Supporting Statement A for Request for Clearance:

# **National Hospital Care Survey**

# OMB No. 0920-0212

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## SUPPORTING STATEMENT

## THE NATIONAL HOSPITAL CARE SURVEY

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) and begin to integrate 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, expired 12/31/2011) 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.

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.

This 3-year period will be one of transition for the NHCS.

- 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. Recruitment efforts are discussed in more detail in A1 and B3.
- 2. Based on the results of the NHCS ambulatory care pretest (OMB No. 0920-0944) conducted in the fall of 2012, we anticipate that NHAMCS and DAWN can be incorporated into NHCS during 2013 and 2014. During 2013, the ambulatory component will consist of two phases: 1) sampling ED visits from Uniform Bill (UB)-04 data with oversampling of drug-related ED visits followed by abstraction and 2) sampling OPD and ASL visits from UB-04 data followed by abstraction. The results of the pretest showed that most hospitals have the capability to provide both UB-04 data and sign-in sheets for sampling ED, OPD, and ASL visits and that the two visit sampling frames (UB-04 and. sign-in sheets) were comparable. More details on the pretest are found in A1, B1, and B4.
- 3. For DAWN activities, however, the analysis of the ED drug-related visits found that only about one-third of "likely drug" cases as defined by the ICD-9-CM code list actually

were drug-related; therefore, more work needs to be done to capture these visits. In addition, NCHS and SAMHSA are still studying the optimal sample size of drug-related ED visits to produce statistically reliable estimates.

4. Additionally, while ED visits could be readily identified in the UB-04 data, the OPD and ASL visits were more problematic and further research on classifying the ambulatory UB-04 data for these settings is required.

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. Thus, NHAMCS will be operating in tandem with the ambulatory component of NHCS until the NHCS is fully implemented, 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
June 1, 2013 -	Start ED visit data collection
Sept. 1, 2013 -	Start OPD and ASL visit data collection
March 2014 -	Decision on whether NHAMCS will be continued in addition to NHCS
March 2015 -	Full integration of NHAMCS and DAWN into NHCS

A new listing of freestanding ambulatory surgery centers (FSASCs) will be obtained in 2013/2014 and recruitment will begin in 2014 or 2015 after we complete the construction of a new sampling frame.

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

- Continuation of recruitment of hospitals for the National Hospital Care Survey (NHCS).
- Collection of facility-level data for both the inpatient and ambulatory components.
- Collection of data on inpatient discharges as well as ED, OPD, and ASL visits which will be accomplished by capturing all UB-04 administrative claims data or EHR data from participating hospitals.
- Collection of additional clinical data from a sample of ED, OPD, and ASL visits through abstraction of medical records.
- Beginning the collection of drug-related ED visit data previously collected by DAWN through the ED component of NHCS.
- Recruitment of a new sample of FSACSs, after a new sampling frame is developed within the three-year clearance period. The current FSASC sampling frame is outdated. We plan to develop a new frame in 2013. Once this is complete, we plan to incorporate FSASCs into the NHCS in 2014 or 2015. FSASC-level data will be collected by interview and abstraction of medical records as well as UB-04 claims.
- Approval to make relatively minor additions, deletions, and changes to the survey through the use of nonsubstantive change submissions.

# A. Justification

# 1. Circumstances Making the Collection of Information Necessary

## **Background**

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 (OMB No. 0920-0234), National Nursing Home Survey (OMB No. 0920-0353), National Home and Hospice Care Survey (OMB No. 0920-0298), the National Survey of Residential Care Facilities (OMB No. 0920-0780), 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).

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 2013. It is designed to collect data on the utilization and provision of ambulatory care services in hospital emergency and outpatient departments 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 drug-related 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 their UB-04 administrative database, as well as facility level data through a facility questionnaire.

NHCS will continue to provide the national general purpose health-care statistics as the NHDS provided. The NHCS will have some distinct advantages over NHDS. First, more information at the facility level will be collected. This includes, but is not limited to, the hospital's

infrastructure for health information technology and volume of care provided by facility. Thus, analyses of the effect of the facility characteristics on the quality of care provided can be conducted.

The data being collected from the UB-04s on the inpatient discharges are collected from all inpatient discharges, not just a sample. 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/or ASC 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. Obtaining all the UB-04 data from a hospital also allows the sampling of hospital discharges with specific diagnoses and procedures for special studies that use medical record abstraction to collect more clinically relevant data.

NCHS plans to move toward greater collection of health-care data by electronic means. Since 2011, the UB-04 claims have been electronically transmitted to NCHS or its contractor for the inpatient component of the NHCS. As hospitals adopt electronic health records (EHRs), NCHS will be poised to accept electronic files from hospital medical records for components of the NHCS.

## Ambulatory Component of NHCS

Beginning in 2013, hospitals participating in the NHCS will be asked to provide data on the utilization of health care services in their emergency and outpatient departments (ED and OPD) and ambulatory surgery locations (ASLs).

The Patient Protection and Affordable Care Act of 2010 (ACA) authorizes programs targeted toward prevention and wellness. Information on the clinical management of conditions that put patients at increased risk for heart disease and stroke will be collected in NHCS in 2013 in what is referred to as the "lookback module". The lookback module is funded from prevention funds from the ACA (Attachment A). The data collected in this module will be used to monitor and evaluate the effects of increased insurance coverage on the quality of care provided in OPDs to prevent heart disease and stroke. Furthermore, this information could identify shortfalls in the quality of care that in turn could lead to improvements in clinical and public policy to improve prevention.

The ED component of the NHCS also 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 drug-related 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 drug 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 drug-related 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 drug-related 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 drug use and abuse and to identify emerging trends and changing patterns of drug 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.

## Visit Sampling and Data Collection within the Ambulatory Component

## Hospitals

In addition to the collection of electronic UB-04 claims data, more detailed clinical information will be abstracted from the medical record. The results of the ambulatory care pretest (OMB No. 0920-0944) showed that different approaches are necessary for the collection of the additional detailed visit data because not all hospitals have electronic health records systems and differences exist in hospitals' capabilities in providing ambulatory data. Hospitals will be divided into four main categories with regard to visit sampling and data collection methods. Attachment F shows how hospitals will be separated into each category. The following approaches are ranked according to the priority of the preference for the data collection method:

1) EHR extraction hospitals. These hospitals will extract the demographic and clinical variables required to complete the Patient Record forms for all patient visits that occurred in each of the ED, OPD and ASL settings during a 3-month maximum reporting period. These data will be extracted from electronic health record systems and transmitted to the contractor via a secure data network.

2) Remote-reporting hospitals with EHRs. With hospital approval, contractor staff will access the electronic records from contractor headquarters and then review all ED records for visits that occurred on a systematic random sample of days during a 3-month maximum reporting period and abstract data for all drug-related visits that are identified. In addition, contractor staff will select a systematic random sample of all visits from the ED, OPD, and ASLs during the same period and data for all selected visits will be abstracted by contract staff onto a laptop PC-based data collection tool.

3) Non-remote-reporting hospitals – UB-04 sampling. These hospitals will use a UB-04based visit sampling list that will allow contractor staff to 1) sample/oversample drug-related ED visits during a 3-month maximum reporting period; and 2) select a systematic random sample of all visits from the ED, OPD, and ASLs during the same period. Hospitals will provide either paper records or EHRs for contract staff to abstract onto a laptop PC-based data collection tool. 4) Non-remote reporting hospitals – sign-in sheet sampling. These hospitals will use sign-insheet-based sampling. Contractor staff will select a systematic random sample of all visits made to the ED, OPD, and ASLs during a 3-month maximum reporting period. Hospitals will provide either paper records or EHRs for contract staff to abstract onto a laptop PCbased data collection tool.

#### Freestanding Ambulatory Care Surgery Centers

The FSASC component of the NHCS will be conducted after a new sampling frame of FSASCs is developed. Ambulatory surgery locations that are not affiliated with a hospital are considered to be FSASCs. The universe of FSASCs includes those that are regulated by the states or certified by the Centers for Medicare and Medicaid Services (CMS) for Medicare participation. Out-of-scope FSASCs include those dedicated exclusively to dentistry, podiatry, abortion, births, and family planning. Once construction of the FSASC frame is completed, a new sample will be drawn.

The visit sampling and data collection methods for the FSASCs will be the same as in nonremote reporting hospitals.

## Integration of DAWN into NHCS

The terms of clearance for the NHCS Ambulatory Pretest (OMB No. 0920-0944) was as follows: "Request to incorporate NAMCS [sic] and DAWN into ICR must include a detailed discussion of how the design chosen was influenced by the results of the pre-test." The Ambulatory Pre-Test (OMB #0920-0944) showed that hospitals are in various stages of EHR adoption and must be given options for inclusion in the NHCS. To accommodate the sampled hospitals' technical capabilities hospitals will be assigned to one of four sampling paths. The four paths, as described above, are – (1) EHR extraction hospitals where no visit sampling will be performed. (2) remote-reporting hospitals (i.e., hospitals with fully functioning electronic health records (EHRs), that is, all parts of the chart are stored electronically, thereby allowing the contractor to remotely access the medical records from their headquarters), (3) non-remote reporting hospitals with UB-04-based visit sampling, and (4) non-remote reporting hospitals with sign-in sheet based sampling. For the inpatient component, UB-04 claims are the only source of data. However, ED data will come from UB-04 claims and medical record abstraction of a sample of visits. Any ambulatory UB-04 claims collected will be used for sampling ED cases and to supplement the abstracted ambulatory data.

Integrating DAWN into NHCS will increase the value of the data to SAMHSA as the data abstracted for each drug-related visit will also include items not formerly collected by DAWN (e.g. diagnostic services, procedures, and medications prescribed). However, the integration of DAWN into NHCS will likely eliminate annual, reliable reporting of those drugs that present extremely infrequently in the ED, e.g., synthetic cannaboids.

The decision to integrate the DAWN into the NCHS was made by senior SAMHSA officials with approval of senior Office of National Drug Control Policy officials. In reaching the

decision, the benefits of obtaining increased information were found to be greater than the loss of rare drug information.

## Data collection on mental illness-related ED visits

SAMHSA is interested in data on mental illness-related ED visits, including psychiatric and medical co-morbidities. Since the ED serves as an entrance to subsequent treatment for mental disorders, SAMHSA would also like to learn more about psychiatric referrals, hospital admissions, and transfers. The NHCS will allow for the analysis of the episode of care for mental illness-related ED visits that resulted in admission to the sample hospital. NHCS will produce reliable estimates of mental illness-related ED visits, which have not been reported on before. Such analyses will advance health services research and inform policy, especially as it relates to the Mental Health Parity and Addiction Equity Act which took effect in 2009.

#### 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, OPDs and ASLs of non-Federal, non-institutional hospitals with six or more inpatient staffed beds in the 50 states and the District of Columbia, and patient visits to FSASCs. Introductory letters from NCHS (Attachments C, D, and E) along with endorsement letters from professional associations will be followed by a telephone call from the contract staff to verify facility 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, OPD, and ASLs and/or FSASCs.

For facilities selected into the survey, facility-level data will be collected via telephone and personal interviews with facility staff. For the inpatient component and for some facilities in the ambulatory component, UB-04 claims data will be sent electronically from the participating sample of facilities to a contractor's secure network. For the ambulatory component, facilities will be asked to provide data to assist with sampling visits as well as data on patient visits to the ED, OPD, and ASL. 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 facility 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 facility-level data will be collected from hospitals: survey eligibility criteria, service characteristics, financial descriptors, expected number of visits, information related to ED crowding and use of electronic health records (EHRs). The following facility-level data will be collected from FSASCs: eligibility criteria, expected number of ambulatory visits, and use of EHRs. For the inpatient component, discharge-level data collected includes data elements on the UB-04 form. These include patient demographics, diagnoses and procedures, source of payment information, charges, and information related to revenue codes. For the ambulatory component and FSASCs, visit-level data will be collected through both the UB-04 as well as through abstraction of medical records.

## Information in Identifiable Form:

The NHCS will collect protected health information (PHI), also referred to as Information in Identifiable Form (IIF) for all components of the survey. 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 linkage among survey components (inpatient discharges and ED, OPD and ASL 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 twelve data elements for patients, one data item for physicians and four for hospitals:

#### *UB-04*:

- 1. Patient name
- 2. Birth date
- 3. Address
- 4. ZIP Code
- 5. Dates of admission and discharge (for the inpatient component)
- 6. Date of visit (for the ambulatory components)
- 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. Facility name
- 14. Facility address
- 15. Facility telephone number
- 16. Contact name

For both the inpatient and ambulatory components, UB-04 claims are being transmitted from the hospital to the contractor's secure network. After processing, the UB-04 data will eventually be sent to NCHS via CDC's secure data network (SDN). The SDN is a secure data transfer service offered by CDC, and provides 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 within the SDN environment are required to have digital certificates (x.509) installed on their machines to provide assurances of their identity when they log on. The SDN provides system monitoring on a 24 x 7 basis, data redundancy features, and disaster recovery features for select information systems. On receipt at NCHS, the direct PII data 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 NCHSdesignated staff. All 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. Non-PII data and indirect PII will be downloaded onto the specially designated and configured NCHS/DHCS server, which is a Windows 2008 server (w/server operating system - Windows Server 2008 R2 Standard) which provides on-line storage. The server is physically located at NCHS and protected under Windows firewall system security features and the CDC firewall.

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

A website dedicated to the new National Hospital Care Survey

(http://www.cdc.gov/nchs/nhcs.htm) will describe the survey, answer frequently asked questions, display letters of support for the NHCS from national and regional organizations, describe how the Privacy Rule permits data collection for NHCS, and provide a link to the participant page (http://www.cdc.gov/nchs/nhcs/participant.htm). There is no website with content directed at children under 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, ambulatory medical care, and ambulatory surgery. NHCS uses a new independent national probability sample of hospitals and FSASCs 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, OPDs, and ambulatory surgery. NHCS also provides a flexible platform which will permit collection of special data as needs arise for policy and research demands. With the collection of UB-04 information for all discharges, NCHS will be able to stratify by diagnosis or discharge status, allowing the survey to oversample specific diagnoses groups as needed to satisfy potential special policy and research needs.

A second objective of the NHCS is to close gaps in available information about hospitals at the facility level, and relate the hospital level 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 K and L). 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 facility 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, OPD, and ASL 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, OPD, and ambulatory surgery 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 NHDS, NHAMCS, and DAWN will be merged into the NHCS, and will continue to 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 as well as potentially those who use free-standing ASCs for 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 new survey provides 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 facility, and this information can then be linked to the efficiency and quality of care provided.

Similarly, the NHCS continues to 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 inclusion of observation care and potentially outpatient care when patients occupy hospital beds will facilitate comparison of services provided by the Nation's hospitals over time. We will continue to collect NHDS data items and will continue to calculate trends.

The wide varieties of uses of these data are best exemplified by the diversity of its users. 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 the Centers for Disease Control and Prevention (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 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). 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 frequently 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. Please refer to the NHDS website http://www.cdc.gov/nchs/data/nhds/nhds\_article\_list.pdf for an extensive compendium of articles using NHDS data and the NHAMCS website http://www.cdc.gov/nchs/data/ahcd/namcs\_nhamcs\_publication\_list.pdf for an extensive

11

## compendium of publications using NHAMCS data.

#### **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 facility 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 researchers to link the characteristics and processes of one admission with a later admission and the location of the admission (inpatient, ASL, ED) with later care received.

Continuity of care, particularly as patients transition from the hospital environment (inpatient, ED, OPD, or ASL) 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, 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, offering the ability to link the individual patient's care with the specialty of the providers from whom care was received. Information linking provider identifiers to their characteristics (e.g., specialty, provider age) is available from CMS for research purposes (<u>https://nppes.cms.hhs.gov/NPPES/</u>). 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 sampled discharges to NCHS's National Death Index (NDI) and potentially data from the Centers for Medicare & Medicaid Services (CMS). Likewise, National Provider Identifiers of attending and operating physicians are captured to facilitate the linkage between individual patient care and the specialty of the providers from whom care was received. The ability to make such linkages greatly expands the usefulness of these data at a low cost and burden to hospitals.

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.

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. See Attachment G for more details on the contractor's data security plan.

## 3. Use of Improved Information Technology and Burden Reduction

For the inpatient and ambulatory component of NHCS, hospitals are being asked to electronically transmit the UB-04 claims data for all patients (inpatient and ambulatory) to a contractor's secure network. Burden on hospital personnel is reduced, as most of the data are acquired electronically. To obtain the clinical information for the ambulatory component of NHCS, hospitals will either submit data electronically or through medical record abstraction onsite or remotely. FSASCs will only participate in non-remote reporting. For the facilities that are asked to provide UB-04 billing data or sign-in sheets, contract staff will abstract medical record data. Burden to staff would be incurred at facilities with paper medical records that need to be pulled and re-filed. The contractor staff would abstract the data onto a computerized data collection instrument. For the remote-reporting hospitals, burden on hospital personnel will be minimal. These hospitals will grant contract staff remote access to their EHR system and contract staff will access the networks from contractor's offices. Also, the ambulatory component only requires a sample of patient visits.

In addition, using a computer-assisted interviewing instrument for the ambulatory component facility interview will allow contract staff to skip unneeded questions and quickly populate writein fields with drop-down menus. Use of a computerized data entry system 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, and medications. Overall, using a computerized data entry system should reduce contract staff and respondent burden, and ultimately improve overall data quality. In addition, collecting the data electronically will speed 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 and total births, to weight the inpatient data. Each participating hospital will be asked to complete an Annual Inpatient 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 or FSASCs.

## 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 emergency and outpatient departments and hospital and free-standing ambulatory surgery centers. No other survey collects PHI that allows for linkage among the survey components (inpatient discharges, ED, OPD and ASL) 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 data similar to the inpatient data component of the NHCS through its Nationwide Inpatient Sample (NIS), HCUP does not collect data on the facility characteristics and does not collect data on PHI allowing data linkage.

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 emergency department. 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 emergency department 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. These data are not from a national probability sample

and they are limited in most cases to hospital-based ambulatory surgery data, unlike the ambulatory surgery component of the NHCS that includes both hospital-based and free standing ambulatory surgery centers from a national sample. In addition, because of the 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 facilities 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 facility. 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 and some FSASCS 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 both the inpatient and ambulatory components 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.

b) The NHCS is a sample of hospitals. Additionally, only a sample of a hospital's ambulatory visits will be selected for abstraction. Similarly, only a sample of a hospital's inpatient discharges will be selected for abstraction for special studies.

c) Abstraction Data Collection: Some respondents may be small hospitals or FSASCs. 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, OPDs, and ASLs or FSASCs. 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 facility staff, decreasing burden even more. Finally, for some hospitals, medical record data will be accessed from EHRs remotely which will greatly reduce the burden to the 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. <u>Annual estimates</u> - 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, OPD, and ambulatory surgery services; 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. <u>Budgetary considerations</u> - 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 reinducting hospitals into the survey and training new contractor staff every 2-3 years.

C. <u>Data quality</u> - 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 five CFR 1320.5

There is one special circumstance that applies to collection of NHCS data. Both the inpatient and ambulatory 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 ambulatory 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 77, Number 195, Pages 61411-12, on 10/09/2012. A copy of the notice is included as Attachment B. No public comments were received.

B) The inpatient component of 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:

• Al Woodward, Ph.D., regarding sampling drug-related 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: <u>Albert.Woodward@SAMHSA.hhs.gov</u>,

• 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 ambulatory component of the NHCS.

# 9. Explanation of Any Payments or Gifts to Respondents

NCHS pays a one-time \$500 to each sampled hospital and FSASC to set up the electronic UB-04 transmission to participate in the survey. In addition, NCHS compensates each of the 500 sampled hospitals and each of the FSASCs \$500 after a full year of UB-04 data is received by the contractor's secure network. Another \$500 is paid to each hospital and each FSASC after the abstraction of ED, OPD, and ASL visits is completed. Payment is intended to help facilities that otherwise would be unwilling to take on the added burden of transmitting UB-04 billing data, as well as for medical records' staff time to pull and re-file paper charts. 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 reimbursement payments are distributed to participating hospitals after completion of 12 months of data collection. The hospital primary contact works with contractor staff to determine which hospital personnel or department receives the payment. The same payment policy will apply to FSASCs.

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 facilities 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."

## Privacy Impact Assessment Information

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 H.

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 physician/provider name, 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 facilities, 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 G) 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)<sup>1</sup> for meeting the requirements of the Federal Information Security

<sup>&</sup>lt;sup>1</sup> See http://csrc.nist.gov/sec-cert/ca-compliance.html.

Management Act (FISMA).<sup>2</sup> 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 products and systems will comply with the FISMA regulations and supporting NIST guidelines (NIST Special Publication (SP) 800-60).

C. For the NHCS, the NCHS ERB granted a waiver of the requirement to obtain informed consent from the patient and a waiver of the requirement to obtain informed consent from physicians.

D. 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 linkage between survey components (inpatient discharges, ED, OPD and ambulatory surgery). 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 and ED ambulatory components)
- 6. Visit dates (for the ambulatory components)
- 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

<sup>&</sup>lt;sup>2</sup> See http://csrc.nist.gov/policies/FISMA-final.pdf.

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)<sup>3</sup>.

Dates of admission and discharge (for the inpatient and ED ambulatory components) 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

<sup>&</sup>lt;sup>3</sup> www.hsph.harvard.edu/thegeocodingproject/webpage/monograph/publications.htm

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, 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.

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 discharges collected in the inpatient component of the NHCS as well as sampled patients in the ED and OPD components of the NHCS. 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. It will also be collected as part of the NHCS' ambulatory components for hospitals able to transmit UB-04 data, when available. 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 (<u>https://nppes.cms.hhs.gov/NPPES/</u>).

# 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 2013-2015 survey will consist of approximately 500 hospitals and, upon completion of the new sampling frame, 250 FSASCs. The time period 2013-2015 is a transition period for this survey. Hospitals are still being inducted into the survey, for both inpatient and outpatient care. Freestanding Ambulatory Surgery facilities are being identified and inducted later in this period. Thus the expected burden

is lower for 2013 and increased to 2015 when the largest number of facilities will be providing data. Table 1 provides an annualized estimate of the average burden over the three-year period.

Hospital recruitment interviews will be conducted by contractor staff. The first part of recruitment includes an Initial Hospital Intake Questionnaire that is conducted over the telephone or by paper to verify the hospital's eligibility. This screener is conducted on all hospitals, but since 100 have already been conducted under the previous clearance, 400 hospitals remain for a total of 133 annualized burden hours (Attachment I).

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 133 annualized hours. As needed, the presentation will be used to complement the telephone recruitment (Attachment J).

Once a hospital has been confirmed as eligible, contractor staff conducts the Annual Inpatient Hospital Interview and also the Annual Ambulatory Hospital Interview annually for all inducted hospitals. Each participating hospital will be asked to complete an Annual Inpatient Hospital Interview that will be conducted by telephone or mail, whichever format is less burdensome for the respondent. Since hospitals are being inducted over time, an annual figure of 275 hospitals is estimated. A web portal may be constructed for the 2014 or 2015 data collection years. This interview collects annual statistics needed for weighting the inpatient component data which include hospital characteristics such as total numbers of admissions, discharges, and live births. The Annual Ambulatory Hospital Interview responses 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 (e.g., inclusion of self-pay). The Annual Inpatient Hospital Interview will take 1 hour to complete and will be conducted annually for a total of 275 burden hours (Attachment K). The Annual Ambulatory Hospital Interview will take 1.5 hours to complete with an annual burden of 413 hours (Attachment L).

Beginning in 2013 at each of the participating hospitals, we will approach the ED, OPD, and any ASLs and will induct ambulatory units from each. Each ambulatory unit will take 15 minutes to complete an annual induction interview (Attachment M). It is anticipated that approximately 1,000 ambulatory units (hospitals can have multiple units) will be inducted annually, for a total annual burden of approximately 250 hours.

Over the time period 2013 - 2015, hospitals will be asked to transmit UB-04s on a quarterly basis for all 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. This represents 1,100 annualized hours (Attachment N).

For hospitals with an eligible ED, OPD or ASL, patient records can be abstracted three ways. 1.) For remote-reporting hospitals and the hospitals submitting EHR files, no records will be pulled; therefore, there is no burden to the staff. 2.) For non-remote reporting facilities, contract staff will enter the data into the computerized Patient Record forms (Attachments R, S, and T); therefore, there is no burden to the facility for this activity. 3.) In situations where there are no electronic records, staff will have to pull and re-file medical records at a burden of 1 minute per Patient Record form. The total number of records staff are expected to pull in these hospitals is 50,000 per year (ED, OPD and ASL combined) (Attachment O). One medical record clerk from each of the 500 ambulatory units in the hospitals will have to pull and re-file an expected average of 100 records. At an average of 1 minute per record, the total annual burden to medical record clerks is 833 hours. Records will then be abstracted by contract staff at no burden to facility. Once the new sampling frame is completed, each of the FSASCs will be asked to complete an Annual FSASC Interview (Attachment P) which will take 30 minutes. Since FSASCs will not be inducted until late 2014, it is anticipated that only 2 years of data will be collected. This results in an overall response burden of approximately 140 hours.

FSACSs will be asked to transmit UB-04s on a quarterly basis for all claims. It is estimated that this will take 4 hours per FSASC per quarterly submission to prepare and transmit the data file. There are 167 FSASCs (250 per year for 2 of the 3 years), so this represents 668 annualized hours (Attachment W).

At FSASCs, it is anticipated that one-half of the facilities will have EHRs and thus have burden for providing patient data. The other half will have paper medical records; therefore, one medical record clerk from each of the 84 ambulatory units in FSASCs will have to pull and refile an expected average of 100 records (Attachment V). At an average of 1 minute per record, the total annual burden to medical record clerks is 140 hours.

The total burden is 4,029 hours.

			Number of	Avg. Burden	
		Number of	responses per	per Response	Total Burden
Respondents	Form	respondents	respondent	(in hours)	Hours
Hospital DHIM or DHIT	Initial Hospital Intake Questionnaire	133	1	1	133
Hospital CEO/CFO	Recruitment Survey Presentation	133	1	1	133
Hospital CEO/CFO	Annual Inpatient Hospital Interview	275	1	1	275
Hospital CEO/CFO	Annual Ambulatory Hospital Interview	275	1	1.5	413
Hospital Medical and Health Services Manager	Ambulatory Unit Induction	1,000	1	15/60	250
Hospital DHIM or DHIT	Prepare and transmit UB- 04 for Inpatient and Ambulatory	275	4	1	1,100

Table 1. Estimated Annualized Burden Hours

Hospital Medical	Pulling and re-filing	500	100	1/60	833
Record Clerk	Patient Records (ED,				
	OPD, and ASL)				
FSASC Chief	Annual FSASC Interview	167	1	30/60	84
Executive Officer					
FSASC DHIM or	Prepare and transmit UB-	167	4	1	668
DHIT	04				
FSASC Medical	Pulling and re-filing	84	100	1/60	140
Record Clerk	Patient Records				
TOTAL					4,029

## **B.** Burden Costs

The average response burden cost for the NHCS is estimated to be **\$189,189**. 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.

Type of	Response burden	Hourly Wage Rate	Respondent
Respondent	hours		Cost*
Hospital CEO/CFO	821	\$60.50	\$49,671
Hospital Director of health	1,233	\$50.60	
information management			\$62,390
Hospital Medical and	250	\$58.30	
Health Services Manager			\$14,575
Hospital Medical Record	833	\$20.90	
Clerk: Pulling and refiling			
medical records			\$17,410
FSASC Chief Executive	84	\$100.19	
Officer			\$8,416
FSASC Director of health	668	\$50.60	
information management			\$33,801
FSASC Medical Record	140	\$20.90	
Clerk: Pulling and refiling			
medical records			\$2,926
Total			\$189,189

Table 2. Estimated Annualized Burden Costs

\*Hospitals and FSASCs 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

Inpatient and Ambulator	y Components 2013-2015
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 3,520 hours; the proposed burden for the NHCS is 4,029 hours per data collection year. The burden hours increased by 509 hours due to the transitioning of the ambulatory component into NHCS. This includes collecting data from EDs, OPDs, ASLs as well as FSASCs.

## 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, OPDs, and ASLs 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, OPD, and ASL 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 online. 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, Ambulatory Surgery Center Association, and Society for Ambulatory Anesthesia. These presentations deal with specific aspects of the survey or special analyses of survey data.

This clearance request covers three years, 2013-2015, 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 2013 and beyond.

#### **Inpatient Component**

Recruitment Training	
Hospital recruitment	
Transmission of first quarter of 2013 UB-04 data	5/2013
Transmission of second quarter of 2013 UB-04 data	
Transmission of third quarter of 2013 UB-04 data	
Transmission of fourth quarter of 2013 UB-04 data	2/2014
First tabulations from the 2013 National Survey	7/2014
Public use file	12/2014

#### **Ambulatory Component**

Development and testing of laptop-based PC data	
collection tool for ambulatory data collection	
Abstractor training for ambulatory data collection - ED	6/2013
New sample for freestanding ASCs drawn	TBD
Induction of freestanding ASCs	TBD
Make contact with hospitals for	
ambulatory recruitment	6/2013
Abstraction for ambulatory data collection – OPD and ASL	6/2012 12/2012
Abstraction for announding under Confection – OFD and ASL	0/2015-12/2015
End data collection	
	5/2014
End data collection	5/2014 5/2014
End data collection Close out field work for ambulatory components	5/2014 5/2014 6-7/2014
End data collection Close out field work for ambulatory components Data processing by contractor	5/2014 5/2014 6-7/2014 9/2014
End data collection Close out field work for ambulatory components Data processing by contractor Final data file delivered to NCHS	5/2014 5/2014 6-7/2014 9/2014 5/2015

#### 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.