Emerging Infections Program (0920-0978)

Request for OMB approval of a Revision

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SUPPORTING STATEMENT PART A

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Centers for Disease Control and Prevention
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Table of Contents

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

List of Attachments

1) Authorizing Regulations_T42 section 241
2) 60-Day Federal Register Notice
3) Public Comment
4) Privacy Impact Assessment
5) Human Subjects Determination Memo
6) Explanation for Program Changes
7) Data Collection Instruments
   a. ABC.100.1 ABCs Case Report Form
   b. ABC.100.2 ABCs Invasive Pneumococcal Disease in Children and Adults Case Report Form
   c. ABC.100.3 ABCs H. influenzae Neonatal Sepsis Expanded Surveillance Form
   d. ABC.100.4 ABCs Severe GAS Infection Supplemental Form
   e. ABC.100.5 ABCs Neonatal Infection Expanded Tracking Form
   f. FN200.1-200.8_FoodNet Variable List
   g. FN200.9 FoodNet HUS Case Report Form 2024
   h. FN200.10 FoodNet Lab Survey Variable List 2024
   i. FSN.300.1 FluSurv-NET Case Report Form
   j. FSN.300.2 Phone Script and Consent Form
   k. FSN.300.3 Provider Vaccination History Fax Form and notification letter
   l. FSN.300.4 FluSurv-NET Lab Survey
   m. HAIC.400.1 HAIC Multi-site Gram-Negative Surveillance Initiative MuGSI Case Report Form
   n. HAIC.400.2 HAIC MuGSI CA CP-CRE Health interview
   o. HAIC.400.3 HAIC MuGSI Supplemental Surveillance Officer Survey
   p. HAIC.400.4 HAIC Invasive Staphylococcus aureus Infection Case Report Form
   q. HAIC.400.5 HAIC Invasive Staphylococcus aureus Laboratory Survey
   r. HAIC.400.6 HAIC Invasive Staphylococcus aureus Supplemental Surveillance Officers Survey
   s. HAIC.400.7 HAIC CDI Case Report and Treatment Form
   t. HAIC.400.8 HAIC Annual Survey of Laboratory Testing Practices for C. difficile Infections
   u. HAIC.400.9 HAIC CDI Annual Surveillance Officers Survey
   v. HAIC.400.10 HAIC C. difficile Surveillance Nursing Home Telephone Survey
   w. HAIC.400.11 HAIC Candidemia CRF
   x. HAIC.400.12 Laboratory Testing Practices for Candidemia
   y. HAIC.400.13 HAIC Death Ascertainment Project

A. Justification

1. Circumstances Making the Collection of Information Necessary

A three-year OMB clearance revision is requested for “Emerging Infections Program (EIP)” (OMB Control No. 0920-0978). A revision is being submitted to make existing collection instruments clearer and more comprehensive. Clearance approval for 3 years is sought under this request. Approval is consistent with the understanding that CDC will continue to add (and keep current)

language on each program's website and in their reports that clearly caveats the interpretation of longitudinal trends due to temporal changes in methods, definitions, geographic coverage.

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.

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

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

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

- Active Bacterial Core surveillance (ABCs): active population-based laboratory surveillance for invasive bacterial diseases.
- Foodborne Diseases Active Surveillance Network (FoodNet): active population-based laboratory surveillance to monitor the incidence of select enteric diseases.
- Influenza: active population-based surveillance for laboratory confirmed influenza-related hospitalizations.

- Healthcare-Associated Infections-Community Interface (HAIC) surveillance: active population-based surveillance for healthcare-associated pathogens and infections.

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

Activity	Form Number	Surveillances/Projects
ABCs	ABC.100.1	ABCs Case Report Form
	ABC.100.2	ABCs Invasive Pneumococcal Disease in Children and Adults Case Report Form
	ABC.100.3	ABCs H. influenzae Neonatal Sepsis Expanded Surveillance Form
	ABC.100.4	ABCs Severe GAS Infection Supplemental Form
	ABC.100.5	ABCs Neonatal Infection Expanded Tracking Form
FoodNet	FN.200.1	FoodNet Active Surveillance – Campylobacter

	FN.200.2	FoodNet Active Surveillance – Cyclospora
	FN.200.3	FoodNet Active Surveillance – Listeria monocytogenes
	FN.200.4	FoodNet Active Surveillance – Salmonella
	FN.200.5	FoodNet Active Surveillance – Shiga toxin producing E. coli
	FN.200.6	FoodNet Active Surveillance – Shigella
	FN.200.7	FoodNet Active Surveillance – Vibrio
	FN.200.8	FoodNet Active Surveillance – Yersinia
	FN.200.9	Hemolytic Uremic Syndrome (HUS) Surveillance
	FN.200.10	FoodNet Clinical Laboratory Practices and Testing Volume
FluSurv-NET	FSN.300.1	FluSurv-NET Influenza Hospitalization Surveillance Network
	FSN.300.2	FluSurv-Net Influenza Hospitalization Surveillance Project Vaccination Phone Script and Consent Form (English/Spanish)
	FSN.300.3	FluSurv-Net Influenza Hospitalization Surveillance Project Provider Vaccination History Fax Form (Children/Adults) and Notification Letter
	FSN.300.4	FluSurv-NET Laboratory Survey
HAIC	HAIC.400.1	HAIC- Multi-site Gram-Negative Surveillance Initiative (MuGSI) Case Report Form
	HAIC.400.2	HAIC MuGSI CA CP-CRE Health interview
	HAIC.400.3	HAIC MuGSI Supplemental Surveillance Officer Survey
	HAIC.400.4	HAIC- Invasive *Staphylococcus aureus* Infection Case Report Form
	HAIC.400.5	HAIC- Invasive *Staphylococcus aureus* Laboratory Survey
	HAIC.400.6	HAIC- Invasive *Staphylococcus aureus* Supplemental Surveillance Officers Survey
	HAIC.400.7	HAIC - CDI Case Report and Treatment Form
	HAIC.400.8	HAIC- Annual Survey of Laboratory Testing Practices for *C. difficile* Infections

	HAIC.400.9	HAIC- CDI Annual Surveillance Officers Survey
	HAIC.400.10	HAIC- Emerging Infections Program *C. difficile Surveillance Nursing Home Telephone Survey (LTCF)*
	HAIC.400.11	HAIC Candidemia Case Report Form
	HAIC.400.12	HAIC- Laboratory Testing Practices for Candidemia Questionnaire
	HAIC.400.13	HAIC Death Ascertainment Project

In this Revision, form numbers have been assigned to each data collection instrument to improve form identification.

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

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

2. Purpose and Use of Information Collection

Active Bacterial Core surveillance (ABCs):

Active Bacterial Core surveillance (ABCs) is a core component of CDC's Emerging Infections Programs (EIP) network, which is a collaboration between CDC, state health departments, and universities. ABCs is an active, laboratory- and population-based surveillance system for five invasive bacterial pathogens of public health importance (group A *Streptococcus,* group B *Streptococcus, Hemophilus influenzae, Neisseria meningitidis, and Streptococcus pneumoniae*). At this time ABCs is currently conducted among 10 EIP sites (California, Colorado, Connecticut, Georgia, Maryland, Minnesota, New Mexico, New York, Oregon, and Tennessee).

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

bacterial disease. Continuation of these activities is essential to reduce the burden of invasive disease due to these pathogens.

For each case in the surveillance population, ABCs personnel complete a standardized case report form with basic demographics and other clinical information for all five pathogens (ABC.100.1). Surveillance personnel obtain some of the data of interest from the microbiology laboratories. However, all data that are essential for describing the population-based epidemiology of these diseases may not be available in many microbiology laboratories. Therefore, ABCs sites collect patient medical records data to complement laboratory information. Sites obtain medical records data through the cooperation of on-site hospital personnel (e.g., infection preventionists) or through medical record review by county health department personnel or ABCs personnel. ABCs personnel may need to complete additional supplemental forms for a subset of cases. For *Streptococcus pneumoniae* cases ≥2 months to <5 years of age and ≥65 years of age with an isolate available for serotyping, an expanded Invasive Pneumococcal Disease form (ABC.100.2) is also completed to obtain additional information on vaccine history from medical charts and state immunization information system (IIS). For children <5 years of age with incomplete vaccination information, additional parent/guardian or health care provider follow up may also be attempted to obtain complete vaccine history. The Severe GAS Infection Supplemental Form (ABC.100.4) will be completed for all group A *Streptococcus* cases. Clinical and laboratory information collected on this form will be used to determine if the case meets the clinical definition for streptococcal toxic shock syndrome. The Neonatal Infection Expanded Tracking form (ABC.100.5) is completed for all group B *Streptococcus cases* <90 days of age, which collects additional information from infant and maternal labor and delivery charts. The *Haemophilus influenzae* Neonatal Sepsis Expanded Surveillance form (ABC.100.3) is completed for neonatal (≤30 days of age), pregnant, and post-partum cases and collects additional information on the infant and maternal labor and delivery charts. Exports of the de-identified data are sent to CDC on a monthly basis.

Foodborne Diseases Active Surveillance Network (FoodNet):

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 2019, the surveillance area included 50 million persons (15% of the U.S. population).

FoodNet conducts population-based active surveillance for laboratory-based infections of select pathogens and a condition commonly transmitted through food: including *Campylobacter*, *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.

In 2019, a pilot for surveillance of Enterotoxigenic E. coli (ETEC) was conducted in select sites. FoodNet collects standardized data elements from Connecticut, Georgia, Maryland, Minnesota, New Mexico, Oregon, and Tennessee and selected counties within California, Colorado, and New York. 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 electronic laboratory records, chart review, patient interview, or directly from providers or clinical laboratories. In addition, laboratory practices and testing volume are assessed for clinical laboratories within the surveillance area. FoodNet collects standard data elements for the 7 pathogens, and for one additional pathogen, Norovirus, as part of clinical laboratory surveillance, 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 active laboratory-based surveillance data is made monthly and transmitted to CDC. Data elements for clinical laboratory practices and testing volume are submitted to CDC annually. HUS data is either directly entered or imported into a centralized database and data is reviewed annually. No individually identifiable information is collected at CDC, data are only identifiable at the state level.

Influenza Hospitalization Surveillance Network (FluSurv-NET):

The Influenza Hospitalization Surveillance Network (FluSurv-NET) is used to obtain population-based surveillance data about laboratory-confirmed influenza-associated hospitalizations in children and adults. These data are used to produce weekly laboratory-confirmed influenza-associated hospitalization rates overall and stratified by select demographic characteristics, describe characteristics of persons hospitalized with severe influenza illness, contribute to national estimates of influenza disease burden 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 data are also used to estimate the averted burden of influenza through vaccination.

The need for data on influenza impact in children was first highlighted during the 2003-2004 season when anecdotal reports of influenza-associated pediatric deaths and severe complications in otherwise healthy children emerged. When CDC launched an emergency response in December 2003, no systems were in place that could substantiate these anecdotal reports in a timely manner. To address this need, the available surveillance infrastructure of the Emerging Infections Program (EIP) was used to commence FluSurv-NET. In 2005, adult influenza surveillance was added to this platform. In 2006, data from FluSurv-NET were used by the Advisory Committee on Immunization Practices (ACIP) in its decision to expand the ages for which it recommended influenza vaccination from 6–23-month-olds to 6-59 month olds, and to evaluate influenza vaccine effectiveness based on these recommendations. FluSurv-NET data were used by the ACIP in its decision to expand influenza vaccination recommendations for all persons aged 6 months or older. The utility of these data was further underscored during the 2009 H1N1 pandemic. During the 2009 pandemic, additional states

were added through a cooperative agreement with the Council of State and Territorial Epidemiologists (CSTE) to enhance surveillance by collecting hospitalization data in the same manner as EIP sites, and several of those states have continued surveillance to present. FluSurv-NET is comprised of these sites supported by CSTE and is also part of the EIP, an established CDC-state-academic institution collaborative network which still includes the states of California, Colorado, Connecticut, Georgia, Maryland, Minnesota, New Mexico, New York, Oregon, and Tennessee and later expanded to Michigan and Washington. FluSurv-NET data were used to identify groups at highest risk for influenza-associated hospitalizations (e.g., pregnant women during the 2009 H1N1 pandemic), mathematically model the morbidity and mortality burden of the influenza pandemic and provide data for several peer-reviewed journal articles describing seasonal and pandemic influenza among high-risk groups in the population.

Upon verification of an influenza positive laboratory result and confirmation of residence within the pre-defined FluSurv-NET catchment area, each FluSurv-NET site conducts data abstraction of the medical chart and laboratory report to complete the project's standardized case report form. Starting with the 2017-18 influenza season, FluSurv-NET has implemented a sampling strategy to collect clinical data from the case report form on an age-stratified random sample of cases. Influenza vaccination status is an important piece of information that is used to evaluate the influenza vaccine program. To obtain as complete an influenza vaccine history as possible sites will use the following sources to collect this information: 1) review the patient's medical chart, 2) consult the state vaccination registry, 3) contact the patient's provider via fax or telephone and/or 4) contact the patient or their proxy. If providers and/or patients or proxies need to be contacted, a Consent Form and Provider Vaccination History Fax Form will be used to obtain influenza vaccination history. Sites can also mail a letter to patients or proxies notifying them of the need for contact to obtain influenza vaccination history. In addition, to better understand how influenza testing practices may impact influenza hospitalization rates, all sites will be asked to distribute laboratory surveys to determine what processes are in place to conduct influenza testing and what types of influenza tests are performed at each participating laboratory at the beginning of each season.

Healthcare Associated Infections-Community Interface (HAIC):

The HAIC activity of EIP, launched in 2009, is a collaboration between CDC and the 11 state health departments and academic partners of the EIP network, in California, Colorado, Connecticut, Georgia, Maryland, Michigan, 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, and elimination of HAIs is a U.S. public health priority. The HAIC activity contributes to the goal of eliminating HAIs through its mission to promote patient safety and healthcare quality by critically evaluating the epidemiology and public health impact of HAIs, to understand emerging pathogens and populations-at-risk, and to inform prevention interventions. The HAIC activity conducts population-based surveillance for certain pathogens that are classified urgent threats to patient safety because of their increasing resistance to the antibiotic or antifungal drugs used to treat them and associated high morbidity and mortality. They include, *Clostridioides difficile* infection (CDI), several Gram-negative bacilli (referred to collectively to as MuGSI – the Multi-site gram-negative Surveillance Initiative), invasive *Candida* infections, and invasive *Staphylococcus aureus* infections.

The HAIC activity also conducts periodic HAI and antimicrobial use prevalence surveys under OMB Control Number 0920-0852 (hospital survey, expiration 03/31/2025)—this project is not population-based surveillance, are methodologically distinct from 0920-0978, and were therefore not incorporated into 0920-0978 and will maintain their own OMB control numbers.

HAIC surveillance performed under the HAIC activity is unique in that 1) it collects detailed data on all cases in the population under surveillance and not only for the cases that occur within a hospital, and as such includes "community associated cases", meaning those not associated with hospitalizations or without healthcare exposures and 2) because laboratory isolates of the pathogens under surveillance are submitted to CDC for molecular characterization HAIC provides an enhanced understanding of antimicrobial resistance and transmission.

Data collected through HAIC have utility for the government, public health officials, healthcare facilities, and the public. HAIC data have served as the foundation for several important public health reports, including major national CDC reports "Antibiotic Resistance Threats in the United States, 2019" (https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf), and "Special Report: COVID-19 U.S. Impact on Antimicrobial Resistance, 2022" (https://www.cdc.gov/drugresistance/pdf/covid19-impact-report-508.pdf); CDC Vital Signs reports on CDI (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6109a3.htm) and, in persons with *Staphylococcus aureus* bloodstream infections (https://www.cdc.gov/mmwr/volumes/72/wr/mm7206e1.htm?s_cid=mm7206e1_w); and CDC Morbidity and Mortality Weekly Reports (MMWR)on invasive MRSA infections (https://www.cdc.gov/mmwr/volumes/67/wr/mm6722a2.htm) and Candida infections (https://www.cdc.gov/mmwr/volumes/68/wr/mm6812a3.htm) among people who inject drugs, and emerging antibiotic resistance (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6209a3.htm).

Each EIP site conducts data abstraction of the medical chart and laboratory report to complete the standardized case report forms. These forms are used by EIP site personnel to collect demographic and clinical information on laboratory-confirmed cases of CDI, select Gram-negative bacilli (MuGSI), invasive *S. aureus* infection, and invasive *Candida* infections.

The CDI, MuGSI and invasive *S. aureus* surveillance activities annually survey the EIP program staff (using "Surveillance Officer" surveys) to evaluate program practices and quality. CDI, invasive *Candida* infections, and invasive *S. aureus* infections perform an annual survey of the laboratories (using "Laboratory" Surveys) reporting surveillance cases. The CDI surveillance activity provides an additional tool for EIP sites to use to gather information about the laboratories used by long term care facilities (LTCFs) within the EIP catchment areas.

For select Gram-negative bacilli surveillance (MuGSI), a formal laboratory survey is not conducted, although questions related to laboratory testing are included in the MuGSI Supplemental Surveillance Officer Survey. Additionally, for MuGSI there are four additional variables that are collected, the unique identifier (ID) assigned by the state public health laboratory (i.e., the state public health ID), the National Notifiable Disease Surveillance System (NNDSS) ID that is assigned to a subset of MuGSI cases (i.e., the NNDSS ID), the type of healthcare facility as classified by the Centers for Medicare and Medicaid (CMS) (i.e., the CMS ID), and the type of testing laboratory (e.g., state health department laboratory, clinical laboratory). These variables are known and accessible to EIP site staff

and do not affect the burden of data collection, and are entered in the MuGSI data management system only and transmitted to CDC through the secure methods described elsewhere.

For the select Gram-negative bacilli program (i.e., MuGSI), a sub-set of cases will be eligible to have the Community-Associated Carbapenemase-Producing Enterobacteriaceae (CA CP-CRE) health interview conducted. The data collected through this health interview is used to identify other known potentially modifiable risk factors for CP-CRE acquisition, such as international travel, previous use of antibiotics, occupation, exposure to animals, household contacts with risk factors for CRE acquisition, and other risk factors.

Through the death ascertainment project, the HAIC also collects information through the linking of cases to the state health department's vital records death registry to determine if a patient died within 90 days of the initial specimen culture date. This linking performed is performed by EIP site personnel and the following data elements are obtained: the date of death as reported in the state vital records death index, the date 90-days after the date of initial culture, the EIP site determined date of death, the patient's outcome at 90 days after the date of initial culture, comments about the linking process. The linking between the HAIC surveillance data the state vital records death index has been ongoing since 2018for the purpose of better assessing mortality because of a healthcare-associated infection.

3. Use of Improved Information Technology and Burden Reduction

CDC provides each surveillance site with a REDCap (Research Electronic Data Capture) database where sites can enter surveillance data directly into the CDC instance of REDCap or enter surveillance data on their local instance of REDCap and submit a REDCap export to CDC. Surveillance staff at each participating site will enter data from the case report form into the database and submit the data, stripped of identifiers, to CDC each week during the season. Alternatively, sites that do not use the REDCap database must send CDC a dataset that matches the output of the REDCap database. All data transfers to CDC take place via a secure CDC SAMS site. At CDC, data from all sites will be concatenated and exported into SAS.

For ABCs, case report forms data are entered and maintained at each surveillance area in their respective electronic databases (e.g., state electronic disease reporting system). CDC provides and help maintain a REDCap database that mirrors the data collection forms to all interested surveillance areas for data entry. Surveillance staff at each participating EIP site will enter data from the data collection form into their respective database. The computerized databases, with personal identifiers removed, will be transmitted to CDC by the fifth of every month. All the forms included in this package will be submitted to CDC electronically. All data transfers to CDC take place via a secure CDC SAMS (secure access management services).

For FoodNet, data are housed in an electronic database at each site and an extract is transmitted to CDC once a month or as needed through CDC's secure access management file transfer. FoodNet is continuously working to modernize data transmission by the states. This will allow for more

automated and timely data transmission while reducing staff burden at the sites. FoodNet data elements are incorporated into state case report forms. FoodNet collects standard data elements. FoodNet does not require states to administer a separate standardized questionnaire 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.

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. Sites will survey all participating FluSurv-NET laboratories about testing practices for influenza through an annual laboratory survey.

CDC provides each surveillance site with a REDCap (Research Electronic Data Capture) database based on the case report form where sites can enter surveillance data directly into the CDC instance of REDCap or enter surveillance data on their local instance of REDCap and submit a REDCap export to CDC via SAMS (Secure Access Management System) or through encrypted API (application programming interface) scripts. Surveillance staff at each participating site will enter data from the case report form into the database and submit the data, stripped of identifiers, to CDC each week during the season. Alternatively, sites that do not use the REDCap database must send CDC a dataset that matches the output of the REDCap database. At CDC, data from all sites will be concatenated and imported into SAS. CDC also provides each surveillance site with a REDCap database for the laboratory survey that will be transmitted to CDC once a year.

For all HAIC cases data used to complete standardized case report forms is collected by EIP site personnel on paper or electronically. CDC provides each EIP sites with the necessary database or data entry system to support HAIC case tracking and reporting of case data to CDC. For CDI, MuGSI and invasive *Candida* infection surveillance, case tracking information is entered into secure locally housed case tracking systems and is then imported or automatically transmitted via a secure web service into CDC-approved, web-based data management systems (including .NET and REDCap systems). The additional case report form data for CDI, MuGSI, and invasive *Candida* infection are then entered directly by EIP site personnel into these secure web-based systems. For invasive *S. aureus* CDC provides each participating EIP site with a database (either REDCap or Microsoft Access) and EIP surveillance staff enter data from the data collection forms into the database. Data on case-patient census tracts and case=patient data on mortality 90-days after the initial culture are uploaded by EIP site personnel to site-specific, encrypted, secure CDC SAMS or CDC File Transfer Protocol (FTP) sites.

The HAIC laboratory surveys are collected through a REDCap web-based data management system. For each laboratory that responds to these surveys, an EIP site staff member enters responses into the system using a unique identifier for each laboratory that CDC cannot link to the identity of the responding laboratory. The HAIC surveillance officer surveys are completed by an EIP staff member

and collected in a Microsoft Word document and emailed to CDC, except for the MuGSI surveillance officer survey which is entered in a REDCap data base by the EIP site staff person completing the survey. Data elements obtained from the CDI LTCF survey are shared by EIP site with CDC through Microsoft Excel spreadsheets. No facility specific information or laboratory information is shared with CDC. The data collected in these surveys is for the purpose of program evaluation and they do not contain identifying facility or laboratory information.

All HAIC data collection databases remove personal identifiers before transmitting to CDC. All data from EIP sites are submitted to CDC electronically and all data transfers to CDC take place via a secure CDC SAMS or CDC FTP site. The databases used by EIP site personnel 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 is exported out to the respective databases for review and analysis by CDC project staff.

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 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 to describe it on a national level and to assess changes in incidence over time. We allow sites to use their existing structure and databases to avoid duplicate data entry. All analyses of multi-site data must be proposed and approved by the FoodNet steering committee to avoid duplication of publications.

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

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

HAIC surveillance for CDI, selected Gram-negative bacilli (MuGSI), invasive *Candida* infections, and invasive *S. aureus* infections provides unique information not available through other systems,

including detailed clinical and demographic data on all cases of infection, not limited to healthcare or hospital-associated cases, and isolates of the pathogens under surveillance for testing and molecular characterization. The CDC National Healthcare Safety Network (NHSN, OMB Control Number 0920-0666) receives data from U.S. healthcare facilities on CDI, and on selected infections due to *S. aureus*, *Candida*, and select Gram-negative bacilli, and device associated infections that could be caused by *E. coli*. However, data received byNHSN includes no or limited patient-or person- level data (e.g., no information on underlying conditions), are collected by healthcare facility staff rather than trained epidemiologists and are limited to healthcare-associated cases (i.e., community-associated infections and other infections not requiring hospitalization are generally not included). Unlike HAIC, NHSN does not have an isolate submission component.

Healthcare facilities participating in NHSN complete an annual survey that provides information to CDC. Data elements that are collected include facility characteristics, microbiology laboratory practices, infection control practices, antibiotic stewardship practices, and facility water management. Questions asked about antifungal susceptibility testing (e.g., *Candida*) and methods used to detect *C. difficile* are similar to the EIP *Candida* and CDI lab survey, but provide far less detail. The HAIC laboratory surveys for *Candida*, CDI and invasive *S. aureus* surveillance are designed to capture changes in trends in the testing methodology for these pathogens over time and to monitor how these changes could impact surveillance. The EIP surveys include types of laboratories not included in NHSN (e.g., commercial, outpatient, laboratories serving long-term care facilities).

CDC's Antibiotic Laboratory Network (AR Lab Network) provides nationwide laboratory capacity through state and regional laboratories to rapidly detect antibiotic resistance in healthcare, food, and the community and to inform local response to prevent spread and protect people. The AR Lab Network currently collects isolates of *C. difficile*, *Candida* species, and resistant Gram-negative bacilli (e.g., CRE;). The AR Lab Network's collection of *C. difficile* isolates do not overlap with or duplicate EIP HAIC activities. *C. difficile* isolate testing is only conducted at a single AR Lab Network regional laboratory: the Minnesota Department of Health Public Health Laboratory. This laboratory tests Minnesota EIP's *C. difficile* isolates, are not additionally tested by CDC; the results of testing are shared with CDC. In the past, the collection of CRE and *Candida* isolates through the AR Lab Network could in some instances overlap with CRE isolate collection through the EIP. CDC staff are working to minimize and eliminate potentially duplicative efforts through a data modernization project involving CDC EIP HAIC and AR Lab Network staff who are working to automate and facilitate the sharing of laboratory isolate and test results from each program and ensure they are not duplicative and that isolate activities are complementary. Of note, the AR Lab Network does not collect epidemiological data on the isolates that are tested, and therefore the data that is collected through the EIP is unique.

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 or other healthcare facilities where the cases are identified. However, in some sites, data collection is performed in cooperation with on-site medical personnel (e.g., Infection Control Practitioners or Medical Records Personnel). The impact on these facilities should be minimal since the hospital has entered into an agreement with the State health department.

6. Consequences of Collecting the Information Less Frequently

For ABCs and FoodNet, partnering state health departments submit data collection forms or standardized data elements to CDC monthly. Prompt notification to CDC allows for timely data analysis, tracking of the effects of prevention measures, and policy development. Collecting data less frequently would result in a delay in analysis and subsequent reports and publications.

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

HAIC EIP personnel complete data collection on cases as they are identified from laboratory reports on an ongoing basis, this allow for rapid classification of cases into epidemiologic categories (e.g. community-associated) and identification of epidemiologic changes, including rates and severity of disease. Linking these epidemiological changes to 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.

Collection of the laboratory survey data less than annually would prevent our programs from documenting changes in testing methods that are important to the interpretation of EIP HAIC data. The surveying of HAIC surveillance officers less than once annually would prevent us from ensuring high quality data are being collected and would prevent us from identifying any issues that are ongoing that might need to be addressed. These surveys are important to maintaining high quality data collection for the HAIC program.

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

For FluSurv-NET, for the reasons described in A.6 above, respondents are required to report information more often than quarterly (monthly). FluSurv-NET requires weekly reporting during the influenza season (October 1- April 30), unless influenza activity is observed outside of the active surveillance period and influenza hospitalization surveillance could be extended beyond the established surveillance period to ascertain cases; however, reporting frequency will vary as some weeks during the influenza season might not include influenza cases. Surveillance reports are requested on a periodic basis to permit timely data analysis and prompt initiation of prevention and

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

This request fully complies with the regulation 5 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 February 27, 2024 Volume 89, No. 39, p. 14501 (Attachment 2). CDC received one non-substantive comment (Attachment 3).

B. ABCs and FoodNet are the gold standards for the collection of population- and laboratory-based bacterial disease data in the U.S. CDC conducts a conference call with site surveillance officers to discuss surveillance-related issues monthly. CDC conducts conference calls with ABCs and FoodNet Principal Investigators to discuss bi-monthly and quarterly, respectively. CDC also organizes the annual ABCs and FoodNet Steering Committee meetings with each site's Principal Investigators in attendance and an annual Site coordinator meeting which includes representatives from all sites. These meetings offer the opportunity to discuss ongoing projects and plan for future priorities.

FluSurv-NET organizes annual meetings sites among Principal Investigators meeting to discuss program priorities and analytic projects and a separate annual meeting among site Surveillance Officers to address successes and challenges in information collection activities. Additionally, bi-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 conduct quarterly conference calls with EIP site HAIC principal investigators and hold an annual in-person meeting at CDC with the principal investigators and other key participants to discuss progress and scientific direction for the activity. Regular calls are also held with EIP site and CDC project leads and coordinators to discuss progress and challenges for individual projects.

9. Explanation of Any Payment or Gift to Respondents

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

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

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

As a measure of EIP's data protection plan, the ABCs, FoodNet, FluSurv-NET, and HAIC activity utilize data transfer methods that are password protected to protect the data. CDC and EIP sites have the option to utilize the CDC SAMS platform or API scripts to transmit data. 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 can transfer data in a secure portal to keep data protected. Similarly, the API scripts are encrypted and only allow access to de-identified information, and CDC users follow each site's necessary approval process to use these API's.

ABCs sites conduct data abstraction of the medical chart and laboratory report to complete the standardized case report forms upon verification of a positive laboratory result and confirmation of residence within the pre-defined EIP catchment area. Previously approved ABCs data collection forms are used by sites to review medical records and collect demographic and clinical information on cases. Information in Identifiable Form (IIF) will be collected by each EIP site, however personally identifying information such as names and addresses are not shared with CDC. Date of birth and coded ABCs ID field are shared with CDC. The code linking the ABCs ID field to other personal identifier is maintained confidentially and securely with the ABCs site that reported the case; it is not shared with CDC. 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.

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) 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 and certain fields are often aggregated into groups to minimize the ability to link to other data sources to identify a person.

For FluSurv-NET, in addition to using the CDC SAMS platform, sites also have the option to enter data directly into the CDC instance of REDCap (Research Electronic Data Capture) database. Names or other direct personal identifiers (such as address, medical record number, social security number, etc.) may be collected by the EIP site to assist in managing case information, but they are not shared with CDC. There are no direct personal identifiers in the data submitted to CDC for any of the forms included in this package. Patient information that is collected and shared with CDC include date of birth, age, sex, race, ethnicity, census tract, and clinical dates (e.g., dates of admission and discharge).

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.

Financial records, supporting documents, statistical records, and all other records pertinent to the grant program must be retained for a minimum of 3 years after the end of a budget period, or until completion and resolution of any audit in process or pending resolution. In all cases, records must be retained until resolution of any audit questions. Property records must be retained in accordance with 45 CFR 92.42. Line lists and CRFs should be retained for a minimum of 3 years in addition to the current surveillance year, or per site regulations. Forms related to special studies should be retained for a minimum of 3 years after the publication of the study, or per site regulations. If storage space becomes an issue, sites are advised to document which paper documents will be destroyed.

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

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

The HAIC activity conducts population-based surveillance for urgent threats to patient safety, including CDI, select Gram-negative bacilli (MuGSI), invasive *Candida* infections, and invasive *S. aureus* infections. As with ABCs surveillance described above, upon verification of a positive laboratory result and confirmation of residence within the pre-defined EIP catchment area, each EIP site conducts data abstraction of the medical chart and laboratory report to complete the standardized case report forms.

Information in Identifiable Form (IIF) will be collected by each EIP site. Other information that may be collected could include hospitalization history, lab test results and culture information, symptoms, discharge diagnosis, antimicrobial treatments, ICD-9 and/or ICD-10 codes, healthcare worker status, influenza vaccination status, and underlying medical conditions. Information transmission occurs via a secure CDC website. The case report form does not involve web-based data collection methods, although case report form data are entered into a CDC-developed, approved web-based data management system for some activities and does not refer respondents to websites.

For HAIC projects, personally identifying information such as names and addresses are not shared with CDC. Date of birth, race, ethnicity, sex, hospitalization dates, type of healthcare facility as

defined by the Centers for Medicare and Medicaid (CMS), 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.

Privacy Impact Assessment Information

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

2. For FluSurv-NET, consent forms are not needed to collect clinical data because the scope of work is considered public health surveillance. FluSurv-NET consent forms are obtained from patients undergoing telephone interview for influenza vaccination history. Copies of the consent form will be retained at the participating site and will not be submitted to CDC. CDC only receives vaccine status information and does not receive any personally identifiable information.

   For the medical review component of HAIC, consent is not applicable as EIP personnel perform review of existing medical record data in participating facilities or via remote access and submit these data to CDC in a secure manner, as described previously, without having any interaction with individual patients. Information received by CDC are stored in secure databases (certification and accreditation at appropriate level according to current information security procedures and standards) or will be uploaded by EIP site personnel to site-specific encrypted, secure CDC FTP sites or other secure sites meeting current information security requirements. Case-specific information received by CDC will be provided only to those individuals at CDC with a need to know.

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

4. For the HAIC MuGSI CA CP-CRE Health Interview, cases will be contacted via phone with the use of telephone interview introductory script and consent (agreement) to participate will be obtained from patients undergoing the telephone health interview. Copies of the interview introductory script will be retained at the participating site and will not be submitted to CDC. CDC will receive the information collected during the health interview, but this information is not identifiable. Information received by CDC for this health interview will be stored in a secure manner (certification and accreditation at appropriate level according to current information security procedures and standards). Case-specific information received by CDC will be provided only to those individuals at CDC with a need to know.

Data will be kept private to the extent allowed by law.

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

IRB Approval

NCEZID's Human Subjects Advisor has determined that information collection is not research involving human subjects (Attachment 5). The data collection forms included in this package constitute public health surveillance. Therefore, the protocols associated with the forms included in this package are not subject to IRB review.

Justification for Sensitive Questions

For ABCs, sensitive information such as the presence of HIV/AIDs and other underlying conditions, alcohol use, drug use, race, and ethnicity are collected from medical records and analyzed to describe risk factors for infection with the purpose of contributing valuable knowledge to the field of public health.

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

In FluSurv-NET, age and variables related to documentation of laboratory-confirmed influenza-associated hospitalization are of central importance to this study. Additional clinical and, underlying health conditions, influenza vaccination status, 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.

For HAIC surveillance, demographic and clinical data (including information on the presence of chronic conditions, smoking, drug and alcohol use, and incarceration) are collected from medical records and analyzed to describe risk factors for infection with important healthcare-associated and antimicrobial-resistant pathogens.

12. Estimates of Annualized Burden Hours and Costs

For this revision, the total estimated burden is 41,483 hours. The previous approval (non-substantive change request approved January 2, 2024) was for an estimated annual burden of 56,133 hours.

Table A.12-A1. Estimated Annualized Burden Hours

Type of Respondent	Form Number	Form Name	No. of respondents	No. of responses per respondent	Avg. burden per response (in hours)	Current Total burden (in hours)
State Health Department	ABC.100.1	ABCs Case Report Form	10	809	20/60	2697
	ABC.100.2	ABCs Invasive Pneumococcal Disease in Children and Adults Case Report Form	10	127	10/60	212
	ABC.100.3	ABCs *H. influenzae* Neonatal Sepsis Expanded Surveillance Form	10	6	10/60	10
	ABC.100.4	ABCs Severe GAS Infection Supplemental Form	10	136	20/60	453
	ABC.100.5	ABCs Neonatal Infection Expanded Tracking Form	10	37	20/60	123
	FN.200.1	FoodNet Campylobacter	10	970	21/60	3395
	FN.200.2	FoodNet Cyclospora	10	42	10/60	70
	FN.200.3	FoodNet Listeria monocytogenes	10	16	20/60	53
	FN.200.4	FoodNet Salmonella	10	855	21/60	2993
	FN.200.5	FoodNet Shiga toxin producing E. coli	10	290	20/60	967
	FN.200.6	FoodNet Shigella	10	234	10/60	390
	FN.200.7	FoodNet Vibrio	10	46	10/60	77
	FN.200.8	FoodNet Yersinia	10	55	10/60	92
	FN.200.9	FoodNet Hemolytic Uremic Syndrome	10	10	1	100
	FN.200.10	FoodNet Clinical	10	70	10/60	117

		Laboratory Practices and Testing Volume				
	FSN.300.1	FluSurv-Net Influenza Hospitalization Surveillance Network Case Report Form	15	576	25/60	3600
	FSN.300.2	FluSurv-Net Influenza Hospitalization Surveillance Project Vaccination Phone Script and Consent Form (English/Spanish)	13	16	10/60	34
	FSN.300.3	FluSurv-Net Influenza Hospitalization Surveillance Project Provider Vaccination History Fax Form (Children/Adults) and notification letter	13	126	5/60	136
	FSN.300.4	FluSurv-NET Laboratory Survey	15	16	10/60	40
	HAIC.400.1	HAIC- Multi-site Gram-Negative Surveillance Initiative (MuGSI) Case Report Form (CRF)	11	1581	29/60	8406
	HAIC.400.2	HAIC MuGSI CA CP-CRE Health interview	10	10	30/60	50
	HAIC.400.3	HAIC MuGSI Supplemental Surveillance Officer Survey	11	1	20/60	4
	HAIC.400.4	HAIC- Invasive *Staphylococcus aureus* Infection Case Report Form	10	788	29/60	3809

	HAIC.400.5	HAIC- Invasive *Staphylococcus aureus* Laboratory Survey	10	11	9/60	17
	HAIC.400.6	HAIC- Invasive *Staphylococcus aureus* Supplemental Surveillance Officers Survey	10	1	11/60	2
	HAIC.400.7	HAIC - CDI Case Report and Treatment Form	10	1650	38/60	10450
	HAIC.400.8	HAIC- Annual Survey of Laboratory Testing Practices for *C. difficile* Infections	10	16	17/60	45
	HAIC.400.9	HAIC- CDI Annual Surveillance Officers Survey	10	1	15/60	3
	HAIC.400.10	HAIC- Emerging Infections Program *C. difficile Surveillance Nursing Home Telephone Survey (LTCF)*	10	45	5/60	38
	HAIC.400.11	HAIC Candidemia Case Report Form	10	170	40/60	1133
	HAIC.400.12	HAIC- Laboratory Testing Practices for Candidemia Questionnaire	10	20	14/60	47
	HAIC.400.13	HAIC Death Ascertainment Project	10	8	24	1,920
TOTAL						**41,483**

B. The following table shows estimated burden costs associated with each instrument. The salaries are based on the Bureau of Labor Statistic's May 2023 wages. The mean hourly wage for epidemiologists was used (https://www.bls.gov/oes/current/oes191041.htm).

Type of Respondent	Form Number	Form Name	Total burden hours	Hourly wage rate	Total Respondent costs
State Health Department	ABC.100.1	ABCs Case Report Form	2697	$41.29	$111,359.13
	ABC.100.2	ABCs Invasive Pneumococcal Disease in Children and Adults Case Report Form	212	$41.29	$8,753.48
	ABC.100.3	ABCs *H. influenzae* Neonatal Sepsis Expanded Surveillance Form	10	$41.29	$412.90
	ABC.100.4	ABCs Severe GAS Infection Supplemental Form	453	$41.29	$18,704.37
	ABC.100.5	ABCs Neonatal Infection Expanded Tracking Form	123	$41.29	$5,078.67
	FN.200.1	FoodNet Campylobacter	3395	$41.29	$140,179.55
	FN.200.2	FoodNet Cyclospora	70	$41.29	$2,890.30
	FN.200.3	FoodNet Listeria monocytogenes	53	$41.29	$2,188.37
	FN.200.4	FoodNet Salmonella	2993	$41.29	$123,580.97
	FN.200.5	FoodNet Shiga toxin producing E. coli	967	$41.29	$39,927.43
	FN.200.6	FoodNet Shigella	390	$41.29	$16,103.10
	FN.200.7	FoodNet Vibrio	77	$41.29	$3,179.33
	FN.200.8	FoodNet Yersinia	92	$41.29	$3,798.68
	FN.200.9	FoodNet Hemolytic Uremic Syndrome	100	$41.29	$4,129.00
	FN.200.10	FoodNet Clinical Laboratory Practices and Testing Volume	117	$41.29	$4,830.93

	FSN.300.1	FluSurv-Net Influenza Hospitalization Surveillance Network Case Report Form	3600	$41.29	$148,644
	FSN.300.2	FluSurv-Net Influenza Hospitalization Surveillance Project Vaccination Phone Script and Consent Form (English/Spanish)	34	$41.29	$1,403.86
	FSN.300.3	FluSurv-Net Influenza Hospitalization Surveillance Project Provider Vaccination History Fax Form (Children/Adults) and notification letter	136	$41.29	$5,615.44
	FSN.300.4	FluSurv-NET Laboratory Survey	40	$41.29	$1,651.60
	HAIC.400.1	HAIC- Multi-site Gram-Negative Surveillance Initiative (MuGSI) Case Report Form (CRF)	8406	$41.29	$347,083.74
	HAIC.400.2	HAIC MuGSI CA CP-CRE Health interview	50	$41.29	$2,064.50
	HAIC.400.3	HAIC MuGSI Supplemental Surveillance Officer Survey	4	$41.29	$165.16
	HAIC.400.4	HAIC- Invasive *Staphylococcus aureus* Infection Case Report Form	3809	$41.29	$157,273.61
	HAIC.400.5	HAIC- Invasive *Staphylococcus aureus* Laboratory Survey	17	$41.29	$701.93
	HAIC.400.6	HAIC- Invasive *Staphylococcus aureus* Supplemental Surveillance Officers Survey	2	$41.29	$82.58
	HAIC.400.7	HAIC - CDI Case Report and Treatment Form	10450	$41.29	$431,480.50

	HAIC.400.8	HAIC- Annual Survey of Laboratory Testing Practices for *C. difficile* Infections	45	$41.29	$1,858.05
	HAIC.400.9	HAIC- CDI Annual Surveillance Officers Survey	3	$41.29	$123.87
	HAIC.400.10	HAIC- Emerging Infections Program *C. difficile Surveillance Nursing Home Telephone Survey (LTCF)*	38	$41.29	$1,569.02
	HAIC.400.11	HAIC Candidemia Case Report Form	1133	$41.29	$46,781.57
	HAIC.400.12	HAIC- Laboratory Testing Practices for Candidemia Questionnaire	47	$41.29	$1,940.63
	HAIC.400.13	HAIC Death Ascertainment Project	1,920	$41.29	$79,276.80
TOTAL					$1,712,833.07

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

There are not costs to respondents other than their time.

14. Annualized Cost to the Federal Government

Estimated cost based on 2023 figures

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

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

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government	CDC Principal Investigator (0.8 FTE); CDC Surveillance Coordinator (0.8 FTE); Program Analyst (1.0 FTE), Data Manager (1.0 FTE)	660,500
	Subtotal, Direct Costs to the Government	660,500
Cooperative Agreement Expenses	California Site Cost and Fees	970,091
	Colorado Site Cost and Fees	762,447
	Connecticut Site Cost and Fees	809,755
	Georgia Site Cost and Fees	1,603,781
	Maryland Site Cost and Fees	837,213
	Minnesota Site Cost and Fees	1,062,451
	New Mexico Site Cost and Fees	607,413
	New York Site Cost and Fees	662,472
	Oregon Site Cost and Fees	613,851
	Tennessee Site Cost and Fees	1,057,596
	Subtotal, Contracted Services	8,987,070
	TOTAL COST TO THE GOVERNMENT	9,647,570

Foodborne Diseases Active Surveillance Network (FoodNet)

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

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government	CDC Principal Investigator (1.0 FTE); CDC Doctoral staff (2.0 FTE); CDC surveillance officers (2.0 FTE); Epidemiology Fellows (4.0 ORISE Fellows)	850,000
	Subtotal, Direct Costs to the Government	850,000
Cooperative Agreement Expenses	California Site Cost and Fees	600,000
	Colorado Site Cost and Fees	548,300
	Connecticut Site Cost and Fees	500,400
	Georgia Site Cost and Fees	747,300
	Maryland Site Cost and Fees	291,000
	Minnesota Site Cost and Fees	742,200
	New Mexico Site Cost and Fees	295,400
	New York Site Cost and Fees	535,900
	Oregon Site Cost and Fees	532,200
	Tennessee Site Cost and Fees	605,700
	Subtotal, Contracted Services	5,398,400
	TOTAL COST TO THE GOVERNMENT	6,248,400

Influenza - All Age Influenza Hospitalization Surveillance Network

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

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government	CDC Principal Investigator (1.0 FTE); CDC Deputy Lead (1.0); CDC Project Officer (2.0 FTE); Data Manager (3.0 FTE)	851,244
	Subtotal, Direct Costs to the Government	851,244
Cooperative Agreement Expenses	California Site Cost and Fees	577,600
	Colorado Site Cost and Fees	418,517

	Connecticut Site Cost and Fees	580,000
	Georgia Site Cost and Fees	625,933
	Maryland Site Cost and Fees	370,737
	Michigan Site Cost and Fees	207,561
	Minnesota Site Cost and Fees	569,555
	New Mexico Site Cost and Fees	555,094
	New York Site Cost and Fees	735,803
	Oregon Site Cost and Fees	490,440
	Tennessee Site Cost and Fees	530,734
	Washington Site Cost and Fees	380,399
	Subtotal, Contracted Services	6,042,373
	TOTAL COST TO THE GOVERNMENT	6,893,617

Healthcare Associated Infections-Community Interface (HAIC)

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

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government	CDC HAIC Directors (2.0 FTE), Principal Investigators (3.0 FTE); CDC Surveillance Coordinators (3.25FTE); HAIC Coordinator (0.25 FTE), Business Analysts (0.75 FTE), Laboratory Scientists (6.0FTE); AMD Science Contributions (1.0 FTE), Data Manager (1.0 FTE); Statistical Consultation (0.2), Contractor Support (3.0)	2,622,917
Annualized Total Cost to the Federal Government		41,699,051
	Subtotal, Direct Costs to the Government	2,622,917
Cooperative Agreement Expenses	California Site Cost and Fees	1,527,53
	Colorado Site Cost and Fees	1,384,936
	Connecticut Site Cost and Fees	2,270,339
	Georgia Site Cost and Fees	3,580,109
	Maryland Site Cost and Fees	1,162,372
	Michigan Site Cost and Fees	310,351
	Minnesota Site Cost and Fees	1,662,192
	New Mexico Site Cost and Fees	972,450
	New York Site Cost and Fees	2,464,921
	Oregon Site Cost and Fees	1,670.054
	Tennessee Site Cost and Fees	1,795,225
	Subtotal, Contracted Services	18,909,464
	TOTAL COST TO THE GOVERNMENT	21,532,381

15. Explanation for Program Changes or Adjustments

This is a request for a revision. There are 13 total forms being changed as a part of this revision and no new forms being added. Most of the collection activities remain the same, however, there are a few proposed revisions including minor revised language and rewording to improve clarity and readability of the data collection forms.

Details of each collection instrument for the revision are included in attachment entitled ***Explanation for Program Changes*** (Attachment 6)**.**

16. Plans for Tabulation and Publication and Project Time Schedule

For ABCs, CDC receives and reviews data monthly and provides each surveillance site with several forms of feedback including data integrity checks and summary tables in the format of a Power BI dashboard (i.e., Feedback packet and Site-Level Trends Dashboard). The dashboard includes a summary of case counts, data completeness, isolate submission rates, and additional visualizations on

demographics, geographic and clinical characteristics. Feedback from sites to local hospitals, laboratories, and other constituents is at the discretion of each site.

CDC generates pathogen-specific ABCs surveillance reports annually (https://www.cdc.gov/abcs/reports-findings/surv-reports.html). ABCs has also made surveillance data available through Bact Facts Interactive, an interactive data visualization dashboard that allows users to view ABCs pathogen specific case counts and rates by key demographic and laboratory characteristics (https://www.cdc.gov/abcs/bact-facts-interactive-dashboard.html). Additionally, the underlying data populating the Bact Facts Interactive dashboard is available at data.cdc.gov (https://data.cdc.gov/browse?q=abcs%20bactfacts&sortBy=relevance) and these public use datasets are downloadable in a variety of formats (CSV; CSV for Excel; RDF; RSS, TSV for Excel; XML) for offline use with any standard statistical software package.

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, and published yearly in an MMWR and are publicly available online through a web-based interface (https://wwwn.cdc.gov/foodnetfast/).

For FluSurv-NET, prospective surveillance will be conducted for hospital admissions occurring each influenza season between October 1 and April 30. Surveillance may be extended beyond the designated surveillance period in seasons when influenza activity may occur outside the typical influenza season.

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, staff members at CDC and in the EIP sites are engaged in an ongoing fashion in data analysis. Annual Surveillance Reports are produced for each HAIC surveillance activity. It is routine for several abstracts and papers to be presented at national meetings and published in peer-reviewed journals throughout the year.

FoodNet publishes surveillance data online through a web-based interface (https://wwwn.cdc.gov/FoodNetFast/).

FluSurv-NET has made hospitalization rates publicly available through FluView Interactive (https://gis.cdc.gov/GRASP/Fluview/FluHospRates.html). Cumulative and weekly rates have been published, as well as rates by season, age group, sex, and race/ethnicity. Additionally, demographic and clinical data on hospitalizations are publicly available (https://gis.cdc.gov/grasp/fluview/FluHospChars.html, https://www.cdc.gov/surveillance/resp-net/dashboard.html, Groups Most Impacted—Hospitalizations (cdc.gov)).

HAIC has made surveillance data available through CDC HAIC Viz () and CDC Antimicrobial Resistance & Patient Safety Portal (https://arpsp.cdc.gov/) This data is updated on a regular basis. Additionally, the underlying data populating the HAIC Viz platform is available on data.cdc.gov.

17. Reasons Display of OMB Expiration Date is Inappropriate

Data collections for ABCs and HAIC forms generally remain constant from one expiration date to the next. To make the most efficient use of the forms that have already been distributed to state health department personnel we request that the OMB expiration date not be printed on these forms. Therefore, the display of the OMB expiration date is not appropriate. For FoodNet and FluSurv-NET 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.