New Information Collection Request for:

All Age Influenza Hospitalization Surveillance Project (All Flu Hosp)

Part A

Laurie Kamimoto, Principal Investigator
Telephone: (404) 639-4653
E-mail: lek0@cdc.gov
Fax: (404) 639- 3688

Lyn Finelli, Collaborator
Telephone: (404) 639-2554
E-mail: lyf8@cdc.gov

Joyce Gyamfi, Project Manager
Telephone: (404) 639-2476
E-mail: gcx3@cdc.gov
Fax: (404) 639-3970

March 28, 2008

All Age Influenza Hospitalization Surveillance Project

A. Justification

1. Circumstances making the collection of information necessary

Background

Classification of Information Collection Request (ICR): New

The Centers for Disease Control (CDC), National Center for Immunization and Respiratory Diseases (NCIRD) is committed to achieving health promotion, disease prevention, and wellness objectives of "Healthy People 2010" and to obtaining population based surveillance data related to influenza-associated hospitalizations. The data collections in this package comprise an All Age Influenza Hospitalization Surveillance (Flu Hosp) project. The Flu Hosp project is comprised of the Pediatric Influenza Hospitalization Project and the Adult Influenza Hospitalization Surveillance Project (Adult Flu Hosp). The Adult Flu Hosp project will consist of two phases, a prospective data collection, and a retrospective discharge audit. Both projects address priority areas and surveillance goals and are in alignment with CDC NCIRD's performance goals(s) to protect America's health.

The Influenza Division's objective for collecting this information is to obtain population-based surveillance data associated with laboratory-confirmed influenza in children and adults. The Pediatric Influenza Hospitalization Project and Adult Flu Hosp will characterize the burden of and risk factors for laboratory-confirmed influenza-associated hospitalizations in several geographic locations in the United States. The discharge audit will reveal limitations in case identification in the first phase of the Adult Flu Hosp Surveillance project. The results of the data collection will assist the Influenza Division to determine whether groups at risk for severe outcomes of influenza are appropriately targeted for the pediatric influenza vaccine and will provide information about severe influenza hospitalization among adults. Furthermore, the Adult Flu Hosp project will provide insight into the role of statin medications in reducing morbidity and mortality from influenza infection.

The need for more data on influenza impact in children was highlighted during the 2003-04 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. The Advisory Committee on Immunization Practices' (ACIP) recommendations for the prevention and control of influenza included a recommendation to expand vaccination from 6-23 month olds to 6- 59 month olds in 2006 based on studies suggesting elevated hospitalization rates and outpatient visits among patients of this age group. However, more data are needed to determine if current vaccine recommendations adequately cover all children at increased risk for complications of influenza.

Currently there is no national surveillance system in place that is able to estimate the burden of laboratory-confirmed adult hospitalizations during seasonal or pandemic influenza within a given season. Furthermore, although statins have been shown to reduce mortality associated with

bacterial sepsis in animal models and in observational studies in humans, less is known about their utility in reducing mortality associated with influenza. Additionally, because influenza is often underreported, including a retrospective discharge audit in addition to conducting prospective surveillance is needed to identify limitations in current surveillance efforts.

Section 301 of Public Health Service Act (42 U.S.C. 241) (Attachment 1) authorizes the collection of these data.

Privacy Impact Assessment

A.1.B. Overview of the Data Collection System

Approval is sought for an Adult Case Report Form (Attachment 3) and a Pediatric Case Report Form (Attachment 4) that collect demographic and clinical information from laboratory-confirmed influenza hospitalized adults and children who reside in a geographic- and population-defined area of the United States. The case report forms included in this package are based on case report forms that have been used to assess flu burden in participating sites in previous years. The Adult Case Report Form will be used to collect information on patients over the age of 18 years old, and the Pediatric Case Report form will be used for patients under 18 years and younger. The primary difference between the two forms is that the Adult Case Report form includes collection of information related to Statin use, and the Pediatric Case Report form does not.

The data collection network is an established CDC-state-academic institution collaborative network, the Emerging Infections Program (EIP) which includes the states of California, Colorado, Connecticut, Georgia, Maryland, Minnesota, New Mexico, New York, Oregon, and Tennessee. Medical chart review and data abstraction using the project's case report form will be conducted by the EIP site upon verification of an influenza positive lab result to collect more detailed clinical and epidemiologic information. For all persons meeting the case definition and inclusion criteria, a standardized case report form will be completed using data obtained from the laboratory and medical chart review (Attachments 3 & 4). To obtain influenza vaccine history, sites will either: 1) review medical chart, or 2) contact patients, their proxies or long term care facilities, from where a case resided prior to hospitalization, and/or primary care providers by fax to obtain that information. When influenza vaccination history is absent from the medical records, all sites will conduct either a telephone interview of the case or proxy or medical provider to obtain influenza vaccination history.

CDC's participating partners will also perform a discharge audit to assess the completeness of the case surveillance data by conducting an evaluation of the hospitalized influenza cases found by Flu Hosp versus an independent, administrative hospital dataset. Each of the ten participating sites will complete four standardized forms that describe the evaluation process and the number of cases missed by Flu Hosp, in aggregate. If missing cases are identified, a case report form that is almost identical to the case report form used in the prospective data collection phase will be used (Attachment 5). The data for cases identified in the discharge audit will be collected through medical chart review and telephone interview when necessary, as described above. Additional Discharge Audit forms consist of a matching form (Attachment 6) that serves to assist data collectors in identifying missed cases, a sampling strategy form (Attachment 7), a summary form (Attachment 8) which includes information from the matching and sampling strategy forms, and an electronic questionnaire (Attachment 9) that assesses barriers in case

ascertainment and future plans for surveillance, which are all completed by the health departments participating in the data collection. 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.

A.1.C. Items of Information to be Collected

Information in Identifiable Form (IIF) will be collected by collaborators, 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 will be collected includes:

- Hospitalization history
- Lab test results and culture information
- Discharge Diagnoses
- Symptoms
- Use of Statins
- Case Identification Method
- Influenza Vaccination Status
- Treatments
- Number of missed cases
- ICD 9 and CPT codes
- Number of positive and negative flu test results
- Challenges of Case Ascertainment
- Future plans for Surveillance

A.1.D. Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

Information transmission occurs via a secure CDC website, but the information collection forms do not involve web-based data collection methods and do not refer respondents to websites.

2. Purpose and use of the information collection

Publications of clinically significant findings will be sought to add to the understanding of influenza. Any new or unexpected findings that result from this surveillance will be made publicly available, including to advisory groups charged with developing recommendations for vaccination and chemotherapy to prevent and treat influenza.

Preliminary aggregate pediatric hospitalization rates by age group will be made available through publication in the Weekly Influenza Surveillance Report (http://www.cdc.gov/flu/weekly/fluactivity.htm) on a biweekly basis. Aggregate results also will be published periodically in the Morbidity and Mortality Weekly Report (MMWR) and peer-reviewed literature and will be shared with relevant CDC programs and the Advisory Committee on Immunization Practices (ACIP). Aggregate results from the Adult Flu Hosp project will be

shared with relevant CDC programs, including the ACIP. Results from the Adult Flu project will be widely disseminated following verification of data by the discharge audits.

The data collection has important practical utility to the government (specifically the Influenza Division) as well as EIP populations and the American population as a whole in future influenza seasons. The data will benefit public health by aiding in the modification of influenza prevention and control recommendations and in assessing the impact of the US vaccination program, as well as evaluating the effects of statin use on adult influenza associated morbidity and mortality. Furthermore, the discharge audit will potentially benefit the US adult population as a whole in future influenza seasons by providing accurate estimates of hospitalization rates.

A.2.1 Privacy Impact Assessment Information

Tools within this package will be used to conduct influenza hospitalization surveillance and evaluation for all age groups and to obtain the age-specific rates of laboratory-confirmed, influenza-associated hospitalizations in a several geographic populations. The data collections will allow investigators to study rate of serious influenza-associated complications and risk factors associated with serious influenza-associated complications, and death. Furthermore, the data collection will provide evidence of the effect of statin use on influenza associated morbidity and mortality.

Cases identified through the Adult Flu Hosp project may be an underestimate of the true number of hospitalized influenza-infected adults. Underreporting occurs for many reasons that include: 1) because the case definition requires that an influenza positive test result be documented and yet regional and practice variability in influenza testing exists, persons may be infected with influenza but never diagnosed; 2) false negative test results from insensitive influenza rapid testing; 3) negative test result because adults are more likely delay seeking medical care for their illness and by the time they are tested viral shedding may be so low that the test is unable to detect virus. To address any limitation in completeness of case identification, a retrospective discharge audit will be conducted by each participating site following the 2007-08 flu season. Based on the results of the discharge audit, participating sites may need to modify the list of hospitals under active surveillance or establish relationships with local partners to ensure timely and complete case identification.

No Information in Identifiable Form (IIF) will be collected by CDC. CDC partners will collect IIF about cases, and therefore there will be a likely effect on the patients' privacy if there was a breach of confidentiality. In an effort to prevent 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 the earliest opportunity, unless there is a public health or research justification for retaining the identifiers or are required to by law.

3. Use of improved information technology and burden reduction

The size of the catchment area, and the variations in electronic reporting ability among the health care facilities included in the study precludes an electronic form at each of the sites under surveillance. For all persons meeting the case definition, a standardized case report form will be completed by surveillance officers using data obtained from the laboratory and a manual medical record review. If influenza and pneumococcal vaccine history is not noted in the medical chart, telephone and facsimile equipment will be used to contact primary care providers, patients, and/or proxy to obtain that information.

CDC will provide to each EIP site a Microsoft Access database that mirrors the case report form. Surveillance staff at each participating EIP site will enter data from the case report form into the database and submit the complete database, stripped of identifiers, to CDC biweekly during active prospective surveillance for both pediatric and adult projects. All data transfers to CDC take place via the secure CDC FTP site (ftp://sftp.cdc.gov/) within the Respiratory Disease Activity (RDA) folder. At CDC, data from all sites will be concatenated and exported into SAS.

All states have some type of a state-wide hospital discharge database. In order to participate in the Adult Discharge Audit, not all states will be able to use their state discharge database. It is the policy of a number of states, in order to unlink identifiable information, to exclude admission date and date of birth—two variables that would be included in a matching algorithm. In other states the lag time to obtain a state discharge database is in the order of 18 months, much later than what this protocol proposes. In such instances where the state hospital discharge database is not available, sites will be creating a composite hospital discharge database. All hospitals located within the catchment area, in addition to "buffer" hospitals (ie, hospitals outside the catchment counties but adjacent to the catchment counties) will be included.

The discharge audit forms will all be filled out using a Microsoft Word document and sent electronically to CDC via e-mail. 100% of the forms will be submitted electronically.

4. Efforts to identify duplication and use of similar information

CDC epidemiologists conduct literature reviews continually to stay informed of the current knowledge-base of influenza (See 10). CDC staff has also attended local, national, and international conferences relevant to the topic, communicated frequently with non-federal colleagues at universities and health departments, as well as with colleagues within the government.

Until the recent increase in influenza rapid diagnostic test use, relatively few children were tested for influenza virus infection; therefore, most burden of disease and risk factor studies have relied on mathematical modeling to estimate the proportion of influenza-like illnesses that were most likely due to influenza. Generalizations from modeling studies are limited because the clinical signs of influenza in children and particularly infants are difficult to distinguish from other respiratory diseases.

A recent review article summarized the potential role of statin medications in reducing morbidity and mortality from influenza infection in the setting of a global pandemic, when vaccines and antivirals may not be widely available, particularly in developing nations. Statins have been shown to reduce mortality associated with bacterial sepsis in animal models and in observational studies in humans. However, knowledge about their utility in reducing mortality associated with influenza is lacking.

None of the questions on the case report forms were taken directly from another survey. The questions on the case report forms are basic clinical and demographic characteristics, which are

routinely collected in data collection for surveillance. The only exception are the questions on the adult hospital project form relating to statin use (Page 2, Adult Influenza Hospitalization Surveillance Project Case Report Form [Attachment 3]), which is not included in any other survey.

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, the reporting of flu cases to the state health department may place a small burden on small hospitals, especially those without electronic lab reporting and/or in those states where influenza is not a reportable condition.

6. Consequences of collection of the information less frequently

Respondents are required to submit data for the Adult Flu Hosp project and the Pediatric Influenza Project to the CDC bi-weekly 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. Frequency of reporting will not increase to more than biweekly, unless Subject Matter Experts in the Influenza Division determine that more frequent data collection is needed in the event of a severe outbreak or the identification of a pandemic.

It would not be appropriate to collect influenza surveillance data less than biweekly 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 bi-weekly reporting, respondents are only required to submit data for six variables on the case report form bi-weekly during influenza season. CDC requests the remaining variables to be completed and submitted by September 30.

Data for the Discharge audit will be a one-time data collection; however, sites can submit data monthly or quarterly if they chose (see explanation in question 7). Collection of less information would reduce the ability to reveal limitations in case identification in the Influenza surveillance. There are no legal obstacles to reduce the burden.

7. Special circumstances relating to the guidelines of 5 CFR 1320.5

For the reasons described in A.6. above, respondents are required to report information more often than quarterly (bi-weekly) for the adult and pediatric influenza surveillance projects. Surveillance reports are requested on a periodic 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.

The Adult Discharge Audit that will occur in 2008 using 2006-07 season data, EIP sites should complete the audit by the end of 2008. Since the cases identified from the audit will not be included the case count for the 2006-07 season, the reporting of audit or missed cases is not

time sensitive. It is up to the discretion of the site when they chose to enter data of the missed cases into the same Access Database used for regular surveillance purposes; it is likely to be monthly or quarterly reporting and included in the data uploads of their current season surveillance cases. No plans are in place to repeat the discharge audit after data collection for the 2006-07 season is complete.

Otherwise, there are no 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 60-day FRN was published in the *Federal Register* on November 26, 2007, vol. 27, No. 226, pp. 65965- 65966 (See Attachment 2). There were no comments received in response to the 60 Day Federal Register Notice.

At the 2004 Emerging Infections Program (EIP) annual steering committee meeting, the EIP made a decision to launch a new respiratory diseases activity (the EIP RDA) to foster integration of existing respiratory activities within the program and support development of new respiratory projects. A panel of four external consultants, the RDA steering committee, and CDC respiratory infections subject matter experts met at CDC on February 14, 2005 to identify and discuss priority areas of focus for the EIP RDA. All members of the group agreed that surveillance of laboratory-confirmed influenza in children less than 18 years old should be a priority focus area. Extending the pediatric project to include adults was a recommendation from the meeting.

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

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. Additionally, CDC will not have identifying information on patient health care providers. Each hospital where charts are abstracted will be given a numerical ID (the identification code used in the Active Bacterial Core surveillance) 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 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 primary objective of the Pediatric Influenza Hospitalization Project is to conduct surveillance and evaluation of the magnitude of influenza in children during yearly influenza seasons. The National Center for Immunization and Respiratory Diseases has determined that these activities are not research, but rather a combination of active surveillance and program evaluation. As such, they do not need to be reviewed or approved by CDC's Institutional Review Board (Attachment 11).

The Adult Influenza Hospitalization protocol has obtained IRB approval (Attachment 12).

Privacy Impact Assessment Information

A. This submission has been reviewed by the Information Collection Review Office (IRCO), who determined that the Privacy Act does apply. The applicable Systems of Record Notice is Notice (SORN) 09-20-0147, "Epidemiologic Studies and Surveillance of Disease Problems."
B. 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 the earliest opportunity, unless there is a public health or research justification for retaining the identifiers or are required to by law.
C. 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 (attachments (13 and 14) and verbal consent obtained before proceeding (Attachments 15 and 16). Informed consent in some EIP sites may not be required because influenza hospitalization is a reportable condition in that state. Those EIP sites will 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.

Statin use prior to or during hospitalization will be obtained exclusively from the medical record. In instances where contact with the patient occurs, such as during the phone interview to collect vaccination history, oral consent for the phone interview will also include consent to collect statin use information, if required by local IRB. In the event that a patient refuses consent to allow collecting statin use information, if this information has been extracted from the medical records, the data will be struck from the case report form and will never appear in the local or CDC project database, in keeping with informed consent.

Persons whose influenza vaccination and statin use are documented in the medical chart or persons whose statin use is found in the medical chart but whose vaccination history is obtained from a provider, 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.

D. Respondents are informed about the voluntary nature of their response (See Attachments 13 & 14).

11. Justification for Sensitive Questions

Age and variables related to documentation of laboratory-confirmed influenza-associated hospitalization are of central importance to this study. Additional clinical and, underlying health conditions, influenza vaccination status, diagnosis with secondary bacterial co-infections, and ICU admission are necessary for determining rates of influenza-associated complications and factors associated with these complications.

Questions about pregnancy, past medical history or chronic conditions will be asked to clarify any risk factors for influenza or assess confounding factors of illness. Questions about race and ethnicity will be 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

CDC is requesting approval of seven data collection forms. Earlier versions of the case report forms have been used previously by investigators in previous influenza seasons and the time required to complete these forms has been used to calculate the burden in this package.

"Respondents" for each of the forms are health departments who submit biweekly case report forms for pediatric and adult influenza surveillance, and who submit discharge audit forms to CDC. "Responses" for the case report forms indicate the number of cases that are identified. Number of "responses" for all case report forms must be estimated as we do not know before hand how many cases will occur.

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 2006-07, the rate of laboratory-confirmed influenza-associated hospitalizations in children <18 years ranged from 1.0 to 3.1 per 10,000. With a population of ~5.2 million persons under surveillance we could expect between 500 and 1,500 case patients each influenza season. Because of variations among sites, CDC estimates an average of 75 cases per EIP site per flu season.

Hospitalization rates for pneumonia and influenza have ranged from a low of 6.8 per 100,000 person-years for adults <50 years old to 628.6 per 100,000 person-years for those aged ≥85 years [Thompson, 2004]. Using published [CDC, 2005] and unpublished [New York, Maryland] adult hospitalization surveillance data to determine an incidence range, influenza hospitalization cases from a single EIP site could number as high as 1200 cases. Because of regional influenza variations, CDC estimates an average of 120 laboratory confirmed influenza cases per EIP site per flu season.

"Responses" for Discharge Audit forms A-D indicate the number of times each site is required to fill out the respective form.

Table A.12-A. Estimated Annualized Burden Hours

Form Name	Type of Respondent	No. of respondents	Number of responses per respondent	Avg. burden per response (in hours)	Total burden (in hours)
Pediatric Influenza Hospitalization Surveillance Project Case Report Form	Health Department	10	75	15/60	188
Adult Influenza Hospitalization Surveillance Project Case Report Form	Health Department	10	120	15/60	300
Adult Discharge Audit Case Report Form	Health Department	11	3	15/60	8
Adult Discharge Audit Form A: Description of Matching Method	Health Department	11	1	15/60	3
Adult Discharge Audit Form B: Sampling Strategy	Health Department	11	1	15/60	3
Adult Discharge Audit Form C: Summary	Health Department	11	1	15/60	3
Adult Discharge Audit Form D: Future	Health Department	11	1	15/60	3
	Total				508

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 and Record Keepers

There are no costs to respondents other than their time.

14. Annualized Cost to the Federal Government

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	$152,116
	Colorado Site Cost and Fees	$203,407
	Connecticut Site Cost and Fees	$264,102
	Georgia Site Cost and Fees	$218,694
	Maryland Site Cost and Fees	$196,685
	Minnesota Site Cost and Fees	$107,336
	New Mexico Site Cost and Fees	$215,918
	New York Site Cost and Fees	$351,570
	Oregon Site Cost and Fees	$166,550
	Tennessee Site Cost and Fees	$109,743
	Subtotal, Contracted Services	$1,986,164
	TOTAL COST TO THE GOVERNMENT	$2,141,664

*Annual costs

15. Explanation for Program changes or Adjustments

This is a new data collection.

16. Plans for tabulation and publication and project time schedule

Prospective surveillance will be conducted for pediatric hospital admissions occurring each influenza season between October 1 and April 30.

Activity	Time Schedule
Begin prospective case finding and chart review	October 1
Biweekly: sites send data to CDC	October 1- April 30

End prospective case finding	April 30
Conduct discharge audit (select years only)	May 1- September 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

OMB expiration date will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to certification.