

Supporting Statement A for Request for Clearance:

**National Hospital Care Survey**

**OMB No. 0920-0212**

**(Expiration date: 10/31/11)**

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**April 5, 2011**

## **SUPPORTING STATEMENT**

### **THE NATIONAL HOSPITAL CARE SURVEY**

The National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC) requests a revision of an approved data collection survey (OMB No. 0920-0212, expires 10/31/2011), the National Hospital Discharge Survey (NHDS). The current NHDS is scheduled to end with the 2010 data collection. (OMB approved this change on September 19, 2009). Clearance is now being sought to change the name of the survey to the National Hospital Care Survey (NHCS) and expand data collection over the next several years. The NHCS is scheduled to begin in 2011 with the recruitment of approximately 500 hospitals and collecting data on hospital inpatients for all discharges from those hospitals in 2011 continuing through 2013. Hospitals recruited for the inpatient segment will provide data on hospital inpatients from their Uniform Bill (UB)-04 administrative database. This is a departure from the current NHDS by moving to an electronic system for collection of core data while providing a flexible platform that allows for primary data collection from the medical record for strategic samples of cases. In addition, facility level data will be collected through a facility questionnaire. Then in 2013, the complete NHCS will be formed by integrating the emergency, outpatient departments, and ambulatory surgery centers (ASCs) within the hospitals participating in the NHCS. A sample of free-standing ASCs will also be included. The NHCS would replace the NHDS in 2011 and the National Hospital Ambulatory Medical Care Survey (NHAMCS) (OMB 0920-0278) in 2013. A separate clearance will be submitted to integrate NHAMCS into NHCS. This revision requests a three year approval for the following:

- Recruitment of hospitals for the new National Hospital Care Survey (NHCS).
- Data collection at the facility level. This data collection will be conducted by interview and self-administered questionnaire.
- Data collection at the hospital inpatient level. This data collection will be accomplished by capturing all the data from the UB-04 on all patients discharged from participating hospitals.
- Pretest of a supplement on acute coronary syndrome, sponsored by the National Heart Lung and Blood Institute. This pretest will be conducted in a convenience sample of 32 hospitals recruited on the East coast. These discharges will be identified from the UB-04 by ICD-9-CM codes for a diagnosis of acute coronary syndrome. Data collection for the supplement will be accomplished by abstracting relevant data from the medical record.

#### **A. Justification**

##### **1. Circumstances Making the Collection of Information Necessary**

###### Background and Future Plans

The National Center for Health Statistics' (NCHS) surveys on hospital care includes the National Hospital Discharge Survey (NHDS) and the National Hospital Ambulatory Medical Care Survey (NHAMCS). NHDS has, since 1965, provided critical information on the utilization of the

nation's non-Federal short-stay hospitals and on the nature and treatment of illness among the hospitalized population. NHAMCS has provided data annually since 1992 concerning the nation's use of hospital emergency and outpatient departments. These data have been extensively used for monitoring changes and analyzing the types of care provided in the nation's hospitals.

NCHS is planning to integrate the data collected from these two hospital surveys into one survey- the NHCS. Beginning in 2011, NCHS will recruit a new sample of hospitals for this new survey. During this first year the survey hospitals will be asked to provide data on all inpatients from their UB-04 administrative database, as well as, facility level data through a facility questionnaire. Then in 2013, the sampled hospitals will be asked to provide data on the utilization of health care provided in their emergency and outpatient departments (ED and OPD) and ambulatory surgery centers (ASCs), thus integrating the NHDS and NHAMCS into the newly named NHCS. More details on NHAMCS integration into NHCS will be in a future clearance request.

The new NHCS will continue to provide the national general purpose health-care statistics that NHDS and NHAMCS currently provide. The new survey will have some distinct advantages. First, more information at the hospital 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.

Second, the data collected from the UB-04s on the inpatient discharges will be collected from all inpatient discharges, not just a sample. In 2013, when the hospital ED and OPD are integrated into the survey and visits are sampled from the ED and OPD clinics, the care provided to patients admitted to the hospital through the ED and OPD can be examined. 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.

In 2011, the first phase of the NHCS will begin with the recruitment of 500 hospitals and data collection of electronic claims data in these hospitals. By taking all the UB-04s from the hospital, the new NHCS will be able to sample hospital discharges with specific diagnoses and procedures for special studies that use medical record abstraction to collect more clinically relevant data. Discharges will be selected from the hospitals by ICD-9-CM codes appearing on the UB-04 and medical records abstractors will abstract data from the medical records that are specific to the needs of the study.

A pretest of such a special study will be conducted with the 2011 NHCS data. A supplement on acute coronary syndrome, sponsored by the National Heart Lung and Blood Institute will be conducted in a convenience sample of 32 hospitals recruited on the East coast. These discharges will be identified from the UB-04 by ICD-9-CM codes for a diagnosis of acute coronary syndrome. Data collection for the supplement will be accomplished by abstracting relevant data from the medical record.

NCHS plans to move toward greater collection of health-care data by electronic means as soon as participating hospitals are able to provide such electronic data. In 2011 the UB-04s will be electronically transferred to NCHS. As hospitals adopt electronic medical records (EMRs), NCHS should be poised to accept electronic files from hospital medical records. Our current

surveys are tracking on a national basis the adoption of health information technology (HIT) by health care providers.

### Inpatient Care Data 2011-2013

NHDS, which has been conducted continuously since 1965, is the Nation's principal source of data on inpatient utilization of short-stay, non-Federal hospitals, and is the principal source of nationally representative estimates on the characteristics of discharges, lengths of stay, diagnoses, surgical and non-surgical procedures, and patterns of use of care in hospitals in various regions of the country. It is the benchmark against which special programmatic data sources are compared. NCHS is authorized to collect data on hospital utilization under Section 306(b) of the Public Health Service Act (42 USC 242k) (Attachment A).

Although NHDS has served the country well for over 40 years by providing national data on inpatient care, significant changes have occurred in the role of inpatient care and in the data sources available to understand the characteristics of inpatient care. For NHDS to remain policy relevant, it must reflect the types of care and services now offered in the Nation's hospitals. For example, the average length of hospital stay has declined nearly 40 percent from 1970 to 2007. Many conditions for which, only a decade ago, a patient would have been admitted to a hospital and observed for a day or two are now, at least for patients with some types of insurance, admitted as "observation" patients, a designation that precludes their incorporation into an "inpatient only" database.

To inform efforts to improve NHDS, NCHS has conducted developmental work, carried out focused discussions with people in many Federal and private organizations, and conducted a workshop in March 2006. Using the findings of the workshop and interviews, NCHS identified key data about hospitals and information about discharges. Then, NCHS tested methods and tools in a feasibility study in seven hospitals.

NCHS then conducted further developmental work for the redesigned survey, completing a pilot study during April-May of 2008 in four hospitals in the Washington, DC area. This study tested the use of a laptop PC-based data collection tool and the abstraction of data elements identified in our earlier developmental work. In addition to providing information about the tool itself, the pilot provided important information about the effort required on the part of the abstractors and the hospitals to conduct sampling procedures and obtain specific data elements.

Next, the pretest focused on the design and testing of the operational mechanism to recruit a new panel of hospitals and to collect a broader spectrum of data elements using information technologies. The pretest was conducted in 28 hospitals from October 2008 to April 2009. Through this pretest we gained experience in hospital recruitment, induction, discharge sampling, and data abstraction into a PC-based data collection instrument.

Beginning in 2011, the NHDS will be replaced with the inpatient care part of the NHCS data collection and will be moving to an all electronic data collection starting with UB-04 claims data in 2011 and eventually adding data from electronic medical records. In order to do this, further methodological work needed to be conducted to demonstrate that hospitals can transmit data electronically to NCHS through a secure data network. In 2010 a small pilot study was

conducted to develop and test procedures used to collect electronic data in the form of UB-04s from hospitals, sample discharges according to ICD-9-CM codes from a hospital UB-04 data file, and transmit that data to the PC tool accurately and securely.

### 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 NHDS website.

### Overview of the Data Collection System

The target universe of the segment of the NHCS is inpatient discharges from non-Federal, non-institutional hospitals with six or more beds staffed for inpatient care of patients in the 50 states and the District of Columbia. For hospitals selected into the survey, facility-level data will be collected via telephone and personal interviews with hospital staff, along with hospital-staff self-administered questionnaires. The UB-04 data will be obtained electronically from the participating sample of hospitals.

### Items of Information to be Collected

The following facility-level data will be collected from hospitals, some of which are needed to make national estimates: survey eligibility criteria, service characteristics, financial descriptors, and the utilization of information technology. Discharge-level data to be collected will include 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.

The new NHCS inpatient data 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, providing better information on outcomes of hospitalization. In its approval, the NCHS Research Ethics Review Board agreed that this research could not be conducted practicably without access to and use of PHI. The list of requested IIF includes the following on patient discharges:

1. Patient name
2. Address
3. ZIP Code
4. Dates of admission and discharge
5. Procedure dates
6. Social security number (if available)
7. Medical record number (if available)
8. Medicare health insurance benefit/claim number
9. Birth date
10. National Provider Identifier (NPI)

Data will be transferred from participating institutions to the CDC network through a secure data network (SDN) connection. 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, such as hospitals, 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. Each hospital will need a digital certificate. 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, data will be archived on secure NCHS data servers. These machines are hosted behind an internal firewall, and physically located in a locked cage inside a locked computer room at the NCHS facility. Access to these servers is controlled by NCHS administrators and limited to NCHS program staff that have been cleared to access confidential statistical data. Access to the data for this project will be further restricted to individuals authorized by the program, and the NCHS server administrator.

No potentially identifiable data will be released in any form to the public. Reports produced by NCHS about the data or using the data will not identify an individual hospital or an individual discharge. Public use files will contain no information that can identify any individual or hospital.

#### 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 ([www.cdc.gov/nchs/nhcs.htm](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, and provide a link to the participant page ([www.cdc.gov/nchs/nhcs/participant.htm](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**

Data collected through the current NHDS are essential for evaluating the health status of the population, for the planning of programs and policy to improve the health status of the Nation, for studying trends in morbidity, and for research activities in the health field.

The data collected by the current NHDS are used by governmental, professional, scientific, academic and commercial institutions, as well as the public. The wide variety of uses of NHDS data is best exemplified by the diversity of its users. These include Federal agencies, such as the Centers for Medicare & Medicaid Services (CMS), the National Institutes of Health (NIH), the Food and Drug Administration (FDA), 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 and medical schools; professional organizations, such as the American College of Surgeons and the American Heart Association; state health planning agencies; hospitals; pharmaceutical and medical supply manufacturers; publishing houses; market research groups; and insurance companies.

However, there are many issues with substantial policy importance that the current NHDS cannot address. The new hospital inpatient component of the NHCS will move NCHS forward to

collect data that will better meet current and future policy and research needs and will allow a range of new research and policy questions to be explored. The following paragraphs highlight ways in which the new survey can be used to address questions related to policy-related areas that our developmental work identified as high priority.

Data from the Facility Questionnaire may be used to identify hospitals with different payer mixes (e.g., high or low proportion of Medicaid patients or self-pay patients). These findings might be analyzed for the entire patient mix in participating hospitals or for specific diagnoses and procedures captured through ICD-9-CM codes.

Further, in the new survey, we plan to determine from data collected on the UB-04 whether patients have had an intensive care unit (ICU) stay during hospitalization and the number of days of intensive care during hospitalization. This will allow national estimates of the costs of intensive care, an area of resource use that has been poorly studied to date. In addition, disparities among patient groups and trends in the allocation of intensive care resources could be assessed.

Quality of care, including patient safety, is and will continue to be a critical issue in health services research and policy. The new survey will capture whether diagnoses existed on admission, an important determinant in differentiating between adverse situations that led to hospitalization and complications that resulted from the care provided. In addition a key focus will be to understand the degree to which processes of care are consistent with recognized quality standards and practice guidelines. Drawing meaningful inferences regarding quality of care requires a clinical context in which that care is provided. The new survey will allow special studies that sample discharges by ICD-9-CM codes and use medical record abstraction to expand the survey's clinical information by incorporating laboratory data, medications on admission and discharge, and other clinically relevant variables. For example, in 2011, the new survey will pretest one such special study that samples discharges for patients with acute coronary syndrome and collects additional data on the patient's troponin levels.

#### Privacy Impact Assessment Information

The new survey begins to define variables 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 Facility Questionnaire can be linked with clinical care processes (e.g., surgeries) to understand outcomes of care (e.g., 30-day readmission, mortality). Data from the survey can be used to examine the extent to which earlier discharge places a patient at risk for unanticipated (i.e., non-elective) readmission to the hospital.

The new survey also provides the opportunity to retrospectively examine adoption trends for new procedures and types of care to assess their effect on quality and outcomes. For example, the current NHDS has been valuable in studying disparities in the adoption of cardioverter defibrillators. (Stanley, DeLia, and Cantor, 2007<sup>1</sup>).

Another important quality issue relates to the training and experience of those providing care.

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<sup>1</sup> [www.ihhpar.rutgers.edu/downloads/publications/JoelCantor.pdf](http://www.ihhpar.rutgers.edu/downloads/publications/JoelCantor.pdf)

The new survey will capture 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 (<https://nppes.cms.hhs.gov/NPPES/>). NCHS will, of course, maintain provider confidentiality in all analyses and public use files.

By incorporating data on patients with "observation status" (those patients that are observed for 1-2 days and traditionally not included as inpatients), 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, the new survey 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.

Continuity of care, particularly as patients transition from the hospital environment 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 limit the extent to which longitudinal data could be included in the new survey, the new NHCS will allow 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 will include data on all inpatients discharged and will include PHI. This will allow for determination of whether a patient had returned to that hospital after discharge or by looking back in the UB-04 records, 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.

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 new 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 new survey 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 type (e.g., rural or urban) will offer insight into the extent of differences in care that patients of different SES receive.



The new 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 the electronic health record. The Facility Questionnaire will provide data on the extent to which electronic health records have been adopted within a facility, and this information can then be linked to the efficiency and quality of care provided, using the cost and quality metrics discussed above.

Similarly, the new survey should continue 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 current NHDS data items and will continue to calculate trends.

In addition to inpatient data, both the current NHDS and new survey collect characteristics of discharges, lengths of stay, diagnoses, procedures, and patterns of use of care. The new survey 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 will be 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 will greatly expand the usefulness of the 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 in a breach. 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, and other outside agencies are required to enter into a formal agreement with NCHS. The transmission and storage of data are protected through procedures such as encryption and carefully restricted access. See A10 for more details.

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

In the new NHCS, hospitals will be asked to electronically transmit the UB-04s for discharges to NCHS. Burden on hospital personnel will be reduced, as most of the data will be acquired electronically. In addition, for the pretest of the supplement on acute coronary syndrome for NHLBI, a PC-based tool for discharge level data collection will support survey operations and data abstraction will be conducted by contract staff.

### **4. Efforts to Identify Duplication and Use of Similar Information**

Currently, no other data collection either federally sponsored or privately funded collects nationally representative data on inpatient hospitalization, patient and physician identifiers and facility level data which allows retrospective and prospective follow-up and linkages with other data systems. Although the Healthcare Cost and Utilization Project (HCUP), which is sponsored

by the Agency for Healthcare Research and Quality (AHRQ), contains data similar to the current NHDS, HCUP does not have PHI. By collecting PHI, the new NHCS will be able to conduct special studies such as the supplement on acute coronary syndrome to inform health care policy and practices. The collection of PHI also will allow linkage to the National Death Index to provide information about 30-day mortality.

Although other data collections cover many hospital admissions or large geographic segments of the United States, none provides the detail needed by many health care researchers and policymakers. The new survey adds clinical depth enough to answer questions such as, “Did this patient spend time in the intensive care unit of the hospital?” or “Was this inpatient stay a readmission?”

## **5. Impact on Small Businesses or Other Small Entities**

For the new survey, efforts to minimize the burden, particularly on small hospitals, include the following:

- a) Data elements will come from the electronically available UB-04, which is needed for inpatient billing purposes and routinely collected and recorded by sampled hospitals.
- b) The new survey will also be a sample survey. Additionally, only a sample of a hospital’s discharges will be selected for abstraction for special studies.
- c) Abstractors from the contractor will collect data for the module pretest on a sample of approximately 8 abstracts in each of 32 hospitals. Abstractors from the contractor will input discharge-level data for all the sampled hospitals into the PC-based tool thereby limiting the hospitals' burden. Hospitals will be responsible only for transmitting UB-04 data to NCHS electronically and for pulling and re-filing the medical records that are selected for the pretest of the NHLBI sponsored survey supplement.

## **6. Consequences of Collecting the Information Less Frequently**

There are no legal obstacles to reducing the burden on hospitals. 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 - 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. With the new survey, NCHS plans to continue to make annual estimates of critical utilization statistics.

B. Budgetary considerations - Extensive information captured during data collection procedures from the current NHDS 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 field 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 five CFR 1320.5**

There is one special circumstance that applies to collection of NHCS data. The NHCS collects 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. We will be collecting race and ethnicity in the OMB format to the extent that it is possible.

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

A) The 60-day public comment notice was published in the *Federal Register*, Volume 75, Number 153, Pages 48348-48349, on August 10, 2010. A copy of the notice is included as Attachment B. A request for more information from the American Legacy Foundation was received and copies of the draft OMB documents were forwarded to the requestor.

B) The new 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 new survey.

During 2005-06 NCHS staff held informal discussions and consultations with many organizations, both Federal and non-Federal, to discuss the redesign of the NHDS. In addition to the workshop discussions were conducted with experts in health research, economics, and policy. See Attachment C for a partial list of persons consulted.

In 2006 NCHS selected Rand Health, a division of Rand Corporation, to assist in developing an approach to redesigning the NHDS. 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 redesigned survey. On March 29-30, 2006, NCHS held a workshop composed of government and non-government experts to develop a conceptual framework for a redesigned NHDS. Participants are listed in Attachment C.

In 2006 Rand Health produced a conceptual framework for the redesign and conducted a feasibility study. A final report was produced in 2007.

In 2007-2008, exploratory meetings were held with several agencies to discuss the possibility of adding complementary data collection items, or modules as they were called, to the core set of current NHDS study variables. The subject areas included items related to end-of life, acute coronary syndrome, and infectious diseases. A list of the agencies and the representatives involved in these discussions is noted on Attachment C.

During 2008-2009, debriefings with points of contact from the participating redesigned NHDS pretest hospitals were individually scheduled to obtain feedback on the study's recruitment and data collection procedures. Information gathered from these sessions was used to refine the study's operational procedures.

There were no major problems about which agreement could not be reached by any of the groups that provided input into the redesign.

## **9. Explanation of Any Payments or Gifts to Respondents**

A large part of the success of the NHCS depends on the good will of the hospitals for the continuing voluntary activities that they perform. Once inducted into the survey, hospitals participate for a number of years. To this end, compensation is a necessity.

For the 2011-2013 NHCS inpatient data, NCHS proposes to compensate each of the 500 sampled hospitals \$500 initially to set-up the processes and procedures to transmit the data to NCHS. The \$500 one-time set-up incentive will help defray the cost of a hospital staff person's time to go through the applications procedures for obtaining a digital certificate to send the UB-04 data transmission through the CDC's or the contractor's secure network, to install the software needed on a personal computer for sending the data transmission, for the construction of a computer program to compile the UB-04 data and create an electronic file by either hospital staff or a clearinghouse, and for the preparation of test files for NCHS. Subsequently, hospitals will be compensated \$500 after the hospital completes each full year (12 months of transmitted data) of participation. The \$500 participation incentive will help defray the cost of staff time for four quarterly transmissions per year and any follow-up needed about the transmissions with NCHS staff. Some hospitals use clearinghouses for processing of their UB-04 data and the incentive will help with any additional costs incurred by the hospitals in acquiring a UB-04 file for NCHS. Variables and formats for the UB-04 are modified regularly so the incentive will cover any staff time needed to update or modify computer programs. All the hospitals will be compensated at the same rate, unless they are participating in any additional special studies. The 32 hospitals that are participating in the NHLBI sponsored supplement will be compensated an additional \$500 to assist contractor staff in abstraction of the sampled medical records and for providing the contractor staff with a computer station and a secure location.

In addition, a continuing education module is being developed to serve as an educational and recruitment tool highlighting the National Hospital Care Survey. This web-based instrument will be added to the NHCS web page on the NCHS Internet site ([www.cdc.gov/nchs/nhcs.htm](http://www.cdc.gov/nchs/nhcs.htm)). If the American Health Information Management Association (AHIMA) and Healthcare Information and Management Systems Society (HIMMS) grant approval of the module, health information management and health information technology staff from the hospital-community

will be able to obtain two free continuing education units by completing the NHCS training module.

## **10. Assurance of Confidentiality Provided to Respondents**

The confidentiality of patient information and the identity of individual hospitals participating in the NHDS 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. An assurance of confidentiality will be on any new NHDS 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. The 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 continuation Protocol #2009-21 for the survey for the maximum allowable period of one year is presented in Attachment D.

In keeping with NCHS policy, survey data are 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 and reviewed by the NCHS Disclosure Review Board to avoid data breaches, such as release of detailed geographic information that may allow anyone to identify practices or individuals in the general population. The survey Data Security Plan (DSP) describes the survey procedures and data handling protocols that will be implemented to secure study data and protect confidentiality. The NHCS DSP and the contractor’s DSP follow the same protocol, as described below.

The contractor’s DSP describes the survey procedures and data handling protocols that will be 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>2</sup> for meeting the requirements of the Federal Information Security Management Act (FISMA).<sup>3</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. 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 introductory letter from the NCHS director, it states that participation in the survey 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

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<sup>2</sup> See <http://csrc.nist.gov/sec-cert/ca-compliance.html>.

<sup>3</sup> See <http://csrc.nist.gov/policies/FISMA-final.pdf>.

individually identifiable information is removed. The legal authority for data collection is Section 306 of the Public Health Service Act (42 U.S.C. 242k).

## 11. Justification for Sensitive Questions

In the new inpatient survey, we will be collecting confidential information defined as “private medical information” by the HIPAA Privacy Rule. In their approval of the new survey, the NCHS ERB agreed that this research could not practicably be conducted without access to and use of the protected health information. The list of requested items considered to be sensitive includes the following:

1. Name
2. Address
3. ZIP Code
4. Dates of admission and discharge
5. Procedure dates
6. Social security number (when available)
7. Medical record number (when available)
8. Medicare health insurance benefit/claim number
9. Birth date
10. National Provider Identifier (NPI)

**Patient name and social security number** are not currently collected as part of the NHDS, but are protected health information proposed for inclusion in the new survey . In order to accurately link sampled patients to the NCHS National Death Index (NDI), first and last names of the patient will be 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 will evaluate the linkage to NDI after the NDI becomes available for the time period that corresponds to the first full year of data collection for the redesigned survey. This evaluation will allow us to determine whether less information can create an adequate match to the NDI.

**Patient address and ZIP code of residence** can be linked to 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 the NHCS to track the use of hospital care by SES. Unfortunately, however, 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>4</sup>.

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<sup>4</sup> [www.hsph.harvard.edu/thegeocodingproject/webpage/monograph/publications.htm](http://www.hsph.harvard.edu/thegeocodingproject/webpage/monograph/publications.htm)

**Dates of admission and discharge**, which are currently collected in the NHDS, are essential to calculate days of care, which are needed to measure total inpatient utilization 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 the Prospective Payment System or laws that regulate the early discharge of mothers and newborns. Although it may be possible to measure the number of days of care from admission and discharge dates during the medical abstracting process, this introduces error. With precise dates in hand, NCHS can calculate days of care per patient regardless of the number of days in a month, leap years, or other nuances. Performing these operations once, under the control of NCHS, is far superior to having hundreds of people in the field calculating this information independently.

**Procedure dates** are necessary, in conjunction with admission and discharge dates, to determine the timing of procedures within a hospitalization. Procedure dates help 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 and medical errors, as well as for those interested in risk-adjusted outcomes of hospitalizations.

**Medical record number** is collected and used for sampling purposes in the current NHDS, but not retained. Under the new survey, collection of medical record number would allow the opportunity to collect a single patient's data directly by abstraction from several sources within a hospital, such as the medical record, laboratory records, and billing records. This will provide access to more detailed clinical information, as well as additional outcomes and quality measures. Direct abstraction from the patient's medical record may provide improved clinical data. Special studies such as the pretest on acute coronary syndrome sponsored by the National Heart Lung and Blood Institute require the medical record number to so that the medical record can be accessed.

**Medicare health insurance/claim number** is another piece of protected health information proposed for inclusion in the new survey. 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. In cases of hospitals with a very large number of patients with a particular diagnosis, a sampling strategy may be used. However, most hospitals have indicated that this is rare and most provide complete data. For example, for all cases of pneumonia, Medicare would collect data on whether each patient admitted received antibiotics within four hours of presentation. We intend to discuss with CMS the possibility of linking with Medicare data in order to provide measurements of quality for the patients that are included in the NHCS, as we did for the data from the 2004 National Nursing Home Survey (OMB 0920-0353 expired 5/31/07). This would provide additional important data on quality of care without requiring further primary data collection. In addition, we will discuss linking to the CMS database that contains longitudinal



utilization data for all Medicare patients, thereby adding additional utilization data to our dataset and providing clinical detail that CMS data do not have in its database.

**Date of birth** will be converted to age at NCHS 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.

**National Provider Identifiers (NPIs)** of attending and operating physicians will be captured as part of the discharge abstract, 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 (<https://nppes.cms.hhs.gov/NPPES/>).

NCHS is experienced in working with hospitals to explain HIPAA, and help them overcome concerns they might have. NCHS understands that hospitals will ask questions during the induction process about the privacy and confidentiality of the data. NCHS will include, in advance, materials and information explaining how hospitals are authorized under HIPAA to release the UB-04 data and the abstracted medical chart information. Hospital staff will also be given a copy of our NCHS ERB approval letter.

## **12. Estimates of Annualized Burden Hours and Costs**

### **A. Burden Hours**

The sample size for the 2011-2013 survey will consist of approximately 500 hospitals. Hospital induction activities will be conducted by contractor staff. A four-part questionnaire (Attachment E) will be used to obtain information about the facility. Part A of the questionnaire is a telephone screening to verify the facility's eligibility. Part B is an interview conducted between the contractor and hospital officials to obtain participation in the NHCS and identify a primary hospital contact for the study. Part C obtains systems information, records management and key contacts information. Part D will be left at the hospital for staff to complete on their own and then sent back to the contractor. This section asks hospitals for detailed information on staffing, health information technology and payment. It will also collect aggregate hospital statistics, such as total admissions excluding newborn infants, and total live births, for use in the estimation process. This information will be used to develop the survey weights.

Based on the pretest experience, it may be necessary, prior to conducting Part B of the induction interview, to review with hospital officials the introductory materials previously sent to them and to answer any outstanding questions. Further, after a hospital is initially inducted, it will be asked to annually complete Part D of the facility questionnaire as a means of providing facility level updates. For the total 500 hospitals, the induction process, including completion of Parts A through D of the facility questionnaire, is estimated to take 4 hours per hospital and will represent an estimated 668 annualized hours. The post-induction annual facility questionnaire will take two hours and represents 666 annualized hours (Attachment F).

We anticipate there may be some hospitals that will require additional information about participating in the survey and a one hour survey presentation has been designed for them. This will represent another 167 annualized hours. As needed, the presentation will be used to complement the telephone recruitment (Attachment G).

Over the time period 2011-2013, hospitals will be asked to transmit UB-04 data on a quarterly basis. It is estimated that this will take one hour per hospital per quarterly submission to prepare and transmit the data file. This represents 2,000 annualized hours (Attachment H).

For the acute coronary syndrome pretest module to be conducted in 32 hospitals, it is anticipated that some of the hospitals will require additional information about participating in the abstraction module and a 1 hour survey presentation has been designed for them. This presents 11 annualized hours (Attachment I). Once inducted into the module, we expect that hospital staff will take an average of 15 minutes per sampled discharge to pull the medical records for abstraction and reabstraction (Attachment J). This equals eight annualized hours over three years.

Table 1. Estimated Annualized Burden Hours

Respondents	Form	Number of responding hospitals	Number of responses per respondent	Avg. Burden per Response (in hours)	Total Burden Hours
Hospital CEO/CFO	Survey Presentation for the NHDS	167	1	1	167
Director of health information management (DHIM) or Health information technology (DHIT)	Facility Questionnaire Form for the NHDS	167	1	4	668
DHIM or DHIT	Post-Induction Annual Facility Questionnaire	333	1	2	666
DHIM or DHIT	Quarterly Transmission of UB-04 Data	500	4	1	2,000
Acute Coronary Syndrome(ACS)Pretest					
Hospital CEO/CFO	Survey Presentation for the ACS Module for the NHDS	11	1	1	11
DHIM or DHIT	Abstraction and Reabstraction for the ACS Module of the NHDS	11	3	15/60	8
<b>TOTAL</b>					<b>3,520</b>

**B. Burden Costs**

The average annual response burden cost for the new survey is estimated to be \$162,215 for each survey year. The average annual response burden for the one time only pretest of the NHLBI sponsored supplement on acute coronary syndrome is estimated to be \$951. The average annual response burden for the ambulatory pretest is estimated to be \$4,200. The hourly wage estimate

for hospital executives, directors of health information and health information technology and medical coders is based on the 2008 American Health Information Management Association (AHIMA) Membership Profile. The following table shows how the respondent cost was calculated:

Table 2. Estimated Annualized Burden Costs

<b>New NHCS</b>			
<b>Type of Respondent</b>	<b>Response burden hours</b>	<b>Hourly Wage Rate</b>	<b>Respondent Cost*</b>
Hospital CEO/CFO	167	\$ 53	\$8,851
Director of health information management	3,334	\$ 46	\$153,364
<b>Total NHDS 2011-2013</b>			<b>\$162,215</b>
<b>ACS Pretest</b>			
Hospital CEO/CFO	11	\$ 53	\$583
Director of health information management	8	\$ 46	\$368
<b>Total ACS Pretest</b>			<b>\$951</b>

\*Hospitals in the current survey are compensated for their participation. Likewise, there are plans to compensate hospitals in the redesigned survey. Both are 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 the survey 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 new NHCS to the government will be \$3.9 million.

#### **Average Annual Costs for the NHCS Annualized Over Three Years**

<b>New NHCS</b>	
Data collection contract	\$2,900,000
Staff Salaries	\$1,000,000
<b>Total</b>	<b>\$3,900,000</b>

## **15. Explanation for Program Changes or Adjustments**

The current burden for the NHDS is 5,591 hours. With the new survey moving to an all electronic data collection, this will decrease the burden hours to 3,520 for a decrease of 2071 hours.

## **16. Plans for Tabulation and Publications and Project Time Schedule**

Data are published annually as NCHS *National Health Statistics Reports (NHSRs)* and NCHS *Data Briefs*, articles in professional journals, and other special reports. At a minimum, the annual publication plan is to update the non-medical, medical, and surgical data by characteristics of patients and hospitals. Special reports on utilization trends, specific diagnoses, selected patient and hospital characteristics, source of payment, and methodology are also published in *Series 2, 5, or 13* of the NCHS *Vital and Health Statistics*, *NHSRs*, or journal articles.

Staff of the Ambulatory and Hospital Care Statistics Branch, NCHS, present data at meetings and conferences of professional organizations, such as the American Public Health Association, AcademyHealth, Gerontological Society of America, National Association of Health Data Organizations, and National Rural Health Association. These presentations deal with specific aspects of the survey or special analyses of survey data.

Annual public use files containing information collected by the NHDS since 1970 are available. To facilitate trend analysis, multi-year public use files provide multiple years of NHDS 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. Many of the public use files and reports as well as detailed descriptions of the survey design and data collection methodology are available on the National Hospital Discharge Survey website at: [www.cdc.gov/nchs/nhds.htm](http://www.cdc.gov/nchs/nhds.htm). The new survey website will be [www.cdc.gov/nchs/nhcs.htm](http://www.cdc.gov/nchs/nhcs.htm).

Tabulations are prepared annually and are used by the Ambulatory and Hospital Care Statistics Branch in answering requests for unpublished data. These tabulations provide detailed data on discharges by patient characteristics (age, sex, race, and discharge status) and hospital characteristics (geographic region, type of ownership, and number of beds). Detailed diagnostic and surgical information is also available by patient and hospital characteristics. In addition, special tabulations can be produced upon request.

This clearance request covers three years 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 both the 2011 new inpatient survey and the NHLBI sponsored ACS supplement.

**Inpatient Data 2011**

Recruitment Training.....	5/ 2011
Hospital recruitment .....	6/ 2011-9/2012
Transmission of first quarter of 2011 UB-04 data.....	7-8/2011
Transmission of second quarter of 2011 UB-04 data.....	10/2011
Transmission of third quarter of 2011 UB-04 data.....	12/2011
Transmission of fourth quarter of 2011 UB-04 data.....	3/2012
First tabulations from the 2011 National Survey.....	4/2012
Public use file.....	8/2012

**NHLBI sponsored ACS supplement**

Sampling discharges for ACS supplement.....	9/2011
Field ACS Supplement .....	10/2011- 5/2012
Final edited data files.....	6/2012-10/2012

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

Approval is not being sought to not display OMB expiration date.

**18. Exceptions to Certification for Paperwork Reduction Act Submission**

No exceptions to certification are requested.