Supporting Statement A for Request for Clearance:

National Hospital Care Survey

OMB No. 0920-0212

Contact Information:

Carol DeFrances, Ph.D.
Lead Statistician, Hospital Care Team
Ambulatory and Hospital Care Statistics Branch
Division of Health Care Statistics
National Center for Health Statistics/CDC
3311 Toledo Road, Room 3409
Hyattsville, MD 20782
301-458-4440
301-458-4032 (fax)
cdefrances@cdc.gov

August 28, 2014

A. Justification………………………………………………………………………….. 2
1. Circumstances Making the Collection of Information Necessary…………………. 4
2. Purpose and Use of the Information Collection……………………………….... 8
3. Use of Information Technology and Burden Reduction………………………... 12
4. Efforts to Identify Duplication and Use of Similar Information…………………... 13
5. Impact on Small Businesses or Other Small Entities……………………………. 14
6. Consequences Of Collecting The Information Less Frequently…………………... 14
7. Special Circumstances Relating To The Guidelines For 5CFR1320.5……………. 15
8. Comments In Response To The Federal Register Notice And Efforts To Consult Outside The Agency…………………………………………………………………….. 15
  A. Federal Register Notice……………………………………………………………. 15
  B. Outside Consultation………………………………………………………………. 15
9. Explanation of Any Payment or Gifts to Respondents………………………….. 16
10. Assurance of Confidentiality Provided To Respondents………………………….. 17
11. Justifications for Sensitive Questions…………………………………………... 19
12. Estimates of Annualized Burden Hours and Costs……………………………… 21
13. Estimate Of Other Total Annual Cost Burden To Respondents Or Record Keepers 23
14. Annualized Cost to the Federal Government………………………………….. 23
15. Explanation for Program Changes or Adjustments……………………………. 24
16. Plans for Tabulation and Publication and Project Time Schedule………………. 24
17. Reason(S) Display Of OMB Expiration Date Is Inappropriate……………………. 25
18. Exceptions to Certification for Paperwork Reduction Act Submissions…………... 25

SUPPORTING STATEMENT

THE NATIONAL HOSPITAL CARE SURVEY

SUMMARY

The National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC), requests approval to continue the National Hospital Care Survey (NHCS) (OMB No. 0920-0212) including integrating into NHCS the National Hospital Ambulatory Medical Care Survey (NHAMCS) (OMB No. 0920-0278) and the Drug-Abuse Warning Network (DAWN) (OMB No. 0930-0078, discontinued 10/31/2011) previously conducted by the Substance Abuse and Mental Health Services Administration's (SAMHSA).

With the integration of NHAMCS and DAWN, the NHCS will provide nationally representative data on the utilization of hospital care and general purpose health care statistics on inpatient care as well as care delivered in Emergency Departments (EDs), Outpatient Departments (OPDs), and Ambulatory Surgery Locations (ASLs).

Integration of NHAMCS and DAWN into the NHCS is part of a broader strategy to improve efficiency and data quality by:

- minimizing redundancy in data collection;
- broadening our capability to collect more relevant data on patient movement through the health care system; and
- identifying opportunities to exploit administrative and electronic clinical data systems to augment primary data collection.

On April 30, 2013, the NHCS received a 3-year clearance to begin this integration. The following terms of clearance were part of the approval: " NCHS will communicate regularly with OMB about outcome of its preliminary work regarding combining NHAMCS with the NHCS, and the expected timing of combining these ICRs as well as its progress on developing the frame for the free standing ambulatory care facilities. Initially, NHCS will electronically collect administrative claims data but as more hospitals adopt Electronic Health Records (EHRs), NCHS will be poised to accept electronic files from hospital medical records for the NHCS."

It was understood that the original 3-year period would be one of transition for the NHCS. However, one year into this clearance we recognize that changes in record systems are requiring us to make significant modification to our plans for data collection.

The following activities have been updated since the March 2013 approval.

1. First, the induction of a new sample of hospitals continues for inpatient and begins for hospital ambulatory care. NHCS began recruitment of a national probability sample of 500 hospitals in May 2011; an additional 81 hospitals have been added from the reserve sample to improve the sampling of substance-involved visits. Recruitment efforts are discussed in more detail in A1 and B3.

2. Based on the status of hospital recruitment and the results of the 2013 NHCS ambulatory data collection (OMB No. 0920-0944 discontinued 06/30/2013) (discussed in Section A1), we anticipate that 2014 through 2015 will be a transitional period for collection of inpatient and visit data. The NHCS will have two components: 1) Inpatient and 2) ambulatory. The inpatient component will submit demographic and clinical data on all discharges either via electronic health records (EHRs) or UB-04 claims data. The ambulatory component will submit data on all ambulatory visits using one of two methods. The preferred method is via EHR which contains demographic and clinical data. For hospitals submitting UB-04 claims data, a sample of emergency department (ED) and outpatient department (OPD) visits will be abstracted to obtain clinical information.

The NCHS criterion for discontinuing NHAMCS and collecting data through NHCS will be the participation of a minimum of 250 hospitals with EDs in NHCS. NHAMCS will be operating in tandem with NHCS until the NHCS is fully implemented and so that the data collected in the two surveys can be compared.

Timeline for Implementing the NHCS Inpatient and Ambulatory Component

Ongoing - Recruitment of hospitals
August 201 4 - Start ED and OPD data abstraction
January 2016 - Decision on whether NHAMCS will be continued in addition to NHCS after 2015 data collection.

This request is for a three-year approval of the following:

- Continuation of recruitment of hospitals for NHCS including an additional 81 hospitals with 500 or more beds to improve substance-involved ED visit data collection.
- Continuation of the collection of hospital-level data through a paper questionnaire and the addition of several data elements related to weighting.
- Continuation of the collection of electronic data on inpatient discharges as well as ED and OPD visits through the collection of UB-04 claims or EHR data.
- Revise data items and combine patient record forms used to collect additional clinical information from a sample OPD and ambulatory surgery visits in order to more effectively capture ambulatory procedures in these two settings.
- Continuation of the collection of substance-involved ED visit data previously collected by DAWN through the ED component.
- Approval to make relatively minor additions, deletions, and changes to the survey through the use of nonsubstantive change submissions.
- Elimination of free-standing ambulatory surgery centers as part of the design of NHCS for 2014-2016.

The annual burden will increase by approximately 1,000 hours for a number of reasons: 1) a change from quarterly to monthly data transmission for UB-04 claims as ambulatory data sent for the third month of a quarter were often incomplete, creating a delay in sampling procedures; 2) the addition of 81 hospitals to the sample; and 3) questions added to the Annual Hospital Interview, which are critical for weighting the electronic data.

Meanwhile, the following data collection activities and their respective burden will no longer be needed for the current package: Ambulatory Unit Induction (250 hours) and the pulling and re-filing patient records for ED, OPD or ASL (833 hours). As a result of the elimination of free-standing ambulatory surgery centers (FSASCs), the Annual FSASC interview (84 hours), Prepare and transmit UB-04 (668 hours) and pulling and re-filing of patient records (140 hours) in FSASCs will no longer be needed.

A. Justification

1. Circumstances Making the Collection of Information Necessary

<u>Background</u>

The National Health Survey Act of 1956 initiated a period of intensive survey development in the United States to meet the multiple needs for health statistics in the public and private sectors. In 1960, the National Center for Health Statistics (NCHS) was formed. Since that time the NCHS has implemented, refined, and maintained surveys as necessary to meet the legislative mandate for providing health statistics. NCHS has structured its health care surveys into a family of nationally representative surveys of health care providers called the National Health Care Surveys. The current surveys which comprise the National Health Care Surveys are the National Hospital Care Survey (OMB No. 0920-0212 [formerly the National Hospital Discharge Survey (NHDS)]), National Ambulatory Medical Care Survey (OMB No. 0920-0278), National Hospital Ambulatory Medical Care Survey (NHAMCS) (OMB No. 0920-0234), and the National Study of Long-Term Care Providers (OMB No. 0920-0943). This family of surveys generates data that permit analyses of the relationship between the use of health services and characteristics of providers and patients at both national and regional levels. The National Health Care Surveys are authorized under Section 306(b) of the Public Health Service Act (42 USC 242k) (Attachment A). This package only seeks approval for activities related to the National Hospital Care Survey (NHCS). The National Hospital Discharge Survey is no longer in the field.

NHDS, conducted continuously between 1965 and 2010, was the Nation’s principal source of data on inpatient utilization of short-stay, noninstitutional, non-Federal hospitals, and was the principal source of nationally representative estimates on the characteristics of inpatients according to lengths of stay, diagnoses, surgical and non-surgical procedures, and patterns of use of care in hospitals in various regions of the country.

NHAMCS has been conducted since 1992 and will continue through at least 2015 data collection. It is designed to collect data on the utilization and provision of ambulatory care services in hospital EDs and OPDs and hospital and free-standing ambulatory surgery centers. Findings are based on a national sample of visits to these departments based on noninstitutional, non-Federal, general and short-stay hospitals and freestanding ambulatory surgery centers.

DAWN was conducted from 1972-2011 to monitor substance-involved hospital ED visits and medical examiners' cases. SAMHSA ceased DAWN survey operations in 2011 and requested that NCHS incorporate DAWN into the ED component of NHCS.

Inpatient Component of NHCS

In 2011, NCHS replaced the NHDS with the NHCS; recruitment of a sample of hospitals for this new survey began in May 2011. Hospitals in the NHCS are being asked to provide data on all inpatients from either UB-04 administrative claims or EHR database. Hospital-level data will be collected through a hospital questionnaire (Attachment J). NHCS will continue to provide the national general purpose health-care statistics as the NHDS provided. The NHCS has some distinct advantages over NHDS. First, more information at the hospital level is collected. This includes, but is not limited to, the hospital’s infrastructure for health information technology and volume of care provided by hospital. Thus, analyses of the effect of the hospital characteristics on the quality of care provided can be conducted.

Further, it is anticipated that the collection of electronic data will allow faster turnaround times and more timely release of survey data. The data being collected from the UB-04s and EHRs on the inpatient discharges are collected from all inpatient discharges, not just a sample. These data will be made available in a public use file after combining the UB-04 claims with the items on the EHR that match the UB-04 claim elements. The collection of personal identifiers (protected health information) will allow NCHS to link episodes of care provided to the same patient in the ED and/or OPD and as an inpatient, as well as link sampled cases to the National Death Index (to measure post-discharge mortality) and Medicare and Medicaid data. The availability of hospital identifiers also makes analysis on hospital readmissions and Intensive Care Unit utilization possible. The comprehensive nature of NHCS data opens up future opportunities for surveillance of topics of policy importance including the possibility of analyzing trends and incidence of acute myocardial infarction, heart failure and stroke; trends and point prevalence of healthcare acquired infections and antimicrobial use.

Ambulatory Component of NHCS

Beginning in 2013, hospitals participating in the NHCS are being asked to additionally provide UB-04 and/or EHR data on the utilization of health care services in their ambulatory settings (e.g., EDs and OPDs). The OPD component also includes ambulatory surgery visits.

The preferred method for obtaining ambulatory visit data is by submission of EHR data which contains both demographic and clinical patient information on all visits. For hospitals submitting electronic UB-04 claims data on all ambulatory visits, detailed clinical information is not available. Clinical information will need to be abstracted (or otherwise obtained) from the medical record. Due to the burden of abstraction, a sample of visits will be abstracted over a 3-month period.

Hospitals will be divided into two main categories with regard to visit sampling and data collection methods: remote access or non-remote access. Attachment C shows how the abstraction piece is organized within the ambulatory data component of NHCS.

The ED component of the NHCS supports SAMHSA's mission of drug abuse surveillance, prevention, and treatment objectives. These data will help SAMHSA target program resources to areas of greatest need and assess program impact. Additionally, data on substance-involved ED visits will be used by SAMHSA's Center for Behavioral Health Statistics and Quality (CBHSQ) to prepare reports on topics of interest to the public health community; to provide regular updates to SAMHSA and other federal agencies on trends in substance involvement; and to respond to ad hoc inquiries from a wide variety of groups and individuals. These estimates will be used to monitor trends in major substances of abuse (e.g., heroin, cocaine, marijuana) and to assess alcohol use by minors that result in ED visits. With the incorporation of DAWN into the NHCS, SAMHSA will have expanded data to use for assessment and decision-making, including not only substance-involved but also mental disorder data on clinical history, patient conditions, procedures, health insurance coverage, and more detailed disposition and provider information will be available.

Outside of SAMHSA, data on substance-involved ED visits from NHCS will be used by national, state, and local health professionals, policymakers, law enforcement officers, pharmacologists, and health services researchers to understand the consequences of substance use and abuse and to identify emerging trends and changing patterns of substance use. The White House Office of National Drug Control Policy will use these data to monitor national trends; the Drug Enforcement Administration will use it for surveillance, diversion control, and intelligence; and, at the direction of the Food and Drug Administration, the pharmaceutical industry will use it to conduct post-marketing surveillance of prescription and over-the-counter pharmaceuticals, monitor adverse events associated with medications, and assess the abuse potential that drives labeling and scheduling decisions.

Privacy Impact Assessment

The substantive information required for this section is provided in detail in "Overview of Data Collection System" below. The section titled "Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age" includes discussion of the NHCS website.

Overview of the Data Collection System

The target universe of the NHCS is inpatient discharges, and patient visits made to EDs and OPDs of non-Federal, non-institutional hospitals with six or more inpatient staffed beds in the 50 states and the District of Columbia. Introductory letters from NCHS (Attachments D and E) along with endorsement letters from professional associations will be followed by a telephone call from the contract staff to verify hospital eligibility for the survey and to arrange for an appointment with the chief executive officer and/or whoever is designated as the coordinator for this survey, as well as the directors of the ED and OPDs.

For hospitals selected into the survey, hospital-level data will be collected via telephone and personal interviews with hospital staff. For the electronic data component, either EHR or UB-04 claims data for all inpatient stays and ambulatory visits will be sent electronically from the participating sample of hospitals to a contractor's secure network. For the ambulatory care component, hospitals will be asked to provide data to assist with sampling visits as well as data on patient visits to the ED and OPD. Visit-level data will be obtained by contractor staff on a laptop PC-based abstraction data collection tool and UB-04 data will be transmitted to the contractor through a secure data network.

No potentially identifiable data will be released in any form to the public. Any data transmitted by a hospital to the contractor will be transferred through a secure data transfer system. Reports produced by NCHS about the data or using the data will not identify an individual hospital or an individual discharge/visit. Public use files will contain no information that can identify any individual or hospital. Restricted-use files may be accessed through the NCHS research data center to allow linkage to other data sources.

Items of Information to be Collected

The following hospital-level data will be collected: survey eligibility criteria, service characteristics, financial descriptors, expected number of visits, information related to ED crowding and use of EHRs. Discharge-level and visit data collected includes data elements on the UB-04 and/or from EHR data. These include patient demographics, diagnoses and procedures, source of payment information, charges, and information related to revenue codes. For hospitals submitting EHR data, additional variables include results of testing and procedures and clinician notes. A complete list of items collected can be found in Attachments F, G, H and I.

Information in Identifiable Form:

The NHCS will collect protected health information (PHI), also referred to as Information in Identifiable Form (IIF). One example of the value of PHI is that it will allow linkage to the National Death Index (NDI), providing better information on outcomes of hospitalization. Collection of PHI will also allow for linkages (e.g., inpatient discharges with ED and OPD visits). In its approval of the NHCS, the NCHS Ethics Review Board agreed that this research could not be conducted practicably without access and use of PHI. The list of requested PHI includes the following eleven data elements for patients, one data item for physicians and four for hospitals:

EHR and UB-04:

1. Patient name
2. Birth date
3. Address
4. ZIP Code
5. Dates of admission and discharge
6. Date of visit
7. Procedure dates
8. Social security number (where available)
9. Medical record number (where available)
10. Patient control number
11. Medicare health insurance benefit/claim number

12. NPI (National Provider Identifier) number

Hospital Interview:

13. Hospital name
14. Hospital address
15. Hospital telephone number
16. Contact name

EHRs and UB-04 claims are being transmitted from the hospital to the contractor's secure network. After processing, these data will eventually be sent to NCHS via CDC's Secure Access Management Services (SAMS). SAMS provides a secure data transfer service along with a strong suite of security controls to host applications and exchange data between CDC programs and public health partners while providing a high level of data integrity, confidentiality, reliability, and security. This meets NCHS/CDC policies for data transmission via the Internet. Users accessing systems protected by SAMS are required to adhere to the identity verification and authentication requirements for the Electronic Authentication Assurance Level (EAAL) of the protected system. SAMS provides system monitoring on a 24 x 7 basis, data redundancy features, and disaster recovery features for select information systems. On receipt at NCHS, all of the PII data (direct and indirect) will be downloaded onto the specially designated and configured NCHS *Confidential Information Protection Statistical Efficiency Act* (CIPSEA) File Storage Server within the Consolidated Statistical Platform (CSP) environment. The dedicated NCHS CIPSEA server is a secured physical component of the CSP accessible only by NCHS-designated staff. All direct PII files and data containing personal identifiers (e.g., name, address, phone number, SSN, etc.) will be loaded onto separate files in separate secure sub-shares on the CIPSEA server for verification and editing, with the most strict access controls. The indirect PII will also be downloaded onto the specially designated secure sub-shares on the CIPSEA server but will have different access controls than the direct PII data. Non-PII data (or public use files) will be downloaded onto the specially designated and configured NCHS/DHCS separate secure CDC network sub-shares.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

A website dedicated to the National Hospital Care Survey (http://www.cdc.gov/nchs/nhcs.htm) describes the survey, answers frequently asked questions, displays letters of support for the NHCS from national and regional organizations, describes how the Privacy Rule permits data collection for NHCS, and provides a link to the participant page (http://www.cdc.gov/nchs/nhcs/participant.htm). There is no website with content directed at children less than 13 years of age.

2. Purpose and Use of Information Collection

NHCS has several objectives. The first objective of NHCS is to continue to produce nationally representative utilization statistics for hospital discharges and ambulatory health care. NHCS uses a new independent national probability sample of hospitals that will be updated every third year to ensure that the sample continues to be nationally representative. The survey continues to produce nationally representative estimates of discharges by diagnosis and procedures and visits to EDs and OPDs. NHCS also provides a flexible platform which will permit collection of special data as needs arise for policy and research demands.

A second objective of the NHCS is to close gaps in available information about hospitals at the facility level, and relate these characteristics to discharge level data within the hospital. The NHCS collects an inpatient and ambulatory facility-level questionnaire from every sampled hospital each year (Attachment J and K). New data elements, such as percent of payments to the hospital from Medicaid, allow study of the relationship between hospital characteristics and care provided at the discharge level. The added information for each discharge, and at the hospital level, allows testing of hypotheses that relate to healthcare policy and research questions.

A third objective is to link episodes of care within the hospital, such as for patients seen in the ED and subsequently admitted as inpatients. NHCS collects protected health information which will allow linkages to other episodes of care in the ED and OPD as well as other data sources, such as the NDI and the Medicare and Medicaid claims databases.

A fourth objective of the NHCS is to continue to produce non-identifiable micro-data public use files of inpatient discharges and ED and OPD visits and to disseminate timely data that can be used by health policy researchers, the public and the research community. Using these data files, researchers can study trends and changes in health care practice, conformance to scientific evidence about effectiveness, and changes in patterns of health care seeking behavior. It complements patient-based and population-based information.

Data collected by the NHCS will be used by government, professional, scientific, academic and commercial institutions, and private research organizations, as well as private citizens. NCHS' integration of the data collected from NHDS and NHAMCS into the NHCS was designed to maintain continuity with the current data collections while adding new utility to the data by enabling NCHS to link cases and outcomes both across departments within a hospital and with external data sets. This rich new dataset contains information on the demographic characteristics, medical conditions, and treatment of patients who use hospitals for inpatient and ambulatory medical care. The data NHCS is collecting can be used to investigate a wide range of public health and health services related issues over time rather than focusing on a single specific research question at a single point in time.

The NHCS is expanding its inpatient coverage by incorporating data on patients with "observation status" (those patients that are observed overnight(s) and traditionally not included as inpatients). As a result, the survey will provide a more complete picture of care delivered throughout the hospital than has been possible in recent years. Incorporating these patients into the NHCS will help to reconstitute the patient composition of the survey of previous decades, thereby making possible, for the first time, an understanding of the effect this practice shift has had on the services, intensity of care, costs, payment, and outcomes. For example, NHCS will make it possible to determine whether care differences (e.g., intensity of service and quality of care) exist for patients with similar presenting and treatment situations based on patient admission status.

The NHCS offers both the depth and flexibility to address many other issues as well. For example, the survey can help inform discussions on the role and value of EHRs. The hospital interview provides data on the extent to which EHRs have been adopted within a hospital, and this information can then be linked to the efficiency and quality of care provided. Similarly, the NHCS will be an extremely valuable public health resource by providing trended data on hospital use, including diagnoses and procedures of particular interest (e.g., Cesarean section rates, use of coronary stents).

The wide varieties of uses of future NHCS data are best exemplified by the historical diversity of users of NHDS and NHAMCS. These include Congress and the Office of National Drug Control Policy, Federal agencies, such as the Centers for Medicare & Medicaid Services (CMS), the Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), the National Institutes of Health (NIH), Substance Abuse and Mental Health Services Administration (SAMHSA); various Centers within CDC, the Department of Defense (DOD), and the Department of Veterans' Affairs (VA); international organizations, such as the Organization for Economic Cooperation and Development; universities, medical schools and schools of public health; professional organizations, such as the American College of Surgeons and the American Heart Association; state and local governments; hospitals; individual practitioners, pharmaceutical and medical supply manufacturers; market research groups; insurance companies, health maintenance organizations, researchers and health policy makers.

Of particular importance, NHDS and NHAMCS data are used by the Department of Health and Human Services (DHHS) in the development and monitoring of goals for the Year 2000, 2010 and 2020 Health Objectives for the nation as well as the National Reports on Quality and Disparities. In addition, these data provide annual updates for numerous tables in the Congressionally-mandated NCHS report, *Health, United States.*

Data from the NHDS and NHAMCS provide significant input to the operations of many programs within the CDC. Within the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), NHDS data provide national estimates of hospital utilization for discharges of patients with human immunodeficiency virus (HIV) infection. Staff of the National Center for Injury Prevention and Control use NHDS data as a measure of hospitalizations due to injury. NHDS data are used in a variety of research activities in the National Center for Chronic Disease Prevention and Health Promotion. In addition, NHDS and NHAMCS data often appear in CDC's *Morbidity and Mortality Weekly Report (MMWR).*

Data from the NHDS are frequently used by many other Federal government agencies as well. Staff of the National Heart, Lung, and Blood Institute, NIH, request annual updates of selected coronary diagnoses and procedures to monitor trends in coronary conditions. NHDS data are used by researchers at the National Cancer Institute, NIH, to assist in measuring the incidence of uterine and prostate cancer. Also, DOD and VA use NHDS data to compare inpatient care provided in their hospitals with care provided in the civilian sector. NHDS data are also used extensively by the health research community. An extensive compendium of articles using NHDS and NHAMCS data may be found on these websites:
http://www.cdc.gov/nchs/data/nhds/nhds_article_list.pdf
http://www.cdc.gov/nchs/data/ahcd/namcs_nhamcs_publication_list.pdf .

Privacy Impact Assessment Information

The NHCS defines an approach that will link structure, process, and outcomes of care. Structural information (i.e., information on the hospital and environment in which care is received) provided on the hospital interview questionnaire will be able to be linked with clinical care processes (e.g., surgeries) to understand how structure affects the types of care (e.g., do the type of facilities at the hospital influence what type of surgery a patient has?). Data from the survey can be used to examine the extent to which the process, such as earlier discharge, places a patient at risk for desirable or undesirable outcomes, such as unanticipated (i.e., non-elective) readmission to the hospital. This is only possible because PHI data will allow, in some circumstances, the linking of characteristics and processes of one admission/visit with a later admission/visit and the location of the admission/visit (i.e., inpatient, ED) with later care received through the UB-04 claims or EHR data.

Continuity of care, particularly as patients transition from the hospital environment (i.e., inpatient, ED, OPD) to lower levels of care (e.g., home, assisted living, hospice, intermediate care), is frequently cited by patients as a major weakness. Health policy experts also frequently noted the lack of longitudinal data. Although practical considerations limited the extent to which longitudinal data could be included in the new survey, NHCS allows for examination of patients' discharge arrangements and their use of hospital services. For example, patients recovering from acute brain injury may be discharged home, to acute rehabilitation, or to a long-term care facility. Although individual patients cannot be followed outside the hospital, data collection in the new survey includes data on all inpatients discharged and includes PHI. This will allow for determination of whether a patient had returned to that hospital after discharge or by looking back in the UB-04s and EHRs, we will be able to determine whether the patients had been in the hospital prior to the admission date of the sample discharge. Using these data, one may be able to examine the implications of discharge location on mortality and hospital readmission within 30 days.

Another important quality issue relates to the training and experience of those providing care. The NHCS captures the attending and operating physicians' National Provider Identifiers (NPIs) as part of the UB-04 and EHR, offering the ability to link the individual patient's care with the specialty of the providers from who care was received. Information linking provider identifiers to their characteristics (e.g., specialty, provider age) is available from CMS for research purposes (https://nppes.cms.hhs.gov/NPPES/). NCHS, of course, maintains provider confidentiality in all analyses and public use files.

The Institute of Medicine has included equity among the six key properties or domains of quality. Equitable treatment of patients requires that each individual receive health care of equal quality, irrespective of personal characteristics other than their clinical condition and preferences for care. The NHCS will facilitate studies of equity in care by providing additional detail by which to identify patient personal characteristics unrelated to their clinical conditions. A better understanding of patient socioeconomic status (SES) will be possible, because the inclusion of the address variable, in addition to ZIP Code, will facilitate sophisticated geocoding, thus allowing for better estimates of patient and family income, race and ethnicity, and education. This detailed patient information, of course, will be de-identified before it is made available for public use. Data from the NHCS can also be used to address whether longer lengths of stay occur for some patients with lower SES who cannot be discharged to an appropriate lower level of care. Relating patient SES to insurance status and hospital location type (e.g., rural or urban) will offer insight into the extent of differences in care that patients of different SES receive.

NHCS collects the data needed to link patients to NCHS's National Death Index (NDI) and potentially data from the Centers for Medicare & Medicaid Services (CMS) through collection of UB-04 claims and/or EHR data. The data will also make it possible to link, in some circumstances, across hospital settings (e.g., inpatient, ED, and OPD). The ability to make such linkages greatly expands the usefulness of these data at a low cost and burden to hospitals. The collection of information in identifiable form requires strong measures to ensure that private information is not disclosed. Data will be held confidential according to Section 308(d) of the Public Health Services Act (42, U.S. Code, 242m(d)) and the Confidential Information Protection and Statistical Efficiency Act (Title 5 of PL 107-347). All NCHS employees as well as contract staff receive appropriate training and sign a "Nondisclosure Statement." Staffs of collaborating agencies are also required to sign this statement. The transmission and storage of data are protected through procedures such as encryption and carefully restricted access. No IIF data are shared with researchers. Only NCHS employees and agents who need the personal information for linking to various databases may use such data. Everyone else who uses NHCS data may do so only after all identifiable information is removed. See Attachment L for more details on the NHCS data security plan.

3. Use of Improved Information Technology and Burden Reduction

Hospitals are being asked to electronically transmit EHR data or UB-04 claims data for all inpatient discharges and all ambulatory visits to a contractor's secure network. Burden on hospital personnel is reduced, as most of the data are acquired electronically. Ambulatory data collection through UB-04 claims will require abstraction of a sample of patient visits. For those participating via EHR, onsite abstraction is not necessary as clinical information is provided for all ambulatory visits. To obtain the clinical information on ambulatory visits, hospitals will submit data electronically or through medical record abstraction on-site or remotely. For those hospitals providing UB-04 billing data, contract staff will abstract medical record data. Burden to staff will be incurred at hospitals with paper medical records that need to be pulled and re-filed. The contractor staff will abstract the data onto a computerized data collection instrument. For the remote-reporting hospitals, hospital staff would grant contract staff remote access to their EHR system, and contractor staff would access the networks from contractor's offices.

In addition, using a computer-assisted interviewing instrument for the ambulatory hospital interview will allow contract staff to skip unneeded questions and quickly populate write-in fields with drop-down menus. Use of a computerized data collection instrument for Patient Record form data simplifies data collection activities by reducing data entry errors and omissions, as well as providing on-screen look-up tables for items such as reason for visit, diagnosis, cause of injury, procedures, and medications. Overall, using a computerized data collection instrument reduces contract staff and respondent burden, improves data quality, and increases the speed of editing, transmission, and processing, thereby making the release of statistics more timely.

There is a need to collect annual hospital statistics, such as total admissions, total visits and total births, to weight the inpatient and ambulatory data. Each participating hospital will be asked to complete an Annual Hospital Interview that will be conducted by telephone or mail, whichever format is less burdensome to the respondent. A web portal may be constructed in the future. There are no legal obstacles to reducing the burden on hospitals.

4. Efforts to Identify Duplication and Use of Similar Information

Currently no other data collection mechanisms either within the Federal Government or in the private sector can annually provide statistically valid national estimates of hospital inpatient utilization and ambulatory care services provided in EDs and OPDs. No other survey collects PHI that allows for linkages between inpatient discharges and ED and OPD visits as well as allowing linkage to the National Death Index, providing better indications of outcomes of hospital care.

Although the Healthcare Cost and Utilization Project (HCUP), which is sponsored by the Agency for Healthcare Research and Quality (AHRQ), collects inpatient data similar to the NHCS through its Nationwide Inpatient Sample (NIS), HCUP does not collect data on the hospital characteristics and does not collect data on PHI allowing data linkage. Further, HCUP does not collect data using a random sample design.

There are three provider-based data sources that collect ongoing data from the ED. They are the National Electronic Injury Surveillance System, All Injury Program (NEISS AIP) and the State Emergency Department databases (SEDD). Both of these systems are limited to the ED. NEISS AIP is sponsored by the Consumer Product Safety Commission (CPSC) and designed to provide incidence estimates of all types of and causes of nonfatal injuries and poisonings treated in the ED. NHAMCS data are used by NEISS AIP to benchmark their statistics. SEDD is a set of databases from data organizations in participating States that capture discharge information on ED visits that do not result in a hospital admission.

The purposes of all these data collection systems and the content and utility of the resulting data are distinctly different from those of the ED component of the NHCS. NEISS AIP is limited to a specific public health problem, while the ED component of the NHCS has the broadest coverage of all surveys to provide national general purpose health care statistics. Data from SEDD are not nationally representative and do not contain the level of detail about the ED visit that is captured on the Patient Record Form for the ED component of NHCS. Consequently the data available from these systems are not adequate for the needs described earlier and cannot be used as an alternative for the NHCS.

The State Ambulatory Surgery Databases (SASD) system, a part of AHRQ’s HCUP, includes ambulatory surgery data from some states; however, these data are not from a national probability sample. In addition, because of state budgetary problems, there is a great deal of uncertainty about the number of states that will be willing and able to continue to provide data to SASD in the future.

Three separate national surveys (i.e., NHDS, NHAMCS, and DAWN) will be consolidated into one comprehensive survey. Previously, each of these surveys involved inducting hospitals and collecting basic information from them before obtaining patient-level data. The NHCS eliminates this duplication of effort and allows an integrated set of questions to be asked of each hospital. Combining the three surveys also permits data linkage and the ability to track the patient's continuity of care within the hospital.

5. Impact on Small Businesses or Other Small Entities

For the NHCS only a few hospitals would be considered as small businesses or small entities. Efforts to minimize the burden, particularly on small hospitals, include the following:

a) Data elements for the electronic data component of NHCS come from the electronically available UB-04 claims data, which is needed for billing purposes and routinely collected and recorded by all hospitals, or EHR data coming from an already equipped system at the hospital.

b) The NHCS is a sample of hospitals. Additionally, only a sample of a hospital's ambulatory visits will be selected for abstraction of the UB-04 claims submitted.

c) Abstracted Data Component: Some respondents may be small hospitals. In order to reduce respondent burden for all respondents, several data collection methodologies will be used. These methods are designed to be flexible to meet the varied reporting and record-keeping situations found in EDs and OPDs. Patient visit sampling is used in each of these settings to minimize data collection workload. In addition, contract staff will perform data abstraction from medical records, not hospital staff, decreasing burden even more. Multiple abstractors will be used in some hospitals to minimize the time spent in the hospital. For hospitals sending EHR data, on-site abstraction will not be necessary as visit-level information may be obtained through access of data through SDN or remote transmission to a contractor's computer. This will greatly reduce the burden to hospital staff.

6. Consequences of Collecting the Information Less Frequently

There are three major reasons to continue to collect data on an annual basis: availability of annual estimates, budgetary considerations, and data quality.

A. Annual estimates - With the data from NHCS, NCHS plans to continue to make annual estimates of critical utilization statistics. Annual estimates are critical for modeling health care delivery and for studying specific diseases. A continuous annual survey provides data for trend analysis that is often the basis on which to evaluate the effects of change in Federal programs and policies. One of the most striking examples of this effect, which was tracked by NHDS, was the dramatic decline in inpatient procedures for lens extractions at the time the Medicare Prospective Payment System was implemented. In addition, many years of data on hysterectomies were needed to model the effects of this procedure. NHDS data were used to detect the first decline in hospital use for patients with human immunodeficiency virus (HIV), and, of great public interest, the first increase in the average length of stay for childbirth in the past two decades.

The rapidly changing environment in hospital ambulatory health care delivery and the current interest in health care reform lend importance to having annual data for decision making; describing the use of hospital ED, and OPD services, including ambulatory surgery; monitoring the effects of change; and planning possible changes in payment policies. This information has become even more crucial with the need to track the effects of the health care industry's evolution, by having continuous data collection before, during, and after policy change and possible restructuring. Since data from the surveys are often analyzed by combining data across years, the potential consequence of less frequent data collection would be the loss of the ability to study issues such as ED crowding, EHR adoption, preventive services, and those low frequency procedures that require combining data across time periods. NHDS and NHAMCS data provide annual updates for numerous tables in the Congressionally-mandated NCHS report, Health, United States. In addition, NHDS and NHAMCS data are used by the Department of Health and Human Services (DHHS) in the development and monitoring of goals for the Year 2000, 2010 and 2020 Health Objectives for the nation as well as the National Reports on Quality and Disparities. As a result of the integration of these two surveys, NHCS will be able to continue the provision of these data.

B. Budgetary considerations - Extensive information captured during data collection procedures prior to the NHCS has shown that the cost to the government is less when data are collected annually. Based on this prior experience, it has been determined that conducting this survey less frequently would require the very expensive process of re-inducting hospitals into the survey and training new contractor staff every 2-3 years.

C. Data quality - The highest quality of data can best be maintained when data are collected on an ongoing basis.

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

There is one special circumstance that applies to collection of NHCS data. Both the electronic and abstracted data components of NHCS will collect the OMB race and ethnicity codes in as much detail as possible. States vary with the extent that they require race and ethnicity to be included on the UB-04. In the abstracted data component, race and ethnicity will be collected in the OMB format to the extent that it is possible given that data are being abstracted from medical records.

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

A) The National Hospital Care Survey 60-day public comment notice was published in the *Federal Register*, Volume 78, Number 51, Pages 14709-10, on 03/17/2014. A copy of the notice is included as Attachment B. No public comments were received.

B) The NHCS is intended to provide improved data for the use of policymakers (both governmental and non-governmental), Federal and state agencies, clinical researchers, health services researchers, commercial institutions, and private citizens. Due to the broad audience and stakeholders for this project, NCHS solicited a wide spectrum of views concerning the focus of the inpatient data collection.

During 2005-06 NCHS staff held informal discussions and consultations with many organizations, both Federal and non-Federal, to discuss the inpatient data collections. In addition to the workshop, discussions were conducted with experts in health research, economics, and policy. In 2006 NCHS selected Rand Health, a division of Rand Corporation, to assist in developing an approach to hospital data collection. Input from Rand researchers, policy experts, and a workgroup of government and private sector health policy experts was used to identify critical research questions that might be answered through a hospital survey. Also in 2006, NCHS held a workshop composed of government and non-government experts to develop a conceptual framework for a redesigned hospital survey.

More recently, NCHS consulted with the following:

- David Woodwell, M.P.H., regarding sampling substance-involved ED visits and items on the ED Patient Record form related to substance abuse and mental illness.

  Contact Information:
  SAMHSA/CBHSQ,
  1 Choke Cherry Road, Rockville, MD 20857
  Phone: 240-276-1245
  Email: David.Woodwell@samhsa.hhs.gov

- Stephen Pitts, M.D. regarding ED-level questions related to crowding and items on the ED Patient Record form.

  Contact Information:
  Department of Emergency Medicine
  Emory University School of Medicine
  550 Peachtree Street, Atlanta, GA 30338
  Phone: 770-855-3167
  Email: srpitts@emory.edu

NCHS continues to work closely with SAMHSA and other federal agencies in addressing their needs for ambulatory health care data during the continuation of the NHCS.

9. Explanation of Any Payments or Gifts to Respondents

NCHS provides a one-time $500 compensation to each sampled hospital to set up the electronic data transmission to participate in the survey. In addition, NCHS provides each of the 581 sampled hospitals $500 after a full year of EHR or UB-04 data is received by the contractor's secure network. Another $500 compensation is given to each hospital after the abstraction of ED and OPD visits is completed. These monies are intended to help hospitals that otherwise would be unwilling to take on the added burden of transmitting UB-04 billing data. Additional costs incurred as a result of participation, including labor or purchase of technology, are also covered by NCHS on a case-by-case basis. The contractor has the primary responsibility for ensuring the monies are distributed to participating hospitals after completion of 12 months of data collection.

A continuing education module was developed to serve as an educational and recruitment tool highlighting the NHCS. This web-based instrument was added to the NHCS participant page on the NCHS Internet site (http://www.cdc.gov/nchs/nhcs/participant.htm). Both the American Health Information Management Association (AHIMA) and Healthcare Information and Management Systems Society (HIMSS) have granted approval of the module, so health information management and health information technology staff from the hospital-community are able to obtain two free continuing education units by completing the NHCS module.

10. Assurance of Confidentiality Provided to Respondents

The confidentiality of patient information and the identity of individual hospitals participating in the NHCS are protected by section 308(d) of the Public Health Service Act (42 USC 242m), which states:

> "No information, if an establishment or person supplying the information or described in it is identifiable, obtained in the course of activities undertaken or supported under section...306,...may be used for any purpose other than the purpose for which it was supplied unless such establishment or person has consented (as determined under regulations of the Secretary) to its use for such other purpose and (1) in the case of information obtained in the course of health statistical or epidemiological activities under section...306, such information may not be published or released in other form if the particular establishment or person supplying the information or described in it is identifiable unless such establishment or person has consented (as determined under regulations of the Secretary) to its publication or release in other form..."

In addition, legislation covering confidentiality is provided according to section 513 of the Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA) (PL-107-347), which states:

> “Whoever, being an officer, employee, or agent of an agency acquiring information for exclusively statistical purposes, having taken and subscribed the oath of office, or having sworn to observe the limitations imposed by section 512, comes into possession of such information by reason of his or her being an officer, employee, or agent and, knowing that the disclosure of the specific information is prohibited under the provisions of this title, willfully discloses the information in any manner to a person or agency not entitled to receive it, shall be guilty of a class E felony and imprisoned for not more than five years, or fined not more than $250,000, or both.”

<u>Privacy Impact Assessment Information</u>

A. This submission has been reviewed by Information Collection Review Office (ICRO), who determined that the Privacy Act does apply. The applicable System of Records Notice is 09-20-0167. The NCHS Privacy Act Coordinator and the NCHS Confidentiality Officer have also reviewed this package and have determined that the Privacy Act is applicable.

The following assurance of confidentiality will be on any new paper or electronic forms:

> "All information which would permit identification of an individual, a practice, or an establishment will be held confidential, will be used only by NCHS staff, contractors, and agents only when required and with necessary controls, and will not be disclosed or released to other persons without the consent of the individual or establishment in accordance with section 308(d) of the Public Health Service Act (42 USC 242m) and the Confidential Information Protection and Statistical Efficiency Act (PL-107-347)."

B. NHCS data collection plan has been approved by NCHS Ethics Review Board (ERB) (Protocol #2009-21) based on 45 CFR 46. In addition, the Board has granted (1) a waiver of the requirement to obtain informed consent from the patient, (2) a waiver of the requirement to obtain informed consent from physicians, and (3) in accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Regulation (45 CFR 164.512), a waiver of patient authorization for release of patient medical record data by health care providers.

The ERB letter granting approval for Protocol #2009-21 for the NHCS for the maximum allowable period of one year is presented in Attachment M.

NHCS data will be made available via public-use data files to the public. Confidential data are never released to the public. All personal identifiers such as hospital name and address, patient date of birth, and any other specific information are removed from the public release files. All data releases are reviewed by the NCHS Disclosure Review Board to avoid data breaches, such as release of detailed geographic information that may allow anyone to identify hospitals, practices, or individuals in the general population.

The contractor selected for NHCS was required to provide a comprehensive data security plan to NCHS to ensure safety and confidentiality of the NHCS data. The NHCS Data Security Plan (DSP) (Attachment L) describes the survey procedures and data handling protocols that are being implemented to secure study data and protect confidentiality. The plan follows the structure and guidelines established by the National Institute of Standards and Technology (NIST; 800-series)[1] for meeting the requirements of the Federal Information Security Management Act (FISMA).[2] The DSP complies with all relevant laws, regulations, and policies governing the security of data and the protection of confidentiality, including the Privacy Act of 1974 (5 USC 552a), Section 308(d) of the Public Health Service Act (42 USC 242m) and the Confidential Information Protection and Statistical Efficiency Act (CIPSEA, PL 107-347) of 2002. The DSP considers all known data security and confidentiality protection risks. However, our approaches and specific procedures will evolve as we identify new data security threats and implement improved practices. The DSP will be updated as needed with more detailed, process-oriented data security protocols. Information technology

---

[1] See http://csrc.nist.gov/sec-cert/ca-compliance.html.

[2] See http://csrc.nist.gov/policies/FISMA-final.pdf.

products and systems will comply with the FISMA regulations and supporting NIST guidelines (NIST Special Publication (SP) 800-60).

C. In the recruitment introductory letter from the NCHS director, it states that participation in the NHCS is voluntary. There is no effect on the respondent for not participating. The information is not shared with anyone, although public-use data files are available on the NHCS website once individually identifiable information is removed. The legal authority for NHCS data collection is Section 306 of the Public Health Service Act (42 U.S.C. 242k).

11. Justification for Sensitive Questions

The NHCS collects protected health information (PHI) for all components. These PHI elements have been cleared in a prior approval of this package (OMB # 0920-0212) and also in the Ambulatory Care Pretest: National Hospital Care Survey (OMB #0920-0944). One example of the value of PHI is that it will allow linkage to the National Death Index, providing better information on outcomes of hospitalization. Collection of PHI will also allow for linkages between inpatient discharges and ED and OPD visits). The list of requested items considered to be sensitive includes the following eleven data elements on patients and one data element for physicians:

1. Name
2. Birth date
3. Address
4. ZIP Code
5. Dates of admission and discharge (for the inpatient discharges and ED visits)
6. Visit dates (for ED and OPD visits)
7. Procedure dates
8. Social security number (where available)
9. Medical record number (where available)
10. Patient control number
11. Medicare health insurance benefit/claim number
12. NPI (National Provider Identifier) number

Patient name and social security number are currently collected as protected health information included in the NHCS. In order to accurately link sampled patients to the NCHS National Death Index (NDI), first and last names of the patient are necessary in addition to address, birth date, sex, and state. States vary on whether or not they require the social security number on the UB-04. Although linkages could be made to the NDI without the SSN, researchers planning to use the NDI are encouraged to collect or compile as many of the NDI data items as possible. For more information on the National Death Index, see the web link, NCHS -National Death Index Home Page at http://www.cdc.gov/nchs/ndi.htm. We are likely to need all variables listed above to create an adequate match to the NDI. However, we are in the process of evaluating the linkage to NDI for the time period that corresponds to the first full year of data collection for the NHCS. This evaluation will allow us to determine whether less information can create an adequate match to the NDI. This evaluation is still in progress.

Birth date will be converted to age by the contractor during processing. This is done to minimize error that can be introduced by doing this manually in the field at the time of data collection. This is especially important in going across centuries and for newborns in going across years. Age is, of course, very important to analyze because of its relation to health conditions and treatments which vary by age.

Patient address and ZIP Code of residence are required to link data from the U.S. Census Bureau. It is well known that health status and the use of health services vary strongly by socioeconomic status (SES). Those with lower income and less education, for example, are generally in worse health and sometimes have reduced access to medical care compared to others. It is therefore important to be able to use NHCS to track the use of hospital care by SES. Unfortunately, measures of an individual's SES, such as family income or education level, are not routinely recorded in medical records. Geocoding complete patient addresses to the Census tract or block group level and using Census measures of area SES at these levels will yield accurate proxies for individual-level SES (Krieger N, et al., 2002)[3].

Dates of admission and discharge (for inpatient discharges and ED visits) are essential to calculate days of care, which are needed to measure total inpatient days in the United States and to measure average length of stay. Trends in both of these measures are critical to assessing changes in the health care system. For example, they may reflect factors associated with new Federal programs and policies, such as the implementation of payment changes or laws that regulate the early discharge of mothers and newborns. With precise dates in hand, NCHS can calculate days of care per discharge regardless of the number of days in a month, leap years, or other nuances.

Procedure dates are necessary, in conjunction with admission and discharge dates, to determine the timing of procedures within a hospitalization. Procedure dates were previously collected as part of NHDS, and helped provide a much clearer picture of a surgical patient’s hospital course than would otherwise be available. For example, without procedure dates, a patient who dies from a severe post-operative infection many days after a planned surgery may look identical to a patient who is rushed to the operating room many days into a hospitalization for an emergency procedure and dies in the operating room. Procedure dates provide crucial data for researchers in many areas, including the measurement of complications, medical errors, and risk-adjusted outcomes of hospitalizations.

The retention of medical record number will allow the collection of a single patient’s data from several sources within a hospital, such as the medical record, laboratory records, hospital billing records, emergency department, ambulatory department and ambulatory surgery locations. This will provide access to more comprehensive and detailed clinical information, as well as additional outcomes and quality measures.

Patient control number is a required element on the UB-04 (not in an EHR), which is assigned to patients for billing purposes. Along with medical records number, patient control number can help link to other data sources in the hospital, particularly billing records.

---

[3] www.hsph.harvard.edu/thegeocodingproject/webpage/monograph/publications.htm

Medicare health insurance benefit/claim number is another piece of protected health information included in NHCS. The Centers for Medicare & Medicaid Services (CMS) is in the process of collecting data from hospitals on the quality of care that is provided to each patient admitted to any Medicare certified hospital who has one of a particular set of diagnoses. For example, for all cases of pneumonia, Medicare would collect data on whether each patient admitted received antibiotics within 4 hours of presentation. We are in the process of discussing with CMS the possibility of linking with its database in order to provide measurements of quality for the NHCS inpatient discharges as well as sampled ED and OPD visits. We did a similar linkage with the data from the 2004 National Nursing Home Survey. This would provide additional important data on quality of care without requiring further primary data collection. In addition, we are discussing the feasibility of linking to the CMS database that contains longitudinal utilization data for all Medicare patients, adding additional utilization data to our dataset but providing clinical detail that CMS does not have in its database.

NPI (National Provider Identifier) number is a unique identifier for healthcare providers. It is a required data element on the UB-04 and often available through an EHR. This data element will allow for linkage of physician specialty information to the individual patient's care. Information linking provider identifiers to their characteristics (e.g., specialty, provider age) is also available from CMS for research purposes (https://nppes.cms.hhs.gov/NPPES/).

12. Estimates of Annualized Burden Hours and Costs

A. Burden Hours

Data on burden are shown in Table 1. The total sample size for the 2014-2016 survey will consist of approximately 581 hospitals. Hospital interviews will be conducted by contractor staff. The first part of recruitment includes a one-time Initial Hospital Intake Questionnaire (Attachment N) that is administered over the telephone or by paper to verify the hospital's eligibility. This intake questionnaire is conducted on all hospitals, but since 100 have already been conducted under the previous clearance, 481 hospitals remain for a total of 160 annualized burden hours (481/3) over the course of three years (Attachment N).

We anticipate that hospitals may require additional information about participating in the survey and a one hour survey presentation has been designed for them in the form of a Recruitment Survey Presentation. This will represent another 160 annualized hours (481/3) over the course of the three year clearance. As needed, the presentation will be used to complement the telephone recruitment (Attachment O).

Hospitals will be asked to transmit EHR on a quarterly basis and UB-04s on a monthly basis for all records and claims, both inpatient and ambulatory. It is estimated that this will take one hour per hospital per quarterly submission to prepare and transmit the data file. We estimate about 100 hospitals would submit EHR data, and the remaining hospitals that are not yet EHR equipped would transmit their UB-04 claims. This represents 5,772 annualized hours for hospitals submitting UB-04 claims and 400 annualized hours for hospitals sending EHR data (Attachments P and W).

Each participating hospital of the 581 will be asked to complete an Annual Hospital Interview (Attachment J) that will be conducted by telephone or mail, whichever format is less burdensome for the respondent. A web portal may also be constructed. This interview collects annual statistics needed for weighting both the inpatient and ambulatory data which include hospital characteristics such as total numbers of admissions, total visits, discharges, and live births. The Annual Ambulatory Hospital Interview (Attachment K) is conducted for those hospitals where medical record abstraction will take place. The 100 hospitals estimated to send EHR data will not need to have their records abstracted, leaving 481 hospitals that are divided between five panels. Since only four panels are approached each year, approximately 385 hospitals with EDs would complete this interview in a given year. All responses for this interview are entered into the PC tool. Information collected in both interviews includes but is not limited to: health care system information; general hospital characteristics (e.g., bedsize, service type, ownership and staffing); capability to transmit UB-04 claims and other discharge related questions. The Annual Hospital Interview will take 2 hours to complete and will be conducted annually for a total of 1,162 burden hours (Attachment J). The Annual Ambulatory Hospital Interview will take 1.5 hours to complete with an annual burden of 578 hours (Attachment K).

Please note that the following data collection activities and their respective burden were removed from the burden table since the last revision: Ambulatory Unit Induction (250 hours); the pulling and re-filing patient records for ED, OPD or ASL (833 hours); and as a result of the elimination of free-standing ambulatory surgery centers (FSASCs), the Annual FSASC interview (84 hours), Prepare and transmit UB-04 (668 hours) and pulling and re-filing of patient records (140 hours) in FSASCs were removed.

The total burden is 8,232 hours.

Table 1. Estimated Annualized Burden Hours

Respondents	Form	Number of respondents	Number of responses per respondent	Avg. Burden per Response (in hours)	Total Burden Hours
Hospital DHIM or DHIT	Initial Hospital Intake Questionnaire	160	1	1	160
Hospital CEO/CFO	Recruitment Survey Presentation	160	1	1	160
Hospital DHIM or DHIT	Prepare and transmit UB-04 for Inpatient and Ambulatory	481	12	1	5,772
Hospital DHIM or DHIT	Prepare and transmit EHR for Inpatient and Ambulatory	100	4	1	400
Hospital CEO/CFO	Annual Hospital Interview	581	1	2	1,162

Hospital CEO/CFO	Annual Ambulatory Hospital Interview	385	1	1.5	578
TOTAL					8,232

B. Burden Costs

The average response burden cost for the NHCS is estimated to be **$435,349.20**. The hourly wage estimate the Director of Health Information Management was based on the American Health Information Management Association (AHIMA) salary studies. For all other hospital employees the wage was based on the Hay Group’s Hospital Compensation Survey.

Table 2. Estimated Annualized Burden Costs

Type of Respondent	**Response burden hours**	**Hourly Wage Rate**	**Respondent Cost***
Hospital CEO/CFO	1900	$60.50	$114,950.00
Hospital Director of health information management	6332	$50.60	$320,399.20
Total			**$435,349.20**

*Hospitals will be compensated for their participation as described in Section 9.

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

None. No additional respondent capital and maintenance costs are incurred by NHCS reporting because all hospital purchases of equipment or services are made for reasons other than to provide information or keep records for the government and are part of their usual or customary business practices.

14. Annualized Cost to the Government

The estimated total average annual cost of the NHCS to the government will be $9.2 million.

Average Annual Costs for the NHCS Annualized Over Three Years

NHCS 2014-2016	
Data collection contract	$7,011,000
NHCS Project Staff salaries	2,162,000
Total	**$9,173,000**

15. Explanation for Program Changes or Adjustments

The currently approved burden is 7,224 hours; the proposed burden for the NHCS is 8,232 hours per data collection year; 1,975 hours were subtracted as a result of the removal of several line items; 2,983 hours were added as result of the change to monthly data transmission for UB-04 claims as well as the addition of 81 hospitals to the sample. This results in a net increase of 1,008 burden hours. We are now asking for monthly rather than quarterly submission of UB-04 claims because ambulatory data sent for the third month of a quarter were often incomplete, creating a delay in sampling procedures. The Annual Hospital Interview had a several questions added to it the number and type of claims missing from the data, which are critical for weighting the electronic data.

With regard to the items eliminated from the burden table, to increase efficiency the Ambulatory Unit Induction (250 hours) was combined with questions asked in the Annual Ambulatory Hospital Interview; the pulling and re-filing patient records for ED, OPD or ASL (833 hours) was eliminated as we no longer abstract data from paper records, only electronic; and finally as a cost saving measure, free-standing ambulatory surgery centers (FSASCs) were removed from the overall design of the survey, resulting in the elimination of the Annual FSASC interview (84 hours), Prepare and transmit UB-04 (668 hours) and pulling and re-filing of patient records (140 hours) in FSASCs from the overall burden of NHCS.

16. Plans for Tabulation and Publications and Project Time Schedule

Data from the NHDS and NHAMCS have been published annually as NCHS *Vital and Health Statistics Series 13* reports, *National Health Statistics Reports*, NCHS *Data Briefs*, web tables, articles in professional journals, and other special reports. Special reports on utilization trends, specific diagnoses, selected patient and hospital characteristics, source of payment, prescribing trends, and methodology are also published in *Series 2, 5, or 13* of the NCHS *Vital and Health Statistics*, *National Health Statistics* Reports, or journal articles. It is anticipated that NHCS data will be published in the same publications as NHDS and NHAMCS. Data from the NHCS will be presented separately for inpatient discharges, EDs and OPDs and then in combined reports.

NHDS and NHAMCS public use files and reports as well as detailed descriptions of the survey designs and data collection methodologies are available on the NHDS website (http://www.cdc.gov/nchs/nhds.htm) and NHAMCS website (http://www.cdc.gov/nchs/ahcd/about_ahcd.htm). NHCS data files with confidential information will be made available at the NCHS Research Data Center to allow linkage to other data sources. Annual public use files containing information collected on inpatient discharges and ED and OPD visits will continue under the NHCS. To facilitate trend analysis, multi-year public use files (one for newborns and one for non-newborns) provide multiple years of inpatient data in a standard format with standard definitions across survey years. CD-ROMs for 1970-78 and 1979-2007 in ASCII format are currently available to the public, and 2008-2010 data are available for downloading from the NHDS website. These will continue to be available, although new trend files will be started for the NHCS. However, NHCS has been structured to allow consistent trends continuing from the prior versions of NHDS and NHAMCS.

Staff of NCHS's Ambulatory and Hospital Care Statistics Branch present data from the National Health Care Surveys at meetings and conferences of professional organizations, such as the American Public Health Association, Academy Health, Joint Statistical Meetings, National Association of Health Data Organizations, National Rural Health Association, American College of Emergency Physicians, Society for Academic Emergency Medicine, and Gerontological Society of America. These presentations deal with specific aspects of the survey or special analyses of survey data.

This clearance request covers three years, 2014-2016, of data collection. The data collection and analysis processes will be ongoing. Based on prior experience as well as activities currently underway, the following is a projected data collection schedule for inpatient and ambulatory component in 2014 and beyond.

Electronic Data Component

Hospital recruitment	Ongoing
Begin transmission of monthly UB-04 data	2/2014
Transmission 2014 EHR data	
• 1st Quarter	5/2014
• 2nd Quarter	8/2014
• 3rd Quarter	11/2014
• 4th Quarter	3/2015
End of electronic data collection	4/2015
First tabulations from the 2014 electronic data	9/2015
Public use file	12/2015

Abstracted Data Component

Abstractor training for ambulatory data collection	10/2014
Make contact with hospitals for ambulatory recruitment	Ongoing
Abstraction for ambulatory data collection	10/2014-6/2015
End data collection	6/2015
Data processing by contractor	7-8/2015
Final data file delivered to NCHS	8/2015
Public use data available on Internet	2/2016
Publish additional reports	2/2016

17. Reason(s) Display of OMB Expiration Date is Inappropriate

N/A

18. Exceptions to Certification for Paperwork Reduction Act Submission

No exceptions to certification are requested.