Supporting Statement A for Request for Clearance:

Ambulatory Care Pretest: National Hospital Care Survey

OMB No. 0920-NEW

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SUPPORTING STATEMENT
THE NATIONAL HOSPITAL CARE SURVEY

The National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC) requests approval to conduct a pretest for new data collection activities in the National Hospital Care Survey (NHCS) (OMB No. 0920-0212, expires 4/30/2014). Currently the NHCS collects inpatient data from non-Federal noninstitutional hospitals with six or more beds staffed for inpatient use. Hospital ambulatory data and data from freestanding ambulatory surgery centers are currently collected through the National Hospital Ambulatory Medical Care Survey (NHAMCS) (OMB No. 0920-0278, expires 12/31/2014). NCHS intends to integrate NHAMCS into NHCS in order to increase the wealth of data on health care utilization across episodes of care and to allow for linkages to other data sources such as the National Death Index and data from the Centers for Medicare and Medicaid Services (CMS). NHCS will also collect emergency department (ED) data previously collected through the Substance Abuse and Mental Health Services Administration's (SAMHSA) Drug-Abuse Warning Network (DAWN) (OMB No. 0930-0078, expired 12/31/2011).

The proposed new pretest will test the feasibility of integrating ambulatory data collection for hospitals and freestanding ambulatory surgery centers (FSASCs) into the NHCS, as well as the collection of new data elements related to drug- and mental illness-related ED visits and colorectal cancer screening at ambulatory surgery visits. If successful, NHAMCS and DAWN will be merged with NHCS in the 2013 data collection. The NHCS OMB approval will be revised to include the new 2013 activities.

This new data collection requests a one-year approval to pretest the following:

- integration of NHAMCS into NHCS, including new sampling methods;
- new data collection methods which will reduce the burden on facility staff and allow for an increase in the number of medical records for which data are abstracted;
- integration of DAWN into NHCS and questions related to drug-related ED visits;
- collection of data on mental illness-related ED visits;
- collection of data on the provision of colonoscopy to both symptomatic and asymptomatic patients seen in both hospital-based and FSASC ambulatory surgery locations, in conjunction with the National Institutes of Health's National Cancer Institute (NCI) and CDC's National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) and;
- willingness of facilities to participate in the 2013 NHCS.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Background

The National Center for Health Statistics' (NCHS) surveys on hospital care include the National Hospital Discharge Survey (NHDS) and the National Hospital Ambulatory Medical Care Survey (NHAMCS). From 1965-2010, NHDS 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 departments (EDs), outpatient departments (OPDs), and ambulatory surgery locations (ASLs, since 2009) and freestanding ambulatory surgery centers (FSASCs, since 2010). The Drug Abuse Warning Network (DAWN) was conducted from 1972-2011 to monitor drug-related hospital ED visits and medical examiners' cases. The Substance Abuse and Mental Health Services Administration (SAMHSA) ceased DAWN survey operations in 2011 and requested that NCHS incorporate DAWN into the ED component of NHCS. Data from all of the previously mentioned surveys have been used extensively for monitoring changes in ambulatory care and describing the structure and organization of services and their utilization.

In May 2011, NCHS began recruiting a new sample of hospitals in the newly named National Hospital Care Survey (NHCS) which is authorized under Section 306(b) of the Public Health Service Act (42 USC 242k) (Attachment A). During the first two years (2011-2012) of the survey, hospitals are asked to provide data on all inpatients from their UB-04 billing data (i.e., claims used to bill for hospital services which contain ICD-9-CM and procedure codes), as well as, facility-level data through a questionnaire. Then in 2013, if this pretest is successful, the sampled hospitals will be asked to provide data on the utilization of health care provided in their ED, OPD, and ASLs, thus integrating NHAMCS into NHCS. Data collection from FSASCs will also begin in 2013. NHCS will continue to provide the national health care statistics that NHAMCS currently supplies. In the past, DAWN has reported ED visits involving hundreds of specific drugs; however, the NHCS will only be able to provide ED visit estimates for key drugs, e.g., cocaine, heroin, marijuana.

The proposed pretest aims to test the feasibility of different approaches to integrate NHAMCS data collection from hospitals and FSASCs into NHCS, as well as integrating DAWN into the ED component. The impetus for this integration includes the following:

- a move toward electronic collection of health care data;
- the ability to link episodes of care across hospital units as well as link to other data sources such as the National Death Index (NDI) and Medicare data and;
- the discontinuation of DAWN, as a stand-alone surveillance system.

Pretest Plans

Integration of NHAMCS into NHCS

The integration of the NHAMCS into NHCS is a critical part of the pretest. If all works well, we will be able to collect inpatient and outpatient data from the same hospitals with the future ability to monitor and follow specific patients.

The pretest will test collection of ambulatory care data from a convenience sample of 32 hospitals already enrolled in NHCS and 15 FSASCs currently participating in NHAMCS. Introductory letters from NCHS (Attachments D and E) along with endorsement letters from professional associations will be followed by a telephone call from the contractor's field manager to verify facility eligibility for the survey and to arrange for an appointment with the chief executive officer and/or whoever is designated as the coordinator for this survey, as well as the directors of the ED, OPD, and ASLs and/or FSASCs. At these selected facilities, the pretest will obtain data on facility characteristics at the hospital/FSASC and department level on items such as ownership, electronic health record (EHR) adoption, and visit volume. Facilities will then be asked to provide data to assist with sampling visits as well as data on patient visits to the ED, OPD, and ASLs.

Visit Sampling and Data Collection
Hospitals

Hospitals will be divided into four main categories to test various visit sampling and data collection methods. More than one approach needs to be tested because not all hospitals have electronic health records systems. It is not expected that one optimal approach will emerge from the pretest due to differences in hospitals' capabilities in providing ambulatory data. In one of the approaches (described in the second bullet), two sampling frames will be compared, i.e., UB-04 billing data vs. sign-in sheets/patient logs, and their ability to capture sample visits will be evaluated. Another purpose of the comparison is to see which cases are missing, e.g., left without being seen (ED) and charity. We will also be testing the feasibility of oversampling drug cases using UB-04 claims data. Respondent burden and the ability of the UB-04 data to provide an adequate sampling frame of visits are the evaluation criteria. Attachment F shows how hospitals will be separated into each category.

- 5 remote-reporting hospitals with EHRs. With hospital approval, the contractor's field managers will access the records from their headquarters and then will review all ED records during a 3-month reporting period and select all drug-related visits. Contractor staff will select a systematic random sample of all records during the same period and all selected visits will be abstracted by field managers onto a laptop PC-based data collection tool.
- 15 non-remote-reporting hospitals. These hospitals will use a UB-04-based visit sampling list that will allow contractor staff to 1) sample/oversample drug-related ED visits during a 2-month reporting period; and 2) select a systematic random sample of all records during the same period. Hospitals will provide either paper records or EHRs for field mangers to abstract onto a laptop PC-based data collection tool.
- 10 non-remote reporting hospitals. These hospitals will use sign-in-sheet-based sampling, i.e., the traditional method used in NHAMCS for selecting the sample of visits. Contractor

staff will select a systematic random sample of all records during a 1-month reporting period. Hospitals will provide either paper records or EHRs for field mangers to abstract onto a laptop PC-based data collection tool.

- 2 EHR extraction hospitals. These hospitals will be asked to extract the required demographic and clinical variables required to complete the Patient Record forms from all EHRs and then will transmit these files to the contractor via a secure data network for all visits that occurred during a 3-month reporting period.

Freestanding Ambulatory Care Surgery Centers

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

Additional information on sampling may be found in Supporting Statement B1.

This portion of the pretest was designed to answer the following survey operations questions:

- What proportion of hospitals/FSASCs have the capability to provide UB-04 billing data for all ED, OPD, and ambulatory surgery visits during the reporting period? For hospitals/FSASCs with this capability, what proportion are willing to provide the contractor with UB-04 billing data?
- What proportion of hospitals/FSASCs have the capability to provide daily sign-in sheets/patient logs of all ED, OPD, and ambulatory surgery visits during the reporting period? For hospitals/FSASCs with this capability, what proportion are willing to provide the contractor with their sign-in sheets?
- What proportion of hospitals have the capability to have EHRs remotely accessed? For those hospitals with this capability, what proportion are willing to allow the contractor to remotely access their EHRs?
- Can the ambulatory setting (ED, OPD, ASL, FSASC) be identified from the UB-04 billing data? If yes, can ineligible clinics and visits also be identified?
- How closely do the two frames (UB-04 billing data vs. sign-in sheets/patient logs) compare? This can be examined by ambulatory unit (including all 30 EDs) and by day, week, month and over the reporting period. Facilities that can't give us the sign-in sheets/patient logs for the entire reporting period will be asked to provide what they can.
- Are the 2 EHR extraction hospitals willing and able to identify and extract the required Patient Record form variables and transmit files to the contractor? If yes, can NCHS use these data to complete the most important items on the Patient Record form?
- What proportion of facilities are willing to participate in the 2013 NHCS?

The contractor is working with UB-04 experts to identify criteria to classify records as ED, OPD, or ASL. The correct classification will be confirmed when the abstractor has completed the abstraction. The proportion of hospitals with EHR and remote reporting capabilities will be

ascertained through the hospital interview process and debriefing of abstractors. From the pretest, we will know proportion of hospitals that can provide UB-04 data and sign-sheets.

From the pretest, we'd like to learn if UB-04 billing data can be used for sampling. First, we'd like to know if the UB-04 revenue codes can distinguish visits by setting (i.e., ED vs. OPD vs. ambulatory surgery location), then if they can identify in-scope OPD clinics, and then if they can identify in-scope visits. If the results of the pretest show that this is feasible, then it will obviate the need for sign-in sheets to perform visit sampling. With regard to data collection methods, we'd like to see how the EHR extraction method works in terms of the ease with which hospitals can transmit the files and how much of the information needed to complete the Patient Record forms is contained on the files. This method is preferred over all others as it does not involve abstraction. We know from DAWN, that some hospitals have the capability and are willing to allow a government contractor remote access to their electronic health record system to collect data on ED visits. From the pretest, we will learn if this is feasible for OPD and ASL data collection. In addition, we will learn what proportion of hospitals now participating in the inpatient component will refuse the ambulatory component. Based on the results of the pretest, sampling procedures and data collection methods may need to be modified before fielding the full survey in 2013. Depending on the pretest results, the need for further testing will be considered.

Integration of Drug-Abuse Warning Network into NHCS

SAMHSA is collaborating with NCHS to collect data on drug-related ED visits, since NCHS has the established infrastructure for data collection from hospital EDs. SAMHSA's partnership with CDC/NCHS is expected to both increase efficiency and expand the scope of ED data available to help inform public policy and prevention and treatment initiatives.
Integrating DAWN into NHCS will increase the value of the data to SAMHSA as the data abstracted for each drug-related visit will also include NHAMCS items, not formerly collected by DAWN (e.g. diagnostic services, procedures, and medications prescribed). The same data collection methods will be tested for the integration of DAWN into NHCS as was previously mentioned regarding the integration of NHAMCS into NHCS.

The proposed integration of DAWN into NHCS will likely eliminate annual, reliable reporting of those drugs that present extremely infrequently in the ED, e.g., synthetic cannaboids. The pre-test will help determine the types of drugs which cannot be examined.

The decision to integrate the DAWN into the NCHS was made by senior SAMHSA officials with approval of senior Office of National Drug Control Policy officials. In reaching the decision, the benefits of obtaining increased information were found to be greater than the costs of loss of rare drug information.

Visit Sampling and Data Collection

If we were to use the historic NHAMCS sampling methodology for collecting ED visit data, i.e., 4-week reporting period and abstracting records for 100 visits, then only 2 of 100 sample visits would be drug-related. That sampling plan would produce insufficient drug-related cases to meet SAMHSA's standards (15% Relative Standard Error (RSE)) for national estimates. Therefore, some new methods for increasing the number of drug-related ED visits are required. The following approaches will be tested during the pretest:

- extension of the reporting period from 1 month to 2 months and 3 months;
- collection of UB-04 billing data from non-remote reporting hospitals and use of ICD-9-CM diagnosis codes to identify drug-related cases; and
- review of all ED visits in remote reporting hospitals with the abstraction of all likely drug-related cases and comparing this to the collection of UB-04 billing data to identify drug-related cases. Drug-related items that were previously on the DAWN data collection form will be incorporated into the NHCS ED computerized instrument and tested during the pretest.

- The drug-related data items will be collected by abstractors who previously worked on DAWN and the pretest data will be analyzed by SAMHSA staff. Data quality checking procedures will be used to evaluate the accuracy and reliability of the data.
- The purpose of the pretest is to test methods and procedures, not to compare benchmarks.

Additional information on sampling may be found in Supporting Statement B1.
This portion of the pretest was designed to answer the following sampling and/or operational questions:

- What proportion of drug-related ED cases which can be identified from ICD-9-CM code screening of UB-04 billing data are actually drug related?
- What proportion of drug-related cases can be identified by remote chart review, but missed by ICD-9-CM code screening of UB-04 billing data?
- What proportion of drug-related cases can be identified by both chart review and ICD-9-CM code screening of UB-04 billing data?
- Do the new drug- and mental illness-related visit items need to be modified or deleted? New (#6) and modified items (#1b, 1h, 1i, 4, 5a, 5b, 9, 11, and 12) on the ED PRF are highlighted in Attachment J.

After the pretest is completed, NCHS will compare the various methods to identify drug-related ED visits to answer the questions above. In addition, this comparison will allow us to determine how well ICD-9-CM codes, which were developed from abstractor coding of 1,000 randomly selected existing drug-related DAWN cases, identify drug-related cases and modify the list, if necessary. The assessment will examine ICD-9-CM code-identified cases for drugs listed in the medical record. The visit data will be analyzed by NCHS to determine if the new ED PRF items need to be modified or deleted.

Data collection on mental illness-related ED visits

SAMHSA is interested in data on mental illness-related ED visits, including psychiatric and medical co-morbidities. Since the ED serves as an entrance to subsequent treatment for mental disorders, SAMHSA would also like to learn more about psychiatric referrals, hospital admissions, and transfers. The NHCS will allow for the analysis of the episode of a care of mental illness-related ED visits that resulted in admission to the sample hospital. ED data from the pretest, will be evaluated to determine if the sample sizes are adequate for some of the new items related to mental illness that were added to the Patient Record form. The proposed 2013 NHCS will produce reliable estimates of mental illness-related ED visits, which have not been reported on before. Such analyses will advance health services research and inform policy, especially as it relates to the Mental Health Parity and Addiction Equity Act which took effect in 2009.

Data collection on colorectal cancer screening at ambulatory surgery visits

The pretest will assess the feasibility of obtaining information on colorectal cancer screening during ambulatory surgery visits where a colonoscopy is performed. In the Spring of 2012, a small pilot test was conducted in 9 facilities to collect data on the performance of colonoscopy. The pilot sites were a mix of hospital-based and freestanding as well as single- and multi-specialty. The pilot questions were drafted based on consultations with experts in colorectal cancer screening and federal partners, and was approved by OMB (OMB No. 0920-0278, expires 12/31/2014). Visits where a colonoscopy procedure was performed were identified and data were collected in 7 categories, including the reason for the procedure, the patient's colonoscopy history, the depth of insertion of the current procedure, the patient's American Society of Anesthesiologists (ASA) score, bowel preparation, polyps and follow-up recommendations. The data were available in the medical record except for the measured depth of insertion and the patient's ASA score. Fifty-one percent of procedures in the pilot sites were performed for screening, and in 53% of procedures, no polyps were found. In cases where polyps were seen, the majority were completely removed and had benign pathology.

Based on the results of the pilot test, 5 questions will be used in the pretest (Attachment N). These questions will be added to the Ambulatory Surgery Patient Record form (Attachment L) and will be completed for patients who had a colonoscopy performed at the sampled visit. Because only a few questions related to specific visits will be added, it is not anticipated that the burden of the Ambulatory Surgery Patient Record form will change for the pretest.

This portion of the pretest was designed to test the colonoscopy questions in a larger number of facilities than in the pilot test (N=9) and to answer the following survey operations questions:

- What proportion of hospital-based ASLs and FSASCs are willing to provide data for the colonoscopy module as part of the 2013 NHCS?
- Do any of the Ambulatory Surgery PRF items related to colonoscopy need to be modified or deleted?

The visit data from the pretest will be analyzed by NCHS and presented to our federal partners.

The intent of this module in the national survey is to answer the following types of public

health/health care policy questions:

- How many colonoscopies are performed at hospital-based ASLs/FSASCs annually among asymptomatic persons for screening purposes?
- What is the annual number of screening colonoscopies performed at hospital-based ASLs/FSASCs per 1,000 population (annual colorectal screening rate)?
- How do annual colorectal screening rates vary according to patient characteristics, such as age, sex, and race?
- How does performance of colonoscopy vary by setting and payer? For example, are a higher percentage of Medicaid visits screened in hospital-based ASLs compared with FSASCs?
- To what extent are providers complying with colonoscopy reporting guidelines?
- Are complication rates measurable or so uncommon as to be inestimable even with a sample size including thousands of procedures?
- How often do screening colonoscopies require follow-up?
- How often are colonoscopies "incomplete" and what are the reasons for incomplete procedures? Do completion rates vary by setting??

The results of the pretest will inform our federal partners as to the feasibility of fielding a module.

Privacy Impact Assessment

Overview of the Data Collection System

The target universe for the pretest is in-person visits made to EDs, OPDs, and ASLs of non-Federal, noninstitutional hospitals with six or more staffed beds and to FSASCs. For facilities selected into the pretest, facility-level data will be collected via telephone and personal interviews with facility staff. In the pretest, additional data will be abstracted from ED, OPD, and ASL visits to hospitals and FSASCs. These data will be abstracted by the contractor's field managers and entered into computerized survey instruments or transferred to the data collection agent through the CDC secure data network.

Items of Information to be Collected

The NHCS ambulatory pretest will collect data on facility-level characteristics as well as data on patient visits, including patient demographic information and visit information.

Facility-level data to be collected include:

- Eligibility criteria (ownership, licensing, ambulatory unit specialty)
- Expected number of visits
- Use of electronic medical records

Patient visit data to be collected include:

- ZIP Code
- Demographic information (age, gender, race, ethnicity, etc.)

- Source(s) of payment
- Reason for visit
- Diagnosis
- Diagnostic services
- Procedures
- Medications
- Substances that led to the ED visit
- Providers
- Disposition

The NHCS ambulatory pretest will also collect protected health information (PHI), also referred to as Information in Identifiable Form (IIF). These data items have already been approved by OMB for the NHCS (OMB No. 0920-0212, expires 4/30/2014). One example of the value of PHI is that it will allow linkage to the NDI, providing better information on outcomes of hospitalization. In its approval of NHCS, 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:

IIF Categories:

- Facility name
- Facility address
- Facility telephone number
- Medicare health insurance/claim number (if applicable)
- Contact name
- Patient name
- Patient address
- Patient Control number
- Medical record number
- Date of birth
- Social security number (if available)
- National Provider Identifier number (Attending and Operating)

No potentially identifiable data will be released in any form to the public. Data collected in this pretest will not be published. Any data transmitted by a facility to the contractor will be transferred through a secure data transfer system.

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

A website dedicated to the National Hospital Care Survey (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 (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

The proposed new pretest will test the feasibility of integrating ambulatory data collection for hospitals and freestanding ambulatory surgery centers (FSASCs) into the NHCS, as well as the collection of new data elements related to drug- and mental illness-related data at ED visits and colorectal cancer screening at ambulatory surgery visits. If successful, NHAMCS and DAWN will be merged with NHCS in the 2013 data collection. The NHCS OMB approval will be revised to include the new 2013 activities.

Privacy Impact Assessment Information

The impetus for the full integration of the surveys includes the following:

- a move toward electronic collection of health-care data;
- the ability to link episodes of care across hospital units as well as link to other data sources such as the National Death Index and Medicare data; and
- the discontinuation of DAWN followed by the collection of similar data in the NHCS.

This specific request is to test the collection of all of these various segments within the NHCS. IIF information is being collected to estimate the proportion of facilities that would be willing to provide these data in the full NHCS.

The IIF data collected in the pretest may be used to test linkage to the NDI. These data are included on the forms being tested.

The collection of information in identifiable form requires strong measures to ensure that private information is not disclosed. Data will be held confidential according to Section 308(d) of the Public Health Services Act (42, U.S. Code, 242m(d)) and the Confidential Information Protection and Statistical Efficiency Act (Title 5 of PL 107-347). All NCHS employees as well as contract staff receive appropriate training and sign a "Nondisclosure Statement." Staffs of collaborating agencies are also required to sign this statement. The transmission and storage of data are protected through procedures such as encryption and carefully restricted access. See A10 for more details.

3. Use of Improved Information Technology and Burden Reduction

In the pretest, hospitals will either submit data electronically or through medical record abstraction on-site or remotely. FSASCs will only participate in non-remote reporting. For the 25 hospitals and 15 FSASCs that are asked to provide UB-04 billing data or sign-in sheets, field managers will abstract medical record data. Burden to staff would be incurred at facilities with paper medical records that need to be pulled and re-filed. The field manager would abstract the data onto a computerized data collection instrument. For the five remote-reporting hospitals, burden on hospital personnel will be minimal. These hospitals will grant field managers remote access to their EHR system, and field manager would access the networks from contractor's offices.

Using a computer-assisted interviewing instrument for the induction interview will allow field managers to skip unneeded questions and quickly populate write-in fields with drop-down menus. Use of a computerized data entry system for Patient Record form data simplifies data collection activities by reducing data entry errors and omissions, as well as providing on-screen look-up tables for items such as reason for visit, diagnosis, cause of injury, and medications. Overall, using a computerized data entry system should reduce field manager and respondent burden, and ultimately improve overall data quality. In addition, collecting the data electronically will speed editing, transmission, and processing, thereby making the release of statistics more timely.

4. Efforts to Identify Duplication and Use of Similar Information

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

The current submission seeks to conduct a one-time pretest to assess the feasibility of integrating NHAMCS and DAWN into the NHCS. The pretest will look at various methods of sampling and data collection which were not previously tested in any of the surveys.

5. Impact on Small Businesses or Other Small Entities

In the pretest, some respondents may be small hospitals or FSASCs. In order to reduce respondent burden for all respondents, several data collection methodologies will be used. These methods are designed to be flexible to meet the varied reporting and record-keeping situations found in EDs, OPDs, and ambulatory surgery. Patient visit sampling is used in each of these settings to minimize data collection workload. In addition, field managers will perform data abstraction from medical records, not facility staff, decreasing burden even more. Finally, for five of the hospitals, medical record data will be accessed from EHRs remotely which will greatly reduce the burden to the staff.

6. Consequences of Collecting the Information Less Frequently

This pretest is a one-time data collection.

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

There is one special circumstance that applies to collection of NHCS pretest data. This pretest will collect the OMB race and ethnicity codes in as much detail as possible. Race and ethnicity will be collected in the OMB format to the extent that it is possible given that data are being abstracted from medical records.

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

The 60-day public comment notice was published in the *Federal Register*, Volume 76, Number 211, Pages 67457 - 67458, on November 1, 2011. A copy of the notice is included as Attachment B. No comments were received.

9. Explanation of Any Payments or Gifts to Respondents

NCHS plans to pay $500 to each hospital and FSASC that participates in the pretest. All facilities will be compensated at the same rate. Payment is intended to recruit facilities that otherwise would be unwilling to take on the added burden of transmitting outpatient UB-04 billing data, as well as for medical records' staff time to pull and re-file paper charts. As the demands on medical records personnel increase due to administrative and legislative requirements, participation in voluntary surveys often depends on staff working overtime. The inpatient component of the NHCS received OMB approval to pay hospitals for participation.

The contractor will have primary responsibility for ensuring that reimbursement payments are distributed to participating facilities after completion of data collection. The facility's primary contact will work with contractor staff to determine which facility personnel or department will receive the payment.

10. Assurance of Confidentiality Provided to Respondents

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

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

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

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

<u>Privacy Impact Assessment Information</u>

A. This submission was reviewed by the NCHS Privacy Act Coordinator, who determined that the Privacy Act does apply. The applicable System of Records Notice is 09-20-0167. The NCHS Confidentiality Officer also reviewed this package for confidentiality issues. The “Assurance of confidentiality” statement will be on the first screen of each pretest instrument:

> “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 was approved by NCHS Ethics Review Board (ERB) (Protocol #2009-21) based on 45 CFR 46. In addition, the Board 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 C.

For the pretest, survey data will be used for methodologic research; however, no NHAMCS public use file will be available.

The contractor's Data Security Plan (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)[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.

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 providers (Attachment C).

D. The pretest introductory letters (Attachments D and E) state that participation in the survey is voluntary. There is no effect on the respondent for not participating. The information is not shared with anyone and pretest data will not be analyzed to create estimates. 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 pretest, we will be collecting confidential information (defined as "private medical information" by the HIPAA Privacy Rule). In their approval of the NHCS, 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 that will be used in the pretest includes the following:

1. Patient name

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

2. Patient address, including ZIP code
3. Dates (e.g., birth, visits, procedures, admissions, etc.)
4. Social security number (when available)
5. Medical record number/Patient control number
6. Medicare health insurance benefit/claim number (if applicable)
7. National Provider Identifier number (Attending and Operating)

In order to accurately link sampled patients to the NDI, first and last names of the patient will be necessary in addition to address, birth date, sex, and state so this pretest will collect these items also. States vary on whether or not they require the social security number on the UB-04 claims form. 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. We are likely to need all variables listed above to 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.

Medical record number is currently being collected by NHAMCS, but is not retained. 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.

Medicare health insurance/claim number is another piece of protected health information proposed for inclusion in the new survey. The Centers for Medicare and 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.

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.

NCHS is experienced in working with facilities to explain HIPAA requirements and helping them overcome concerns they might have. NCHS understands that facilities 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 facilities are authorized under HIPAA to release medical record data. Facility staff will also be given a copy of our NCHS ERB approval letter.

National Provider Identifier (NPI) number is a unique identifier for healthcare providers. It is a required data element on the UB-04 form and will be part of the automated data collection. This data element will allow for linkage of physician specialty information to the individual patient's care. Information linking provider identifiers to their characteristics (e.g., specialty, provider's 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

Each of the 32 hospitals in the pretest will be asked to complete a Hospital Induction Interview (Attachment G). A complete induction will take 1.5 hours. This results in an overall response burden of 48 hours. Each of the 15 FSASCs in the pretest will be asked to complete an FSASC Induction Interview (Attachment H) which will take 30 minutes. This results in an overall response burden of approximately 8 hours.

The field manager will then approach the ED, OPD, and any ASLs and/or FSASCs and will induct ambulatory units from each. Each ambulatory unit will take 15 minutes to complete an induction interview (Attachment I). It is anticipated that 140 ambulatory units will be inducted, for a total annual burden of approximately 35 hours.

Hospital Information Technology (IT) staff will be asked to prepare and transmit the UB-04 outpatient billing data files for 30 hospitals and 15 FSASCs. For 2 hospitals, IT staff will be asked to prepare and transmit EHR files for visits to all 3 settings. The burden to the facility will be 1 hour per file submission for a total burden of 47 hours.

For the 25 hospitals and the 15 FSASCs that are not reporting remotely, staff will have to pull and re-file medical records at a burden of 1 minute per Patient Record form. At the 15 hospitals that will sample visits using UB-04 billing data, 200 ED, 200 OPD, and 100 ASL sample visits will be targeted in each department. The total number of records staff are expected to pull in these 15 hospitals is 9,000 (4,500 ED, 3,000 OPD, and 1,500 ASL). At the 10 hospitals sampling visits from Sign-In sheets, 100 ED, 200 OPD, and 100 ASL sample visits will be targeted in each department. The total number of records staff are expected to pull in these 10 hospitals is 4,000 (1,000 ED, 2,000 OPD, and 1,000 ASL). At the 15 FSASCs, staff will pull a total of 1,500 records. In summary, one medical record clerk from each of the 140 ambulatory units (i.e., 25 emergency service areas, 75 OPD clinics, 25 hospital-based ASLs, and 15 FSASCs) will have to pull and re-file an expected average of 104 records. At an average of 1 minute per record, the total annual burden to medical record clerks is 243 hours (Attachment M). For remote-reporting hospitals and the 2 hospitals submitting EHR files, no records will be pulled; therefore, there is no burden to the staff. For non-remote reporting facilities, field managers will enter the data into the computerized Patient Record forms (Attachments J, K, L); therefore, there is no burden to the facility for this activity. The total burden of the pretest is 381 hours.

Table 12A. Estimated Annualized Burden Hours

Type of Respondent	Form	Number of Respondents	Number of Responses per Respondent	Avg. Burden per Response (hours)	Total Burden Hours
Hospital Chief Executive Officer	Hospital Induction Interview	32	1	1.5	48
FSASC Chief Executive Officer	FSASC Induction Interview	15	1	30/60	8
Medical and Health Services Manager	Ambulatory Unit Induction	140	1	15/60	35
IT Staff	Prepare and transmit UB-04 files	47	1	1	47
Medical Record Clerk	Pulling and refiling records	140	104	1/60	243
				Total	381

B. Burden Costs

The average response burden cost for the NHCS pretest is estimated to be $13,117. The hourly wage estimate for the Hospital Induction interview for hospital executives was based on the Hay Group's Hospital Compensation Survey; for other hospital employees it was based on information from the mean hourly rate for ancillary service executives and medical record clerks published by the Bureau of Labor Statistics (http://www.bls.gov/oes/current/naics4_622100.htm). Mean hourly rates were then adjusted according to the yearly compensation inflation rates provided by the Bureau of Labor Statistics.

Table 12B. Estimated Burden Costs

Type of Respondent	**Response burden hours**	**Hourly Wage Rate**	**Respondent Cost**
Hospital Chief Executive Officer	48	$91.08	$4,372
FSASC Chief Executive Officer	8	$91.08	$729
Medical and Health Services Manager	35	$61.00	$2,135
IT Staff	47	$33.11	$1,556
Medical Record Clerk	243	$17.80	$4,325
		Total	$13,117

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 facility 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 total cost of the pretest is $1,465,000.

Data collection contract	$1,130,000
NCHS staff salaries	$ 313,000
Payments to facilities	$ 22,500

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publications and Project Time Schedule

Visit data from this pretest will not be analyzed for publication. However, the contractor will write a final report summarizing the pretest and methodologic reports may be published.

This clearance request covers one year of data collection for the pretest. After the pretest is completed, the contractor will submit a report of the results, including recommendations on improving data collection and processing and insights from the paradata collected.

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

NA

18. Exceptions to Certification for Paperwork Reduction Act Submission

No exceptions to certification are requested with the exception of race data described in A7.