI Cases)	Screening Form	600	1	5/60	50
	Telephone interview	500	1	40/60	333

Total					22,755

B. Because these data collections are supported through a cooperative agreement, there is minimal additional cost to respondents (see table 14-1).

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

There are not costs to respondents other than their time.

No changes are being made to the ABC, FoodNet and Influenza portions of the EIP OMB clearance order

14. Annualized Cost to the Federal Government

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)**	**300,000**
	Subtotal, Direct Costs to the Government	**300,000**
Cooperative Agreement Expenses	**California Site Cost and Fees**	**565,821**
	Colorado Site Cost and Fees	**410,758**
	Connecticut Site Cost and Fees	**400,986**
	Georgia Site Cost and Fees	**840,797**
	Maryland Site Cost and Fees	**794,927**
	Minnesota Site Cost and Fees	**993,835**
	New Mexico Site Cost and Fees	**697,752**
	New York Site Cost and Fees	**770,569**
	Oregon Site Cost and Fees	**294,760**

	Tennessee Site Cost and Fees	**801,918**
	Subtotal, Contracted Services	**6,572,123**
	TOTAL COST TO THE GOVERNMENT	**6,872,123**

Foodborne Diseases Active Surveillance Network (FoodNet)

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 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)	1,076,797
	Subtotal, Direct Costs to the Government	1,076,797
Cooperative Agreement Expenses	California Site Cost and Fees	489,394
	Colorado Site Cost and Fees	593,227
	Connecticut Site Cost and Fees	617,770
	Georgia Site Cost and Fees	662,229
	Maryland Site Cost and Fees	372,353
	Minnesota Site Cost and Fees	695,318
	New Mexico Site Cost and Fees	286,957
	New York Site Cost and Fees	627,058
	Oregon Site Cost and Fees	576,350
	Tennessee Site Cost and Fees	493,895
	Subtotal, Contracted Services	5,414,551
	TOTAL COST TO THE GOVERNMENT	6,491,348

Influenza - All Age Influenza Hospitalization Surveillance Project

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 Project Officer (1.0 FTE); CDC Principle Investigator (0.8 FTE)	155,500
	Subtotal, Direct Costs to the Government	155,500
Cooperative Agreement Expenses	California Site Cost and Fees	370,000

	Colorado Site Cost and Fees	**146,286**
	Connecticut Site Cost and Fees	**410,900**
	Georgia Site Cost and Fees	**289,000**
	Maryland Site Cost and Fees	**290,000**
	Minnesota Site Cost and Fees	**240,000**
	New Mexico Site Cost and Fees	**293,642**
	New York Site Cost and Fees	**312,000**
	Oregon Site Cost and Fees	**310,000**
	Tennessee Site Cost and Fees	**380,000**
	Subtotal, Contracted Services	**3,041,828**
	TOTAL COST TO THE GOVERNMENT	**3,197,328**

HAIC (based on 2013 costs)

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 HAIC Director (0.10 FTE), Principal Investigators (1.5 FTE); CDC Surveillance Coordinators (2.0 FTE); Laboratory Scientist (1.0 FTE); Data Manager (1.0 FTE); Database Developer (0.5 FTE)**	**720,000**
	Subtotal, Direct Costs to the Government	**720,000**
Cooperative Agreement Expenses	**California Site Cost and Fees**	**213,646**
	Colorado Site Cost and Fees	**348,091**
	Connecticut Site Cost and Fees	**288,080**
	Georgia Site Cost and Fees	**396,729**
	Maryland Site Cost and Fees	**244,225**
	Minnesota Site Cost and Fees	**321,269**
	New Mexico Site Cost and Fees	**274,651**
	New York Site Cost and Fees	**365,747**
	Oregon Site Cost and Fees	**164,787**
	Tennessee Site Cost and Fees	**323,841**
	Subtotal, Contracted Services	**2,941,066**
	TOTAL COST TO THE GOVERNMENT	**3,661,066**
Annualized Total Cost to the Federal Government		**20,221,865**

No changes are being made to the ABC, FoodNet and Influenza portions of the EIP OMB clearance order

15. Explanation for Program Changes or Adjustments

This is a revision request seeking inclusion of additional core EIP activities (HAIC) under one OMB clearance number. Clearance approval for 3 years is sought under this new request.

No changes are being made to the ABC, FoodNet and Influenza portions of the EIP OMB clearance order

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 two times a year. Preliminary surveillance reports are produced in March for the previous calendar year; final surveillance reports are produced 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 and annual report.
For the Flu Hosp project, 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 CDC	September 30
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 will provide 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.

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.

No changes are being made to the ABC, FoodNet and Influenza portions of the EIP OMB clearance order

17. Reasons Display of OMB Expiration Date is Inappropriate

Data collections for 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 inappropriate.

No changes are being made to the ABC, FoodNet and Influenza portions of the EIP OMB clearance order

18. Exceptions to Certification for Paperwork Reduction Act Submissions

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

No changes are being made to the ABC, FoodNet and Influenza portions of the EIP OMB clearance order