Emerging Infections Program

New Submission

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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. Various parts of the EIP have received separate OMB clearance (0920-0802, ABCs, 0920-0806, All Age Influenza Hospitalization Surveillance); however this new request seeks to have these core EIP activities under one OMB clearance order. Clearance approval for 3 years is sought under this new 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.

Over the past 16 years, the EIPs have proved to be a national resource for conducting active, population-based surveillance and special studies for invasive bacterial diseases, enteric infections, influenza, and many other infectious diseases. The network has been instrumental in measuring the impact of the 7-valent pneumococcal conjugate vaccine, informing and evaluating treatment guidelines for Group B Streptococcus, estimating the burden of foodborne illness, documenting the emergence of community-associated methicillin-resistant *Staphylococcus aureus*, and monitoring the safety of the 2009 H1N1 vaccine as part of the influenza vaccine safety network.

Surveillance efforts of the core EIP activities listed below generate reliable estimates of the incidence of certain infections and provide the foundation for a variety of epidemiologic studies to monitor prevention strategies, explore risk factors, validate diagnostics and surveillance methods, and investigate spectrum 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 [previous 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 [previous 0920-0806]

1.1 Privacy Impact Assessment

ABCs collection forms are used by sites to collect demographic and clinical information on laboratory-confirmed cases of invasive bacterial disease for the following pathogens: *Neisseria meningitis*, *Haemophilus influenzae*, group A *Streptococcus* (GAS) group B *Streptococcus* (GBS), *Streptococcus pneumoniae*, methicillin-resistant *Staphylococcus aureus* (MRSA) and *Legionella spp*. who reside in geographic- and population-defined areas 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 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.

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.

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. 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, Antiviral treatments, ICD 9 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 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

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

For ABCs the data collection has important practical utility to the government as well as EIP populations and the American population as a whole. 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. The ABCs surveillance system provides data for those engaged in research or medical practice, health education officials, and manufacturers of pharmaceutical products which may lead to effective prevention strategies and enhanced interventions. Partnering EIP sites submit data collection forms to CDC on a monthly basis. CDC coordination of standardized reporting in EIP sites maintains uniformity so that comparisons can be made from state to state and year to year.

ABCs data has been used to track disease trends, including the decline in pneumococcal disease following introduction of the pediatric pneumococcal conjugate vaccines and the emergence of serogroup Y meningococcal disease. ABCs has also impacted public health policy by providing information which formed the basis of revised CDC guidelines recommending the use of

universal screening of pregnant women to prevent early onset GBS infections and the prevention of GAS infections among household contacts of persons with invasive disease and among postpartum and post-surgical patients. ABCs data is also being used to characterize the changing epidemiology of methicillin-resistant *Staphylococcus aureus*.

ABCs data and methodology have also been shared with both domestic and international programs. Domestically, a program based primarily on lessons learned from ABCs has been developed to assist state and local health departments with surveillance for MRSA and drug-resistant *Streptococcus pneumoniae*. Internationally, ABCs data has been shared with colleagues in an effort to assist with the development, introduction and evaluation of new vaccines in countries outside the U.S.

A FoodNet case is defined as isolation (for bacteria) or identification (for parasites) of an organism from a clinical specimen. To identify cases, FoodNet personnel in the state health departments communicate with personnel from more than 600 clinical laboratories serving the surveillance area either weekly or monthly, depending on laboratory volume. Information collected on all pathogens includes pathogen, age, sex, race, state and county of residence, recent international travel, date of illness onset, date of specimen collection, outbreak-association, isolate source, serotype, date and duration of hospitalization, and patient outcome (see Attachment 9 for complete list). Information on selected exposures is collected from a subset of Campylobacter and Salmonella cases (Attachment 10). Information is used at the state level for monitoring the number of cases over time, outbreak detection, and disease control. FoodNet data are the national gold standard for surveillance of Campylobacter, Cyclospora, Cryptosporidium, Shiga toxin-producing Escherichia coli, Listeria, Salmonella, Shigella, Vibrio, and Yersinia infections. Data are used to describe national incidence rates, determine the burden of foodborne diseases in the United States, monitor trends in the burden of foodborne illnesses over time, and attribute the burden of foodborne illnesses to specific foods and settings.

Active surveillance is conducted for cases of pediatric HUS (i.e., HUS in persons <18 years of age at time of diagnosis) through a network of pediatric nephrologists and infection-control practitioners who report all suspected cases. Cases are defined as any illness diagnosed as HUS by a physician or any hospitalized illness with ICD-9-CM or ICD-10CM codes consistent with HUS. Passive surveillance is conducted for cases of adult post-diarrheal HUS (i.e., HUS in persons aged ≥18 years of age).

Data are summarized quarterly to evaluate progress toward the HHS High Priority Health Objectives and yearly to monitor progress toward CDC's Healthy People 2020 objectives. Data are also routinely summarized in scientific publications to contribute to public health knowledge. In 2012, a supplement was published in Clinical Infectious Diseases which contained 18 scientific articles based on FoodNet surveillance data. This information leads to improvements in public health practice and the development of interventions to reduce the burden of foodborne illness.

The Flu Hosp project data have important practical utility to the government (specifically the Influenza Division and the CDC) as well as EIP populations and the American population as a whole. Participating sites submit de-identified data to CDC on a weekly basis, where they are aggregated and used to calculate population-based rates of laboratory-confirmed influenza-associated hospitalizations in adults and children, and identify groups at highest risk for severe influenza. These aggregated data are shared with the public on a weekly basis via the CDC's Weekly Influenza Surveillance Report (http://www.cdc.gov/flu/weekly). Results from these data have been published in the Morbidity and Mortality Weekly Report (MMWR) and used in numerous scholarly articles to expand the peer-reviewed body of influenza literature. The data also play a critical role in the Advisory Committee on Immunization Practices' (ACIP) decisions related to influenza vaccination recommendations. These data will continue to benefit public health by aiding in the modification of influenza prevention and control recommendations and in assessing the impact of the US vaccination program. These data are continuously shared with the public through the CDC website and through peer-reviewed publications (Attachment 12).

A.2.1 Privacy Impact Assessment Information

The information is being collected to determine the incidence and epidemiologic characteristics of invasive disease due *Haemophilus influenzae*, *Neisseria meningitidis*, group A *Streptococcus*, group B *Streptococcus*, *Streptococcus pneumoniae* and methicillin-resistant *Staphylococcus aureus* and legionellosis in large diverse U.S. populations. The data will benefit public health by aiding in the estimation of disease burden, identification of high risk populations, development of vaccines, and modification of prevention and control recommendations.

Data that come to CDC are non-identifiable; records cannot be linked back to an individual respondent so will not affect a person's right to privacy. Data are shared with state and federal partners or others (e.g. students) for defined analyses and only upon written request. Data have been used to support the development of policies for regulatory action (e.g. *Listeria* risk assessment for ready-to- eat foods), for student master or doctoral-level thesis, or for scientific publications. All persons requesting data must complete a data request form (Attachment 11) that describes how the data will be used and agrees to only use data for the purpose specified. Data requests are reviewed and approved by the FoodNet steering committee (which includes representatives from all 10 sites, CDC, FDA and USDA) once a month.

The Flu Hosp project case report form is used to conduct influenza hospitalization surveillance for all age groups, and to obtain the age-specific rates of laboratory-confirmed, influenza-associated hospitalizations in several geographic populations. The data allow investigators to study the rates of serious influenza-associated complications and death, and their associated risk factors. Additionally, these data are used to make influenza vaccination recommendations and reduce the burden of influenza morbidity and mortality in the U.S.

No Information in Identifiable Form (IIF) will be collected by CDC. CDC partners will collect IIF about cases. Should a breach of confidentiality occur at the site level, there would be a likely effect on the patients' privacy. However, in an effort to prevent such a breach of confidentiality, 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. Each participating EIP site will destroy identifiers at their earliest opportunity, unless there is a public health or research justification for retaining the identifiers or if required by law.

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. Password-protected databases are posted to site-specific folders on a secure 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 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.

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.

5. Impact on Small Businesses or Other Small Entities

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 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.

There are no legal obstacles to reduce the burden.

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

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.

For the Flu Hosp project, respondents are required to report information more often than quarterly (they are required to report weekly) reasons as described in A.6. Surveillance reports are requested on a weekly basis to permit rapid response to public health problems 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 12/04/2012, Volume 77, 233, p. 71799. 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 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.

Attachment 14 provides a complete list of all EIP Principle Investigators, site representatives, and federal partners with their accompanying affiliations and contact information.

9. Explanation of Any Payment or Gift to Respondents

No payments or gifts will be provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

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.

IRB Approval

For ABCs and FoodNet the data collection forms included in this package constitutes public health surveillance and are not considered research. Therefore the protocols associated with the forms included in this package are exempt from 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 15).

Privacy Impact Assessment Information

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

2. Since information is collected primarily through chart review a request to waive written documentation of informed consent is being made for all data collections in this package. Persons who are interviewed are given the opportunity to consent. For the Flu Hosp project, informed consent when required by local IRB will be obtained by participating sites from patients or patient proxy who are contacted by telephone for vaccination information; all of the required elements of informed consent will be included in the phone script (Attachment 16) and verbal consent obtained before proceeding (Attachment 17). Informed consent in some EIP sites may not be required because influenza hospitalization is a reportable condition in that state. Those EIP sites make modifications to the content of informed consent and its process as allowed by their statutory authority and local IRB requirements. Since the primary contact with human subjects is with their medical chart and only by telephone for the subset of patients for whom vaccination information is not available in the medical record, a request to waive written documentation of informed consent is being made for all data collections (that do not require contact with the case patient) in this package as the research presents no more than minimal risk of harm to subjects and does not involve a procedure when done outside of the research context that would require written consent. This project and data collection could not practically be carried out without the waiver (sites might have to track down up to 1000 persons per influenza season to obtain consent). A waiver of informed consent will not adversely affect the rights and welfare of the case patients because healthcare has already been

received and their medical charts will be reviewed retrospective to their hospitalization. Additionally, if a waiver is not granted it is likely to introduce study bias; those persons who are sicker and have more contact with the health care system would have better documented contact information in the medical record than otherwise healthy persons. 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.

3. 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 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. 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.

12. Estimates of Annualized Burden Hours and Costs

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

A. The total burden estimate for collection of all data elements is shown in Table 1. Burden estimates are based on previous experience with collection of these data elements. The number of respondents varies by year; numbers used in Table 1 are based on 2010 data. In previous years, for the Flu Hosp project, separate adult and pediatric case report forms were used to collect demographic and medical information. As most of the information collected on both forms was the same and to ease the burden on surveillance sites, these forms have been consolidated into one. Earlier versions of the case report forms have been used by investigators in previous influenza seasons and the time required to complete these forms has been used to calculate the burden in this package.

The clinical impact of influenza varies from season to season; therefore, it is not possible to definitively calculate the number of case patients expected each year. Based on EIP influenza project data from 2003-04 to 2010-11, the rate of laboratory-confirmed influenza-associated hospitalizations ranged from 6.0 to 32.7 per 100,000 population. With a population of approximately 23 million persons under surveillance and the data collected from previous seasons, we estimate between 1,000 and 6,500 case patients each influenza season. Because of variations among sites, CDC estimates an average of 400 cases per EIP site per flu season.

Table A.12-A. 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
	Invasive Methicillin-resistant *Staphylococcus aureus* ABCs Case Report Form	10	609	20/60	2030
	ABCs Invasive Pneumococcal Disease in Children Case Report Form	10	41	10/60	68
	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
Total					12,319

** Includes ABCs, Foodborne Diseases Active Surveillance Network (FoodNet), and Influenza – All Age Influenza Hospitalization Surveillance Project (Flu Hosp Project).*

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.

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 Principle 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

15. Explanation for Program Changes or Adjustments

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

Additionally, for the Flu Hosp project, in order to simplify the data collection and transmission process and reduce the burden on respondents, the OMB-approved adult and pediatric case report forms (OMB# 0920-0806) have been consolidated into one instrument. As much of the information that was collected on these two forms was the same, the consolidated document will be easier for use in the field. This change will also minimize paperwork at each site, decrease the likelihood of errors in information collection and entry, and improve the timeliness of data transmission to CDC.

As part of the consolidation and to collect more accurate and relevant information about the risk factors associated with severe influenza, the following changes have been made to the Flu Hosp project case report forms that were part of the OMB# 0920-0806 submission:

Questions added:
- Does patient work in the healthcare industry
(This is important because CDC recommends that healthcare workers receive annual influenza vaccine)

- List of dates, dosages and frequencies of antiviral medications during the course of illness
(This is important because since the 2009 influenza pandemic, CDC recommends that all patients hospitalized with suspected or confirmed influenza should be immediately treated with influenza antiviral drugs)

-Reason for hospital admission
(Sites were already requested to look at reasons for hospital admission in order to classify potential healthcare associated influenza infections. However, during site visits and conference call discussions, it became clear that there were discrepancies in the way sites were making this determination. As a group, we agreed to collect reason for hospital admission in a standardized format and therefore, put the burden of having to categorize influenza cases [community-acquired infection vs. healthcare related] on CDC, rather than on the sites)

-Patient height and weight
(This is important because during the 2009 pandemic obesity and morbid obesity were identified as risk factors for severe influenza and/or death related to influenza)

Questions removed:
- Statin medication usage
Additionally, as part of the original OMB submission (0920-0806), the materials needed for sites to conduct a one-time discharge audit were included. Results from this formal audit indicated sufficient case ascertainment, ranging from 60% to 90% per site, of all laboratory confirmed influenza-associated hospitalizations within the pre-defined geographic areas. As this project is now complete, renewal of these documents is not requested.

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

17. Reasons Display of OMB Expiration Date is Inappropriate

Data collections for ABCs 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. 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.

Included EIP Attachments

1. Authorizing Regulations_T42 section 241 (Attachment 1)
2. EIP Published FRN (Attachment 2)
3. ABCs - 2012 ABCs Case Report Form (Attachment 3)
4. ABCs - 2012 Invasive MRSA ABCs Case Report Form (Attachment 4)
5. ABCs - 2012 ABCs Invasive Pneumococcal Disease in Children (Attachment 5)
6. ABCs - 2012 ABCs Neonatal Infection Expanded Tracking Form (Attachment 6)
7. ABCs - 2012 ABCs Legionellosis Case Report Form (Attachment 7)
8. Influenza - 2011-12 Flu Hosp CRF (Attachment 8)

9. Foodborne - FNDataRequest_ActiveSurv_Variable Definitions_0423201204232012 (Attachment 9)
10. Foodborne - CEA Pilot2_Tool_08062012_final (Attachment 10)
11. Foodborne - FNDataRequest-Proposal_ActiveSurv_05092012 (Attachment 11)
12. Influenza - Flu Hosp Publications (Attachment 12)

13. Foodborne - Current HUS case report form (Attachment 13)
14. EIP Principle Investigators and Site Representatives (Attachment 14)
15. Influenza - Nonresearch Determination (Attachment 15)
16. Influenza - Vaccination Telephone Surveys (Attachment 16)
17. Influenza - Consent Form (Attachment 17)
18. ABCs - ABCs 2012 Surveillance Catchment (Attachment 18)
19. Influenza - Flu Hosp Project Flow Chart (Attachment 19)

20. Foodborne - FoodNet PS_clean 03072012 (Attachment 20)