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 goal of the National Hospital Care Survey (NHCS) is to assess the health of the population through the creation of a dataset that contains information on health care utilization as well as the demographic characteristics, medical conditions, and treatment of patients who use hospitals for inpatient and ambulatory medical care in the United States.

- The intended use of the resulting data is to provide government, professional, scientific, academic and commercial institutions, and private research organizations, as well as private citizens with information that can be used to monitor public health and to investigate research questions about health care utilization and delivery over time.

- Inpatient and ambulatory data will be collected from a sample of 598 hospitals via UB-04 claims or electronic health record (EHR) data.   Additionally, hospital-level characteristics for all sampled hospitals are gathered through an Annual Hospital Interview.

- The target subpopulation of the NHCS is inpatient discharges, and patient visits made to Emergency Departments (EDs) and Outpatient Departments (OPDs) of non-Federal, non-institutional hospitals with six or more beds staffed for inpatient use in the 50 states and the District of Columbia.

- NHCS data will be weighted and analyzed using appropriate statistical techniques. Public-use files will be made available where possible. Findings will be released in NCHS reports, journal articles, and research papers as well as released to researchers for analysis

The National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC), requests a three-year approval to continue the National Hospital Care Survey (NHCS) (OMB No. 0920-0212, expires 01/31/2019).

On January 7, 2016, the NHCS received a 3-year clearance to continue the NHCS data collection. The terms of clearance state that "NCHS will communicate regularly with the Office of Management and Budget (OMB) about the outcome of its effort to combine NHAMCS with the NHCS, particularly progress in recruiting hospitals and their ability to efficiently transfer data to NCHS, as well as the expected timing of combining these Information Collection Requests (ICRs) as well as its progress on developing the frame for the free standing ambulatory care facilities." As a part of this submission, a summary update capturing the ongoing work, progress made, future plans for recruitment and data collection as it relates to the terms of clearance are provided in Attachment M.

Activities requested for approval in this ICR:

- Continue recruitment of hospitals in the sample for the NHCS.
- Continue the collection of hospital-level data through an initial intake questionnaire and an Annual Hospital Interview for all sampled hospitals.
- Continue the collection of electronic data on inpatient discharges as well as Emergency Department (ED) and Outpatient Department (OPD) visits through the collection of Electronic Health Record (EHR) data, UB-04 claims, or a state file.
- Continue collection of substance-involved ED visit data through the ED component.
- Eliminate the "Annual Ambulatory Hospital Interview" (578 hours of burden) administered as part of medical record abstraction of a sample of ED and OPD visits.
- Postpone frame development for free-standing ambulatory care facilities.
- Inclusion of future methodological work with the National Health Care Survey hospital registrants to identify factors that may influence them continuing to submit EHR data to the NHCS after the Incentive Programs expire. Details regarding the methodological work will be subsequently submitted to OMB as soon as they are finalized.
- Continue to make relatively minor additions, deletions, and changes to the survey through the use of non-substantive change submissions.

A. Justification

1. Circumstances Making the Collection of Information Necessary

<u>Background</u>

The National Hospital Discharge Survey (NHDS) (OMB No. 0920-0212, Exp. Date 01/31/2019), conducted continuously between 1965 and 2010, was the Nation's principal source of data on inpatient utilization of short-stay, non-institutional, non-Federal hospitals, and was the principal source of nationally representative estimates on the characteristics of inpatients including

lengths of stay, diagnoses, surgical and non-surgical procedures, and patterns of use of care in hospitals in various regions of the country. In 2011, NHDS was granted approval by OMB to expand its content and to change its name to the National Hospital Care Survey (NHCS).

Inpatient Component of NHCS

In May 2011 recruitment of sampled hospitals for the NHCS began. Hospitals in the NHCS are asked to provide data on all inpatients from their UB-04 administrative claims, state file, or EHRs. Hospital-level data are collected through an Annual Hospital Interview (Attachment F). NHCS will continue to provide the same national health-care statistics on hospitals that NHDS provided.

NHCS has some distinct advantages over NHDS. First, NHCS collects more information at the hospital level (e.g., volume of care provided by the hospital), which allow for analyses on the effect of hospital characteristics on the quality of care provided. Second, NHCS data collected from UB-04s, state files, and EHRs include all inpatient discharges, not just a sample. The confidential collection of personally identifiable information (PII) allows 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 patients to the National Death Index (NDI) to measure post-discharge mortality, and Medicare and Medicaid data to leverage comorbidities. The availability of hospital identifiers also makes analysis on hospital readmissions possible. This comprehensive collection of data makes future opportunities for surveillance possible, including analyzing trends and incidence of opioid misuse, acute myocardial infarction, heart failure and stroke as well as trends and point prevalence of healthcare acquired infections and antimicrobial use.

Ambulatory Component of NHCS

Beginning in 2013, in addition to inpatient hospital data, hospitals participating in NHCS were asked to provide UB-04, state file, or EHR data on the utilization of health care services in their ambulatory settings (e.g., EDs and OPDs).

The NHCS offers unique opportunities to study opioid-involved health outcomes, as the ED component of the survey supports identification of substance-involved ED visits. NHCS can link a patient's care history to internal (e.g., across ambulatory and inpatient settings of participating hospitals and time) and external data (e.g., NDI). Repeat encounters for opioid use can be examined and opioid-related mortality rates can be calculated. Also, the collection of clinical notes via EHR provides rich information on the type of drugs taken, the nature of misuse or poisoning, and other risk factors for opioid-involved hospital encounters. 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. The notes can logically be extended to any medical condition, enriching the main data elements collected.

Data on substance-involved ED visits from NHCS will be used by national, state, and local health professionals, policymakers, law enforcement officers, pharmacologists, and health services researchers to understand the consequences of substance use and abuse and to identify

emerging trends and changing patterns of substance use. The White House Office of National Drug Control Policy (ONDCP) plan to use these data to monitor national trends; and, at the direction of the Food and Drug Administration (FDA), the pharmaceutical industry plan to 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.

2. Purpose and Use of Information Collection

NHCS has several objectives. The first objective is to produce nationally representative utilization statistics for hospital discharges and ambulatory health care. NHCS uses an independent national probability sample of hospitals that is planned to be updated every third year to ensure that the sample continues to be nationally representative.   Once fully implemented, the survey will produce nationally representative estimates of discharges by diagnosis and procedures and visits to EDs and OPDs.

A second objective is to close gaps in available information about hospitals at the facility level, and relate these characteristics to discharge level data within the hospital. The NHCS collects data using an Annual Hospital Interview from every sampled hospital (including nonrespondents) each year (Attachment F).

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 PII which allows linkages to other episodes of care in the ED and OPD as well as other data sources, such as the NDI and the Medicare and Medicaid claims databases.

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

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

The NHCS 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. Similarly, the NHCS will be an extremely valuable public health resource by providing trend data on hospital use, including diagnoses and procedures of particular interest (e.g., Cesarean section rates, use of coronary stents).

The various uses of future NHCS data are best exemplified by the historical diversity of users of NHDS and NHAMCS. Of particular importance, NHDS data were used and NHAMCS data are still 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 provided annual updates for numerous tables in the Congressionally-mandated NCHS report, *Health*, *United States.*

Data from the NHDS provided and NHAMCS still 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 provided national estimates of hospital utilization for discharges of patients with human immunodeficiency virus (HIV) infection. Staff of the National Center for Injury Prevention and Control used NHDS data as a measure of hospitalizations due to injury. NHDS data were used in a variety of research activities in the National Center for Chronic Disease Prevention and Health Promotion. In addition, NHDS used to and NHAMCS data still often appear in CDC's *Morbidity and Mortality Weekly Report (MMWR).*

Although current NHCS data are not deemed nationally representative, groups within and outside of CDC are seeing tremendous potential in the uses of NHCS data. For example, the CDC's Division of Unintentional Injury Prevention recently organized an Opioid Response Coordinating Unit (ORCU). ORCU was tasked with identifying and compiling a list of both government and non-governmental sources of opioid-related morbidity and mortality surveillance data to identify and address gaps in established data systems. In March 2018, the Ambulatory and Hospital Care Statistics Branch Chief and the NHCS Team Lead were invited to present on the NHCS' ability to identify opioid-related hospital encounters. Within the same CDC unit, another team member was invited to do a presentation entitled, "Victimization-related Hospital Visits and Hospital-based Victim Services: Developing the National Survey of Hospital-based Victim Services." Also within CDC, a survey team member presented, "Mortality of Emergency Department Suicide Attempt Visits after Discharge: Results from the 2014 National Hospital Care Survey," at CDC's 6th Biennial Mental Health Surveillance Meeting. This presentation shared results from the 2014 NHCS reporting the number of ED visits related to suicide attempts, patient demographics, risk factors, and post-hospital mortality. Outside of CDC, NCHS staff delivered a presentation at the National Institute of Mental Health's meeting, "The State of Suicide Prevention Care in Emergency Care." This presentation was entitled, "Overview: the National Hospital Ambulatory Medical Care Survey (NHAMCS), the National Hospital Care Survey (NHCS), and the NHCS Linkage to the National Death Index."

The NHCS data are important because they define an approach that links structure, process, and outcomes of care. Structural information (i.e., information on the hospital and environment in which care is received) provided on the Annual Hospital Interview can be linked with clinical care processes (e.g., surgeries) to understand how structure affects the types of care. 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 PII data allows, in some circumstances, the linking of characteristics and processes of one admission/visit with a later admission/visit and the location of the admission/visit (i.e., inpatient, ED) with later care received through the UB-04 claims or EHR data. It should be noted that state files are stripped of identifying information, and therefore do not contain the PII data requested.

Another important quality issue relates to the training and experience of those providing care. The NHCS captures the attending and operating physicians' National Provider Identifiers (NPIs) as part of the UB-04 and EHR, offering the ability to link the individual patient's care with the specialty of the providers from who care was received. Information linking provider identifiers to their characteristics (e.g., specialty, provider age) is available from Centers for Medicare & Medicaid Services (CMS) for research purposes (https://www.cms.gov/Research-Statistics-Data-and-Systems/Research-Statistics-Data-and-Systems.html. 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, including ZIP Code, will facilitate sophisticated geocoding, thus allowing for estimates of patient and family income and education (which are not collected in NHCS) and imputation of missing data on patient race and ethnicity which NHCS does collect. 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 from lower SES areas who cannot be discharged to an appropriate lower level of care. Relating patient likely 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.

3. Use of Improved Information Technology and Burden Reduction

Participating hospitals are asked to submit EHR, UB-04 claims or state file data for all inpatient discharges and all ambulatory visits. In 2018, EHR data are being submitted to the NCHS Healthcare Electronic Health Record (HEHR) System described in section A10 and UB-04 claims

and state files are being submitted to the sub-contractor's secure network. Beginning in 2019, hospitals will be asked to submit all data through the HEHR System at NCHS. Burden on hospital personnel is reduced, as most of the data are acquired electronically. The HEHR system is expected to simplify data transmission and reduce burden for hospitals participating in NHCS.

There is a need to collect annual hospital statistics, such as total admissions, total visits and total births, to weight the inpatient and ambulatory data. Every hospital in the sample, regardless of participations status, is asked to complete an Annual Hospital Interview that is conducted via a web portal, with any needed follow-up conducted by telephone or mail.

There are no legal obstacles to reducing the burden on hospitals.

4. Efforts to Identify Duplication and Use of Similar Information

Currently, no other data collection mechanisms, either within the Federal Government or in the private sector, collects PII that allows for linkages between inpatient discharges and ED and OPD visits as well as allowing linkage to the NDI. PII collection allows researchers to better study the outcomes of hospital care.

Although the Healthcare Cost and Utilization Project (HCUP), which is sponsored by the Agency for Healthcare Research and Quality (AHRQ), collects inpatient data similar to the NHCS through its Nationwide Inpatient Sample (NIS), it does not collect data on hospital characteristics and does not collect PII data, allowing data linkage to datasets such as NDI. Additionally, HCUP is not nationally representative in its sampling design and does not collect rich clinical data which is captured in EHRs.

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

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)(0920-0623, Discontinued 01/26/2006) and the State Emergency Department databases (SEDD). All of these systems are limited to the ED. NEISS AIP is sponsored by the Consumer Product Safety Commission (CPSC) and designed to provide incidence estimates of all types of and causes of nonfatal injuries and poisonings treated in the ED. NHAMCS data (OMB No. 0920-0278, Exp. Date 06/30/2021) are used by NEISS AIP to benchmark their statistics. SEDD is a set of databases from data organizations in participating States that capture discharge information on ED visits that do not result in a hospital admission.

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

5. Impact on Small Businesses or Other Small Entities

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

A) Data elements for NHCS come from already electronically available information, including a state file already submitted to the state; UB-04 claims data, which are needed for billing purposes and routinely collected and recorded by all hospitals; or EHR data which are used by hospitals to capture patient data.
B) Non-profit hospitals in the NHCS sample may be eligible for a community benefit tax exemption for participating in the survey. For more information on this community benefit, please see section B3.

6. Consequences of Collecting the Information Less Frequently

There are three major reasons to continue to collect data on an annual basis (or quarterly and monthly as needed to facilitate timely submission of data): availability of annual estimates, budgetary considerations, and data quality.

A) <u>Annual estimates</u> - 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. NHCS aims to continue the reporting of these data by integrating NHDS and NHAMCS. 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 two decades.

The rapidly changing environment of hospital ambulatory health care delivery and the current interest in health care reform lend importance to having annual data for decision making; describing the use of hospital ED, and OPD services, including ambulatory surgery; monitoring the effects of change; and planning possible changes to payment policies. With the need to track the effects of the health care industry's evolution, this information has become even more crucial. Having continuous data collection before, during, and after policy changes and restructuring is essential. Since data from the surveys are often analyzed by combining data across years, the potential consequence of less frequent data collection would be the inability to study issues such as ED crowding, EHR adoption, preventive services, and those low frequency procedures that require combining data across time periods. NHDS provided and NHAMCS still provides annual updates for numerous tables in the Congressionally-mandated NCHS report, *Health, United States*. In addition, NHDS and NHAMCS data were 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.

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 experience, it has been determined that conducting this survey less frequently would require the very expensive process of re-inducting hospitals into the survey and training new contractor staff every two to three years.

C) <u>Data quality</u> - The highest quality of data can best be maintained when data are collected on an ongoing basis. Ongoing data collection minimizes disruption in the field related to re-recruiting and re-starting data collection with hospitals. Ongoing data collection is also essential to have data on health trends in the population.

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

There is one special circumstance that applies to collection of NHCS data. NHCS will collect the OMB race and ethnicity codes in as much detail as possible. States vary with the extent to which they permit race and ethnicity to be collected and included on the UB-04, state file or EHR.

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 83, Number 178, Pages 46488-46490, on 09/13/2018. A copy of the notice is included as Attachment B1. Four non-substantive comments were received and are included in Attachment B2.

B) The NHCS is intended to provide improved data for use by both governmental and non-governmental policymakers, 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, ED, and EHR data collection.

More recently, NCHS consulted with the following individuals:

- Elizabeth Crane
  SAMHSA/CBHSQ,
  1 Choke Cherry Road, Rockville, MD 20857
  Phone: 240-276-1245
  Email: Elizabeth.Crane@samhsa.hhs.gov

- Catherine Dormitzer
  Center for Drug Evaluation and Research
  Food and Drug Administration (FDA)
  10001 New Hampshire Ave, Silver Spring, MD 20903
  Phone: 301-796-1785
  Email: Catherine.Dormitzer@fda.hhs.gov

- Terry Zobeck
  Associate Director of Research/Data Analysis
  Office of National Drug Control Policy
  750 17th Street NW Washington, DC 20503
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- Dan Budnitz
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- Scott Smith
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  Behavioral Scientist
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Outreach Activities:

Outreach activities have included attendance and exhibiting at conferences, publishing announcements in state hospital association and other newsletters, conducting webinars, and creating a new listserv for data related updates. For a list of conferences attended, please see section A16. NCHS published an announcement about the survey and its data uses in the College of Healthcare Information Management Executives (CHIME) electronic newsletter as well as to the email distribution list for the National Drug Early Warning System (NDEWS) state members. Additionally, through NDEWS, NCHS hosted a webinar highlighting the data uses capabilities of the survey in light of the opioid epidemic. NCHS also hopes to reach out to contacts at NDEWS sentinel sites asking them to serve as ambassadors to the survey in their states. The recruitment contractor will bring willing contacts at sentinel sites as consultants to NHCS. Each consultant will take confidentiality training and sign a non-disclosure form. Additionally, 35 state associations have published information about the NHCS in their membership newsletters. Last, outreach efforts included setting up a designated listserv for the NHCS stakeholders and data users. This email distribution list serves over 1,400 members and provides updates on NHCS data availability and newly published reports.

9. Explanation of Any Payments or Gifts to Respondents

NCHS provides a one-time $500 incentive to each sampled hospital to set up the electronic data

transmission to participate in the survey. In addition, NCHS provides each of the 598 sampled hospitals $500 after a full year of EHR, UB-04 data, or state files are received.

A continuing education module is currently being updated with new information about the survey, 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. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The NCHS Privacy Act Coordinator and the NCHS Confidentiality Officer have reviewed this package and have determined that the Privacy Act is applicable because this study includes the collection of information in identifiable form. The applicable System of Records Notice is 09-20-0167 Health Resources Utilization Statistics.

An assurance of confidentiality is provided to all respondents according to section 308 (d) of the Public Health Service Act (42 USC 242m) which states:

"We take your privacy very seriously. All information that relates to or describes identifiable characteristics of individuals, a practice, or an establishment will be used only for statistical purposes. NCHS staff, contractors, and agents will not disclose or release responses in identifiable form without the consent of the individual or establishment in accordance with section 308(d) of the Public Health Service Act (42 U.S.C. 242m(d)) and the Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA, Title 5 of Public Law 107-347). In accordance with CIPSEA, every NCHS employee, contractor, and agent has taken an oath and is subject to a jail term of up to five years, a fine of up to $250,000, or both if he or she willfully discloses ANY identifiable information about you.

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

"**Notice** - CDC estimates the average public reporting burden for this collection of information as XX minutes/hours per response, including the time for reviewing instructions, searching existing data/information sources, gathering and maintaining the data/information needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Information Collection Review Office, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN:

PRA (0920-0212).

Assurance of confidentiality - We take your privacy very seriously. All information that relates to or describes identifiable characteristics of individuals, a practice, or an establishment will be used only for statistical purposes. NCHS staff, contractors, and agents will not disclose or release responses in identifiable form without the consent of the individual or establishment in accordance with section 308(d) of the Public Health Service Act (42 U.S.C. 242m(d)) and the Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA, Title 5 of Public Law 107-347). In accordance with CIPSEA, every NCHS employee, contractor, and agent has taken an oath and is subject to a jail term of up to five years, a fine of up to $250,000, or both if he or she willfully discloses ANY identifiable information about you."

Overview of the Data Collection System

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

For eligible hospitals selected into the survey, hospital-level data will be collected from hospital staff via a secure web portal, with any needed follow up conducted by telephone or mail. Participating hospitals are asked to submit EHR, UB-04 claims or state file data for all inpatient discharges and all ambulatory visits.

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

Patient Items of Information to be Collected:

The following hospital-level data will be collected: survey eligibility criteria, service characteristics, and expected number of visits. Discharge-level and visit data collected includes data elements on the UB-04, state files, and from EHR data. These include patient demographics, diagnoses and procedures, source of payment information, charges, and information related to revenue codes. For hospitals submitting EHR data, additional variables include labs, medications, and clinician notes. A complete list of items collected can be found in Attachments D and E.

Information in Identifiable Form:

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

EHR, UB-04, and State File:

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

Annual Hospital Interview (Attachment F):

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

In 2018, hospitals may submit EHR data to the NCHS HEHR system and submit UB-04 claims and state files to the sub-contractor's secure network. Beginning in 2019, hospitals will be asked to submit all data through the HEHR system at NCHS. The purpose of the HEHR system is to provide the Division of Health Care Statistics the technical support it needs to implement the public health registry component of the NHCS and to support the receipt of data from eligible providers and hospitals in accordance with the MU Program rules. This includes, but is not limited to, planning, designing, developing, and maintaining the infrastructure necessary to operate the surveys registry portal to allow for registration of providers and hospitals that intend to participate in the survey and submit data. Upload interfaces via CDC's Secure Access Management Services (SAMS) and/or DIRECT secure messaging are included to allow for bulk upload of data through the registry portal. Uploaded data are then integrated, harmonized,

and loaded into a data warehouse. An environment for testing and validation will also be set up to allow for providers and hospitals to test the clinical data submitted. EHR data collection for 2018 began on October 15, 2018, when the Testing and Validation Environment became operational. The Production Environment is expected to become operational in January 2019.

SAMS provides a secure data transfer service along with a strong suite of security controls to host applications and exchange data between CDC programs and public health partners while providing a high level of data integrity, confidentiality, reliability, and security. This meets NCHS/CDC policies for data transmission via the Internet. Users accessing systems protected by SAMS are required to adhere to the identity verification and authentication requirements for the Electronic Authentication Assurance Level (EAAL) of the protected system. SAMS provides system monitoring on a 24 x 7 basis, data redundancy features, and disaster recovery features for select information systems. DIRECT is a national encryption standard for securely exchanging clinical healthcare messages/data via the internet. DIRECT provides strong security and privacy protection using a unified standard that all systems can leverage.

On receipt of the data within the HEHR system, all data considered PII, both direct and indirect, and non-PII will be loaded/saved to specially designated and configured file servers and database servers that are in accordance with the Confidential Information Protection Statistical Efficiency Act (CIPSEA). HEHR system servers are secured physical components that are only accessible by NCHS-designated staff.   All direct PII data containing personal identifiers (e.g., name, address, phone number, SSN, etc.) will be loaded onto separate files in separate secure sub-shares and specifically designated tables that will be encrypted. The most strict access controls will be in place for all PII data. The indirect PII data will also be loaded onto the specially designated secure sub-shares and tables. However, these will have different access controls than the direct PII data. Non-PII data (or public use files) will be downloaded onto the specially designated and configured NCHS/DHCS separate secure CDC network sub-shares. The HEHR system will communicate with Consolidated Statistical Platform (CSP) (another CIPSEA compliant system) primarily for analytic purposes.

A website dedicated to NHCS (http://www.cdc.gov/nchs/nhcs.htm) describes the survey, answers frequently asked questions, displays letters of support for the NHCS from national and regional organizations, describes how the Privacy Rule permits data collection for NHCS, and provides a link to the participant page (http://www.cdc.gov/nchs/nhcs/participant.htm).

The collection of information in identifiable form or PII 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." Staff 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 PII data are shared with researchers. Only NCHS employees and agents who need the personal

information for linking to various databases may use such data. Everyone else who uses NHCS data may do so only after all identifiable information is removed.

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

NCHS has two contractors conducting NHCS activities – one for recruitment and another for data collection and processing. Both contractors selected for NHCS were required to provide a comprehensive data security plan (DSP) to NCHS to ensure safety and confidentiality of the NHCS data. The plan follows the structure and guidelines established by the National Institute of Standards and Technology (NIST; 800-series)[1] for meeting the requirements of the Federal Information Security Management Act (FISMA).[2] The DSP complies with all relevant laws, regulations, and policies governing the security of data and the protection of confidentiality, including the Privacy Act of 1974 (5 USC 552a), Section 308(d) of the Public Health Service Act (42 USC 242m) and the Confidential Information Protection and Statistical Efficiency Act (CIPSEA, PL 107-347) of 2002. The DSP considers all known data security and confidentiality protection risks. However, our approaches and specific procedures will evolve as we identify new data security threats and implement improved practices. The DSP will be updated as needed with more detailed, process-oriented data security protocols. Information technology products and systems will comply with the FISMA regulations and supporting NIST guidelines (NIST Special Publication (SP) 800-60).

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

The NHCS data collection plan has been approved by the NCHS Ethics Review Board (ERB) (Protocol #2015-13) 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 #2015-13 for the NHCS for the maximum allowable period of one year is presented in Attachment G.

In the recruitment introductory letter from the NCHS Director, it states that participation in the NHCS is voluntary. There is no negative effect on the respondent for not participating. The collected information that would allow identification of individual hospitals or patients is not shared with anyone, although public-use data files are available on the NHCS website once

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[1] See http://csrc.nist.gov/sec-cert/ca-compliance.html.
[2] See http://csrc.nist.gov/policies/FISMA-final.pdf.

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).

The NHCS collects PII. These PII elements have been cleared in a prior approval of this package (OMB # 0920-0212, Exp. Date 01/31/2019)) and also in the Ambulatory Care Pretest: National Hospital Care Survey (OMB #0920-0944, Discontinued 06/30/2013)). One example of the value of PII is that it allows linkage to the NDI and other data sources, providing better information on outcomes of hospitalization. Collection of PII also allows for linkages between inpatient discharges and ED and OPD visits. The list of requested items considered to be sensitive includes the following eleven data elements on patients and one data element for physicians:

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

Physician:
12.   NPI (National Provider Identifier) number

Patient name and social security number are currently collected as PII included in the NHCS. In order to accurately link sampled patients to the NCHS 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 NDI, see the web link, NCHS -National Death Index Home Page at http://www.cdc.gov/nchs/ndi.htm .

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 considerably 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 reasonable proxies for individual-level SES (Krieger, N., et al., 2002)[3].

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

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

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

Patient control number is a required element on the UB-04 (not in an EHR) and is assigned to patients for billing purposes. Along with the medical records number, the patient control number can be used to 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. 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.

The NPI is a unique identifier for healthcare providers. It is a required data element on the UB-

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

04 and is often available through an EHR. This data element allows for linkage of physician specialty information to the individual patient's care.

Information linking provider identifiers to their characteristics (e.g., specialty, provider age) is also available from CMS for research purposes (https://nppes.cms.hhs.gov/NPPES/).

12. Estimates of Annualized Burden Hours and Costs

A. Burden Hours

Data on burden are shown in Table 1. The total sample size for the 2019-2021 survey will consist of approximately 598 hospitals. Hospital interviews will be conducted by contractor staff.

The first part of recruitment includes a one-time Initial Hospital Intake Questionnaire (Attachment H) that is administered over the telephone or by paper to verify the hospital's eligibility. This intake questionnaire is conducted on all new hospitals and takes 1 hour to complete. Since at least 147 hospitals have already been recruited under the previous clearance, at most 451 hospitals remain for a total of 150 annualized burden hours (451 respondents/3 years) over the course of three years (Attachment H). No changes have been made to this instrument since the last approval was granted.

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 150 annualized hours (451 respondents/3 years) over the course of the three year clearance. As needed, the presentation (Attachment I) will be used to complement the telephone recruitment. The presentation takes 1 hour to complete.

Hospitals will be asked to transmit UB-04 data or a state file on a monthly basis or EHR data on a quarterly basis for all records and claims, both inpatient and ambulatory. It is estimated that this will take one hour per hospital per quarterly submission to prepare and transmit the data file. We estimate about 199 hospitals would submit EHR data, and the remaining hospitals that are not yet ready to send EHR data would transmit their UB-04 claims or a state file. This represents 4,788 annualized hours for hospitals submitting UB-04 claims or a state file and 796 annualized hours for hospitals sending EHR data (Attachments J and L).

Each participating hospital of the 598 will be asked to complete an Annual Hospital Interview (Attachment F) that will be conducted via a web portal. This 2-hour interview collects annual statistics needed for weighting both the inpatient and ambulatory data which include hospital characteristics such as total numbers of admissions, total visits, discharges, and live births; therefore, non-respondents will also be asked to provide this information. The total burden is 1,196 hours.

Please note that the Annual Ambulatory Hospital Interview, with a former annualized burden of 578 hours, has been removed from the burden table since the last revision.

The new total annualized burden is 7,080 hours.

Table 1. Estimated Annualized Burden Hours

Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Avg. Burden per Response (in hours)	Total Burden Hours
Hospital DHIM or DHIT	Initial Hospital Intake Questionnaire	150	1	1	150
Hospital CEO/CFO	Recruitment Survey Presentation	150	1	1	150
Hospital DHIM or DHIT	Prepare and transmit UB-04 or State File for Inpatient and Ambulatory (monthly)	399	12	1	4,788
Hospital DHIM or DHIT	Prepare and transmit EHR for Inpatient and Ambulatory (quarterly)	199	4	1	796
Hospital CEO/CFO	Annual Hospital Interview	598	1	2	1,196
TOTAL					7,080

B. Burden Costs

The average response burden cost for the NHCS is estimated to be **$327,304.20**. The hourly wage estimates for the Director of Health Information Management and the Hospital CEO/CFO were based on the AHIMA salary studies[4].

Table 2. Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total burden hours	Hourly Wage Rate	Total Respondent Costs*
Hospital Director of health information management	Initial Hospital Intake Questionnaire	150	$42.18	$6,327.00

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[4] http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_050798.pdf

Hospital CEO/CFO	Recruitment Survey Presentation	150	$63.48	$9,522.00
Hospital Director of health information management	Prepare and transmit UB-04 or State File for Inpatient and Ambulatory	4,788	$42.18	$201,957.84
Hospital Director of health information management	Prepare and transmit EHR for Inpatient and Ambulatory	796	$42.18	$33,575.28
Hospital CEO/CFO	Annual Hospital Interview	1,196	$63.48	$75,922.08
Total		7,080		**$327,304.20**

*Hospitals will be compensated for their participation as described in Section 9 and this table does not include those costs.

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 $7.5 million. NCHS has begun developing an infrastructure at CDC to collect, process and store data collected from the NHCS. The initial solution proposed by the data collection contractor involved placing the NHCS data in a cloud. Due to CIPSEA concerns, NCHS decided against pursuing a cloud based solution for the short term, and instead procured servers for the processing and storage of the data. The increased costs to the government are for the building of the HEHR System at NCHS.

Average Annual Costs for the NHCS Annualized Over Three Years

NHCS 2019-2021	
Data collection contract	$6,000.000
NHCS Project Staff salaries	$1,500,000
Total	**$7,500,000**

15. Explanation for Program Changes or Adjustments

The currently approved burden is 8,232 hours; the proposed burden for the NHCS is 7,080 hours per data collection year. There were 1,582 hours subtracted as a result of the removal of the Annual Ambulatory Hospital Interview (578 hours); reduction of the number of hospitals receiving the Intake Questionnaire (10 hours) or Recruitment Survey Presentation (10 hours); and a decrease in the number of hospitals transmitting UB-04 claims (984 hours), as more hospitals are anticipated to submit EHR for this clearance. There were 430 hours added as a result of more hospitals in the sample submitting EHR data (396 hours) and the slight increase in sample size requiring more hospitals to complete the Annual Hospital Interview (34 hours). This results in a net decrease of 1,152 burden hours.

With regard to the item that was eliminated from the burden table (Annual Ambulatory Hospital Interview), this was removed because abstraction of a sample of ambulatory records is now removed from the design of the survey. Abstraction was eliminated to save costs and decrease burden on hospitals participating in NHCS.

16. Plans for Tabulation and Publications and Project Time Schedule

Data from the NHDS and NHAMCS have been published annually as NCHS *Vital and Health Statistics Series 13* reports, *National Health Statistics Reports*, NCHS *Data Briefs*, web tables, articles in professional journals, and other special reports. Special reports on utilization trends, specific diagnoses, selected patient and hospital characteristics, source of payment, prescribing trends, and methodology are also published in *Series 2, 5, or 13* of the NCHS *Vital and Health Statistics*, *National Health Statistics* Reports (NHSR), or journal articles. It is anticipated that NHCS data will be published in the same or similar publications as NHDS and NHAMCS data. Data from the NHCS will be presented separately for inpatient discharges, visits to EDs and OPDs, and also 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 2013-2015 data files with restricted access information have been made available at the NCHS Research Data Center (RDC). Additionally, the 2014 NHCS and NDI linked file is also now available in the NCHS RDC allowing researchers to study post-discharge mortality and cause of death.

Annual public use files containing information collected on inpatient discharges and ED and OPD visits will continue under the NHCS. To facilitate trend analysis, multi-year public use files (one for newborns and one for non-newborns) provide multiple years of inpatient data in a standard format with standard definitions across survey years. CD-ROMs for 1970-78 and 1979-2007 in ASCII format are currently available to the public, and 2008-2010 data are available for downloading from the NHDS website. Data on visits to ED for 1992 -2015 and to

OPDs for 1992-2011 are also currently available for downloading from the NHAMCS website. These will continue to be available, as NHCS has been structured to allow consistent trends continuing from the prior versions of NHDS and NHAMCS.

In July 2016, the first demonstration paper using 2013 NHCS data, "National Hospital Care Survey Demonstration Projects: Traumatic Brain Injury," was published highlighting the survey's ability to measure hospital care use for rare but serious conditions such as traumatic brain injury. Two additional demonstration papers were published including: "*National Hospital Care Survey Demonstration Projects: Pneumonia Inpatient Hospitalizations and Emergency Department Visits*" and "*Identification of Substance-involved Emergency Department Visits Using Data from the National Hospital Care Survey*." More demonstration publications are forthcoming on topics including Alzheimer's and stroke. These papers illustrate how NHCS can track patients through settings in the hospital and also how these data can be linked to the NDI to measure post-discharge mortality outcomes.

Survey staff have also presented data on suicides and mortality using 2014 NHCS data at CDC's 6th Biennial Mental Health Surveillance Meeting; 2014 OPD data results at the 2017 Joint Statistical Meetings; and child and adult abuse-related hospital visits to the ED in 2014 at the CDC's Annual Integrative Research and Program Showcase. The theme for 2017 was intimate partner violence and sexual violence as a public health condition.

In the future, staff may also present data at meetings and conferences of professional organizations, such as the, Academy Health, Joint Statistical Meetings, National Association of Health Data Organizations, National Rural Health Association, American College of Emergency Physicians, Society for Academic Emergency Medicine, and Gerontological Society of America. These presentations deal with specific aspects of the survey or special analyses of survey data.

Conferences attended either to promote or conduct outreach for the NHCS since the last clearance include: Health Information Management Systems Society, American Hospital Association Leadership Summit, Health Datapalooza, World Health Care Congress, National Rural Health Association Annual Conference, and the American Health Information Management Association Annual Conference.

This clearance request covers three years, 2019-2021, 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 2019 and beyond.

Hospital recruitment ....…………………………………………………………..Ongoing
Continue transmission of monthly UB-04 data or state file.........immediately after OMB approval
Transmission 2019 EHR data:
- 1st Quarter.………..…………..……….…………..................................3 months after OMB approval
- 2nd Quarter.………..…………..……….…………..…………….……...6 months after OMB approval
- 3rd Quarter.………..…………..……….…………..…………….……...9 months after OMB approval
- 4th Quarter.………..…………..……….…………..................………...12 months after OMB approval

End of electronic data collection..12 months after OMB approval
First tabulations from the 2019 electronic data.............................20 months after OMB approval
Public use file (if sufficient data collected to make
national estimates)...20 months after OMB approval

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.