Supporting Statement A for Request for Clearance:

NATIONAL HOSPITAL AMBULATORY MEDICAL CARE SURVEY

OMB No. 0920-0278
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SUPPORTING STATEMENT
NATIONAL HOSPITAL AMBULATORY MEDICAL CARE SURVEY

The National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC) requests a revision to an approved data collection, the ongoing National Hospital Ambulatory Medical Care Survey (NHAMCS) (OMB No. 0920-0278, expiration 08/31/2012) Clearance is now being sought to continue the survey activities for NHAMCS for 3 years, convert data collection instruments from paper to computer-based instruments, add 167 hospitals to the NHAMCS sample, and expand the data collection to include special supplements.

NHAMCS is a national survey of hospital ambulatory medical care conducted by NCHS. One of NCHS's missions is to monitor health, and NHAMCS supports this mission by collecting data on patient visits to emergency departments (EDs), outpatient departments (OPDs), ambulatory surgery locations (ASLs) of general and short-stay hospitals, as well as freestanding ambulatory surgery centers (FS-ASCs). As part of a broad data strategy for survey integration, NCHS is planning to integrate NHAMCS into the new National Hospital Care Survey (NHCS) in 2013 (OMB No. 0920-0212, expires 4/30/2014). A separate clearance will be submitted to integrate NHAMCS into NHCS at that time. Due to budgetary and recruitment concerns, we feel it is prudent to ensure the continuation of NHAMCS in the event that NHCS encounters difficulty in carrying out the survey. As the NHCS is in its infancy and plans for integration of NHAMCS into NHCS are still being developed, we felt it was best to request clearance for NHAMCS beyond 2012. Once plans for the NHCS are finalized and integration of NHAMCS is certain, NCHS will submit to OMB a request of discontinue all NHAMCS survey activities.

Approval is requested for the following data collection activities:

- Continue collection of facility and patient information from hospital EDs, OPDs, and ASLs and FS-ASCs for the year 2012, continuing through 2013, and 2014.
- Convert NHAMCS induction forms and Patient Record forms (PRF) from paper to computer-based instruments.
- Add 167 hospitals to the NHAMCS survey sample in order to obtain state-based estimates of care provided in EDs in five of the most populous states.
- Collect medical record number for survey operations purposes.
- Add items to the current OPD PRF to measure risk factors and medical care provided during the past 12 months for patients at risk for heart disease and stroke (lookback module).
- Conduct a pretest of additional items to the current ambulatory surgery (AS) PRF to obtain additional information on colorectal cancer screening at ambulatory surgery visits.
- Reduce burden to the respondent by having Field Representatives abstract patient record data instead of current method of having hospital staff perform abstractions.

Additionally, we request approval of slight modifications to our data collection forms based on past performance and recommendations from consultants. These modifications include:

- Addition of data elements to the OPD Patient Record form on cancer stage for patients with a cancer diagnosis and asthma severity for patients with asthma.
- Combining the Diagnostic/Screening Services, Health Education, and Non-Medication

Treatment sections into one section, entitled Services, on the OPD Patient Record form.

- Other minor adjustments to ED, OPD, and AS Patient Record forms, including modifying items based on responses in previous survey years.
- Approval to make relatively small modifications to the survey instruments for 2013 and 2014 through the submission of OMB nonsubstantive change requests.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Background

The National Hospital Ambulatory Medical Care Survey (NHAMCS), initiated in 1992, supports NCHS's mission to monitor health by providing data on utilization at hospital emergency departments (EDs), outpatient departments (OPDs), and ambulatory surgery locations (ASL) and freestanding ambulatory surgery centers (FS-ASCs). The need for more complete ambulatory medical care data has been driven by changes in the health care system which in turn are influenced by factors such as increasing efforts to contain costs and improve access and health care quality; the rapidly aging population; the introduction of new medical technologies; the adoption of electronic health records; and the expansion of health care coverage to the growing number of persons without health insurance. As a result of these societal, technological and policy changes, there has been considerable diversification in the financing, organization, and delivery of ambulatory medical care as manifested by the proliferation of managed care, insurance, and benefit alternatives for individuals; the development of new forms of physician group practices and practice arrangements; and growth in the number of emerging fields of medicine, such as pain management and ambulatory surgery. The data needed to evaluate the performance of the U.S. health care system in terms of the way in which ambulatory health care is organized, financed, and delivered and to track health care trends can be provided by NHAMCS. NHAMCS data collection is authorized under Section 306 of the Public Health Service Act (42 U.S.C. 242k) (Attachment A).

As part of the American Recovery and Reinvestment Act of 2009 (ARRA), the Health Information Technology for Economic and Clinical Health (HITECH) Act set forth a plan for advancing a nationwide health information technology infrastructure in order to improve efficiency and the quality of care in the health care system. Central to the vision of a nationwide electronic health information network is the use of electronic health records (EHRs). HITECH authorizes the Centers for Medicare & Medicaid Services (CMS) to administer incentives to eligible professionals and hospitals for meaningful use of certified EHR technology. The HITECH Act also authorizes the establishment of several new grant programs that will provide resources to facilitate the adoption and use of EHRs by providing technical assistance, the capacity to exchange health information, and the availability of trained professionals to support these activities. Patient Protection and Affordable Care Act of 2010 (ACA) section 1561 requires the Department of Health and Human Services (HHS), in consultation with the Health Information Technology (HIT) Policy Committee and the HIT Standards Committee, to develop interoperable and secure standards and protocols that facilitate electronic enrollment to encourage adoption of modern electronic systems. The aim of both the HITECH act and ARRA includes enhancing efficiency and improve quality in the health care system, expanding access to care,

and improve patient health.

Questions on the facility induction forms pertaining to electronic health records are sponsored by ARRA funds through the Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services (DHHS) (Attachment A). Identical EHR questions are asked of physicians in the National Ambulatory Medical Care Survey (NAMCS). EHR data from NHAMCS and NAMCS will help ONC monitor the adoption of EHR in ambulatory care settings. The EHR questions are anticipated to be a continuing part of NAMCS and NHAMCS data collection activities.

The Patient Protection and Affordable Care Act of 2010 authorizes programs targeted toward prevention and wellness. Information on the clinical management of conditions that put patients at increased risk for heart disease and stroke will be collected on NHAMCS in 2012 in what is referred to as the "lookback module". The lookback module is funded from prevention funds from the ACA (Attachment A). These items would greatly improve the nation's ability to monitor and evaluate the effects of increased insurance coverage on the quality of care provided in outpatient departments to prevent heart disease and stroke. Furthermore, this information could identify shortfalls in the quality of care that in turn could lead to improvements in clinical and public policy to improve prevention.

Privacy Impact Statement

The information required for the Privacy Impact Statement is presented in the sections below.

Overview of the Data Collection System

The target universe of NHAMCS is in-person visits made to EDs, OPDs, and ASLs of non- Federal, short-stay hospitals (hospitals with an average length of stay of less than 30 days) or those whose specialty is general (medical or surgical) or children's general and to freestanding ASCs. In years past, the facility-level data were collected via telephone and personal interviews with hospital staff on paper questionnaires. The patient visit data were abstracted from medical records onto paper Patient Record forms. Completed induction forms and Patient Record forms were transferred to the Washington National Records Center when 2 years old and are destroyed when 7 years old. Starting in 2012, all data collection will be computerized. The facility-level data will still be collected via telephone and personal interviews but answers will be recorded on laptop-based survey instruments instead of paper forms. The patient visit data will also be entered into laptop-based survey instruments. Data from the laptops will be encrypted and securely transmitted to databases at the Census Bureau.

New/modified activities planned for the 2012-2014 survey period

1. Additional hospitals

   In 2012, NHAMCS will include an additional 167 hospitals in order to obtain state-based estimates of the care provided in emergency departments in the five most populous states (California, Texas, New York, Florida, and Illinois). This additional sample is part of an effort sponsored by the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR) to better monitor the role of EDs and the care that they provide as health care reform in the United States proceeds. State-

based estimates will provide both baseline and ongoing information about the status of EDs and ED care as policy changes are implemented.

In each hospital in this additional sample, the induction interview will only involve the core hospital questions and questions about the emergency department. The outpatient department and ambulatory surgery locations of the sample hospitals will not be inducted. Patient Record forms will only be completed for the emergency department.

2. Lookback module

The lookback module, incorporated into the outpatient department Patient Record form, will collect additional information from the 12 month period prior to the sampled visit on risk factors and clinical management of patients with conditions that put people at high risk for heart disease and stroke. For example, the module would record medications prescribed, changes in medications, family history, and contraindications to certain medications. The intent of the lookback module is to improve the nation's ability to monitor and evaluate the quality of clinical care to prevent heart disease and stroke as health reform proceeds. Since the survey already collects selected intermediate outcomes, including blood pressure and cholesterol levels, combining currently collected PRF data with the additional lookback items would permit the evaluation and monitoring of appropriateness of clinical management and the relationship to these outcomes. The lookback module is funded from prevention funds from the Patient Protection and Affordable Care Act of 2010.

The lookback module was pilot-tested in June 2011 and again in September 2011. The June pretest was on paper, and tested the feasibility of finding data in the medical record to answer all of the questions. The pretest was successful, and the lookback questions were programmed into the automated instrument. The September pretest focused on the functionality of the lookback module in the automated instrument. The lookback module was triggered for the appropriate criteria, and the pretest was also successful.

As the lookback module is fielded in 2012, data quality will be continuously monitored as data is received from completed cases. Problems such as difficulties in obtaining data from the medical record and confusion with data elements can be mitigated early on, by sending out updated guidance to field representatives during the survey year. After the completion of the 2012 survey year, additional analysis will help determine the overall success of the lookback module data. NCHS staff will look at which data elements were easily found and which elements were most commonly missing from the medical record. Results from the lookback module will be examined against with literature on the heart disease and stroke to determine the representativeness of the abstracted data.

The utility of the lookback module as an addition to the current NHAMCS starting in 2012 will be considerable. For example, these items would greatly improve the nation's ability to monitor and evaluate the effects of increased insurance coverage on the quality of care provided in hospitals to prevent heart disease and stroke. Furthermore, information on the clinical management of conditions that put patients at risk could identify shortfalls in the quality of care that in turn could lead to improvements in clinical and public policy to improve prevention.

3. Colonoscopy supplement

Finally, a small pretest in hospital-based ASLs and freestanding ASCs will assess the feasibility of obtaining information on colorectal cancer screening during ambulatory surgery visits where a colonoscopy is performed. In late 2011, a small pilot test will be conducted in 5 hospitals and 4 freestanding ASCs. Based on the results of the pilot test, we will use 4-5 questions from the pilot test (Attachment Q) in the pretest. The pilot questions were drafted based on consultations with experts in colorectal cancer screening research and federal partners. The questions will be added to the AS Patient Record form and will be completed for patients that have a colonoscopy performed at the sampled visit. Because the pretest will only add a few questions to the AS Patient Record form, and because the questions will only be asked about specific visits, we do not anticipate that the pretest will change the burden of the AS Patient Record form. Final questions (a subset of those attached) will be submitted to OMB via a nonsubstantive change request prior to the pretest, in Spring 2012. Pretest data will be evaluated by the sponsors and by expert panel to determine the usefulness and representativeness of the abstracted data. We will also look at the number of blanks and missing data to see how often data were unavailable from the record. Funding received from the sponsors covers the pilot and pretest for this supplement. Once the tests are complete, the sponsors will evaluate whether further funding will be granted to add the supplement to regular data collection.

Colonoscopy is a highly effective clinical preventive service delivered in a variety of ambulatory settings, including hospital-based ASLs and FS-ASCs. Currently, most data on patterns of colorectal screening are self-reported and collected directly from patients. However this approach limits the level of clinical detail available, and is subject to reporting bias. Moreover, self-reported data provide no information about the relationships between practice and provider characteristics and the performance of these procedures. Obtaining visit-level data on colonoscopy procedures through NHAMCS will allow researchers to analyze these relationships. The endeavor is sponsored jointly by the National Center for Chronic Disease Prevention and Promotion (NCCDPHP) and the National Cancer Institute (NCI).

Items of Information to be Collected

The following facility-level data will be collected from hospitals and freestanding ASCs:

- Eligibility criteria (ownership, licensing, specialty)
- Expected number of visits
- Number of treatment spaces
- Use of electronic medical records

Patient visit data to be collected include:

- Medical record number
- Demographic information (age, gender, race, ethnicity, etc.)
- Sources of payment
- Reason for visit
- Diagnosis
- Diagnostic/screening services
- Procedures

- Medications
- Providers
- Disposition

The NHAMCS and related supplements collect a variety of information on provider, visit, and facility characteristics. While the majority of the data collected is not considered personally identifiable, a few pieces of information fit the definition of Information in Identifiable Form (IIF). A list of all IIF data items is provided below, and all were previously approved by OMB with the exception of medical record number which will be collected for the first time starting in 2012. No IIF data are released on public-use files.

IIF Categories:

- Facility names
- Facility addresses
- Facility telephone numbers
- Contact name
- Medical record number and date of birth

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

There are no websites directed at children less than 13 years of age.

An ambulatory health care data website dedicated to NHAMCS (http://www.cdc.gov/nchs/ahcd/nhamcs_participant.htm) describes the survey, answers questions respondents may have on why they should participate, and describes how the Privacy Rule permits data collection for NHAMCS.

2. Purpose and Use of Information Collection

NHAMCS data are widely used by all agencies of the Public Health Service and other government, academic and private research organizations in tracking changes in hospital-based ambulatory health care. These data complement those from NAMCS (OMB No. 0920-0234) to provide a complete description of ambulatory health care utilization in the United States. A negative consequence of not having information collected in the NHAMCS is that there would be a paucity of hospital-based ambulatory health care data to monitor health care reform efforts and changes in payment policies before, during, and after the restructuring of the health care system.

Privacy Impact Assessment Information

Ambulatory medical care is the predominant method of providing health services in the United States. NHAMCS is an ongoing survey and was initiated in 1992 to obtain information on how such care was rendered in hospital EDs and OPDs. Data on ambulatory patient visits to physicians' offices have been collected through the NAMCS since 1973. Although NAMCS provides a wide range of data describing the public's use of physician services, it is limited to patient visits to office-based physicians, thus omitting visits to hospitals and FS-ASCs which represent a significant segment of total ambulatory medical care. Valid data concerning both office and hospital ambulatory medical care are needed to make rational decisions for the allocation of resources and training of health

professionals, to aid in efforts to control health care costs, monitor quality of care, and to plan for the provision of ambulatory medical care. According to the 2009 NHAMCS, the estimated number of U.S. hospital ED and OPD clinic visits were 136,072,000 and 96,132,000, respectively. In 2009, there were an estimated 14,065,000 visits to hospital-based ambulatory surgery locations. Annual data on ED and OPD visits collected from 1992-2009 are available to the public.

Impact on the privacy of the patient is negligible, as the only piece of sensitive information being collected is the medical record number. Medical record number will only be used for internal survey operations purposes, and will be eliminated from the dataset prior to transmittal to NCHS. No IIF data are shared with researchers.

In addition to the sampled patient encounter information collected in the NHAMCS, information about the hospital is also obtained. Requests from government agencies to collect more information via special supplements have been made since 2002. Previous special supplements include Emergency Pediatric Services and Equipment, Pandemic and Emergency Response Preparedness, and Cervical Cancer Screening.

Users of NHAMCS data include Congress and federal government agencies, e.g., the Government Accountability Office; the DHHS Office of the Assistant Secretary for Planning and Evaluation (ASPE); the Health Resources and Services Administration (HRSA), the Substance Abuse and Mental Health Services Administration (SAMHSA); CDC's National Center for Injury Prevention and Control, Coordinating Center for Infectious Diseases, and National Center for Chronic Disease Prevention and Health Promotion; state and local governments; medical schools; schools of public health; colleges and universities; private businesses; non-profit foundations and corporations; professional associations; and health maintenance organizations, as well as individual practitioners, researchers, administrators, and health planners.

NHAMCS data are cited frequently to describe quality of care and to assess utilization. Recent journal articles using NHAMCS data have been published on the following topics: ethnic disparities in the management of trauma patients; uninsured adults presenting to the ED; quality of care for pediatric respiratory illness seen in the ED; and screening and diagnostic testing for women seen in OPD clinics. Academic researchers have used the NHAMCS to analyze the following topics: hypertension management, emergency department visits for antibiotic-associated adverse events, inappropriate use of antibiotics for acute asthma, and opioid prescription trends (see Attachment B for a list of publications).

The information collected on patient visits to hospital EDs, OPDs, and ASLs complements the current NAMCS data on office-based ambulatory care. Hospital ambulatory medical care data are used for (a) descriptive analyses of the content of hospital ambulatory medical care; (b) comparative analyses of the content of medical care provided in the hospital and office-based settings; (c) trend analyses of visits to hospital EDs and/or OPDs; (d) analyses of facility–level data; and (e) modeling to predict treatment and the use of services.

Example of descriptive analyses: A study reported in *Psychiatric Services* looked at emergency department visits for mental health related complaints and non-mental health related complaints between 2001 and 2006. The analysis reported that duration of ED visits increased for both categories at an annual rate of 2.3%. Visits for mental health related complaints were an average of 42% longer

than visits for non mental health related complaints (*Psychiatric Services* 2010 Sept; 61(9))

Example of comparative analyses: In the *NCHS Data Brief* (NCHS 2010), "Visits to Primary Care Delivery Sites: United States, 2008," data from ambulatory care visits to OPDs, physician offices, and community health centers (CHCs) in the United States were combined to examine where patients receive ambulatory health care. The study found that the majority of visits to primary care delivery sites (84%) occurred in physician offices, while 11% occurred in hospital OPDs and 5% occurred in community health centers (CHCs). (Available at: http://www.cdc.gov/nchs/data/databriefs/db47.pdf).

Example of visit trend analyses: The NCHS Data Brief (NCHS 2010), entitled "Emergency Department Visits for Chest Pain and Abdominal Pain: United States, 1999-2008" reported that the percentage of noninjury ED visits for which abdominal pain was the primary reason for visit increased by 7.6% between 1999 and 2008. In that same time period, the percentage of noninjury ED visits for which chest pain was the primary reason decreased by 10.0%. (Available at: http://www.cdc.gov/nchs/data/databriefs/db43.pdf).

Example of facility-level data analyses: A report entitled "Emergency department information system adoption in the United States," published in *Academic Emergency Medicine*, used ED-level data from NHAMCS to examine adoption of national emergency department information systems (EDIS). The article reported that 16.1% of EDs had a complete EDIS, and that urban EDs were more likely to have adopted EDIS than rural EDs. (*Academic Emergency Medicine* 2010 23(10) 681-689)

Example of modeling to predict treatment: NHAMCS data were used in a report in *Annals of Emergency Medicine* to identify independent predictors of prescribing antibiotics recommended for community-associated methicillin-resistant *Staphylococcus aureus* skin and soft tissue infections seen in ambulatory care settings. The study found that independent predictors of treatment with these antibiotics included being younger than 45 years of age, living in the South, and being treated in an ED setting. (*Annals of Emergency Medicine* 2008 Mar;51(3))

3. Use of Improved Information Technology and Burden Reduction

Respondent burden in current data collection is held to a minimum through the use of sampling procedures at both the hospital and patient level.

Improved information technology will significantly reduce the burden for NHAMCS respondents when answering induction interview questions. Currently, completing the form requires a Census field representative (FR) to follow the flow of the form from front to back, navigating numerous skip patterns, adding information from complicated lists, and administering flash cards to the respondent. This process can be complicated and lengthy and involve numerous opportunities to enter incorrect data. Using a computer assisted interviewing instrument of the induction interview will allow FRs to skip unneeded questions, quickly populate write-in fields with drop-down menus, and eliminate the need for paper flash-cards that highlight item choices. In the end, we expect the time a respondent spends during the induction interview to be significantly reduced.

Approval to collect Patient Record forms (PRFs) data through an automated instrument is also requested. Use of a computerized data entry system for PRF data will significantly simplify the 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, and medications. Overall, using a computerized data entry system should reduce FR and respondent burden, and ultimately improve overall data quality. In addition, collecting the data electronically will speed editing, transmission, and processing, thereby making release of the yearly statistics more timely.

There are no legal obstacles to reducing the burden.

4. Efforts to Identify Duplication and Use of Similar Information

Based on previous work at NCHS and discussions with other government and professional organizations, five sources of related data were identified.

Survey	**OMB No.**	**Agency**
Drug Abuse Warning Network (DAWN)	0930-0078	Substance Abuse and Mental Health Services Administration
National Electronic Injury Surveillance System, All Injury Program (NEISS AIP)	Not applicable	Consumer Product Safety Commission (CPSC) and CDC
National Health Interview Survey (NHIS)	0920-0214	National Center for Health Statistics (NCHS)
Medical Expenditure Panel Survey (MEPS)	0937-0187	Agency for Healthcare Research and Quality (AHRQ)
State Emergency Department Databases (SEDD)	Not applicable	Agency for Healthcare Research and Quality (AHRQ)
State Ambulatory Surgery Databases (SASD)	Not applicable	Agency for Healthcare Research and Quality (AHRQ)

The Drug Abuse Warning Network (DAWN) is a surveillance system designed solely to monitor drug-related hospital ED visits and medical examiners' cases. Starting in 1988, DAWN included a national probability sample of approximately 685 hospitals. New case criteria, data elements and a sample redesign occurred in 2003, replacing a nonrandom sample. The ED component of DAWN now includes any ED visit related to recent drug use. On average, about 3% of ED visits meet these criteria. DAWN produces national estimates based on a sample of over 600 hospitals. SAMHSA has been collaborating with NCHS to have the information collected through the NCHS family of national provider care surveys. NCHS has the established infrastructure for data collection from hospitals, physician's offices, community health centers, etc., in the NCHS provider surveys, and integrating DAWN with the National Hospital Care Survey (NHCS; OMB No. 0920-0212) will substantially increase the value, precision, and timeliness of the data and will permit longitudinal and data linkage capabilities with CMS, NDI, and other data systems. NCHS is expanding data on hospital care through the NHCS, and SAMHSA's partnership with CDC/NCHS is expected to both increase response rates and improve the quality of data available to help inform public policy and prevention and treatment initiatives. A feasibility study of the integration of DAWN with the NHCS will begin in 2012.

The Consumer Product Safety Commission (CPSC) operates the National Electronic Injury Surveillance System (NEISS) in 64 hospital EDs in the United States. Beginning in 2000, CDC established an interagency agreement with CPSC to conduct the NEISS All Injury Program (NEISS AIP). The NEISS AIP is designed to provide national incidence estimates of all types and external causes of nonfatal injuries and poisonings treated in U.S. hospital EDs. This expansion boosts the percent of covered ED visits from 15% to about 34%. Illness-related ED visits are not covered by this surveillance system; therefore, the use of this system for examining utilization of medical care issues regarding hospital ED visits is very limited. NHAMCS data are used by the NEISS AIP to benchmark their statistics.

The National Health Interview Survey (NHIS) is a population-based survey in which information is obtained through household interviews. In addition to the recall problem that may be associated with household respondents, respondents cannot provide the detailed medical information about diagnoses, diagnostic procedures, medications, or therapeutic procedures that are collected in the NHAMCS.

The Medical Expenditure Panel Survey (MEPS) Household Component, based on a subsample of households in NHIS, provides nationally representative data on health care utilization, expenditures, insurance coverage, sources of payment, and access to care measures at the individual and family level. MEPS is sponsored by AHRQ and co-sponsored by NCHS/CDC. MEPS has a linked Medical Provider Survey that acquires more detailed information on the sources of payment and the associated medical procedures and medical diagnoses that characterize the medical events that the household respondents have experienced. MEPS is a household based complex sample survey of the civilian noninstitutionalized population and health care use data are reported by household respondents. NHAMCS is a provider-based survey with a slightly broader population, covering homeless and institutionalized populations. Health care utilization estimates will differ between MEPS and NHAMCS due to different survey methodologies and various sources of error (sampling and nonsampling).

The State Emergency Department Databases (SEDD) are a set of databases, from data organizations in participating States, that capture discharge information on all ED visits that do not result in an admission. Information on patients initially seen in the ED and then admitted to the hospital is included in the State Inpatient Databases (SID). SEDD and SID are sponsored by AHRQ. Twenty-five states now participate in the SEDD and data files are available beginning with data year 1999. SEDD contain clinical and resource use information included in a typical discharge abstract, such as, all-listed diagnoses, all-listed procedures, patient demographics, and expected payment sources; however, NHAMCS variables such as reason for visit, external cause of injury, and medications are not included. Data collected from SEDD varies from state to state, whereas NHAMCS data collection procedures are standardized nationwide.

The purposes of all of these data collection systems and the contents and utility of the resulting data are distinctly different from those of the proposed data collection. DAWN and NEISS are limited to specific public health problems, while NHAMCS has the broadest coverage of all the surveys described. NHIS and MEPS are population- instead of provider-based surveys. MEPS data cannot be used to make estimates of the frequency of treatment and do not provide the breadth of information available from NHAMCS. Data from SEDD are not nationally representative and do not contain the level of detail about the ED visit as that captured on the NHAMCS Patient Record form (e.g., medications, verbatim reason for visit, and cause of injury). Consequently, the information available from these systems is not adequate for the needs described earlier, and cannot be used as an alternative to the proposed data collection.

Individual states have made varying progress in recent years in collecting ambulatory surgery data. Thirty-two states collect data on ambulatory surgery, but some of those states only collect data from hospital-based ASLs. Also, the format and data elements used in different states vary. Some states collect only aggregate data at the facility level; others have implemented one-time or periodic surveys to collect a limited amount of ambulatory surgery data. In view of states' budgetary constraints, they are struggling to maintain existing data programs rather than planning any expansions.

The State Ambulatory Surgery Databases (SASD) system, a part of AHRQ's Health Care Utilization Project (HCUP), includes ambulatory surgery data from some states which have been put together in a uniform data format. SASD does not have data on all 50 states, and even with the state data they have, there are serious gaps. Many SASD states provide only hospital-based ambulatory surgery data. The gaps and problems with individual states' data described above are carried over into the SASD system. The data from SASD are not nationally representative. In addition, because of the state budgetary problems, there is a great deal of uncertainty about the number of states that will be willing and able to continue to provide data to SASD in the future.

5. Impact on Small Businesses or Other Small Entities

Some NHAMCS respondents are small hospitals or freestanding ASCs. In order to reduce respondent burden for all respondents, several data collection methodologies are used. These methods are designed to be flexible to meet the varied reporting and record keeping situations found in emergency service areas, clinics, and ASLs. Patient visit sampling is used in each of these settings to minimize data collection workload. The data collected on each patient visit are limited to a minimum number of items which adequately describe the utilization of hospital ambulatory medical and surgical care. Field representatives will do data abstraction on laptops with computerized Patient Record forms. If the facility insists upon completing the Patient Record forms, they will be given a laptop with the computerized PRF, which will facilitate data collection. Field representatives monitor reporting and assist staff in data collection.

6. Consequences of Collecting the Information Less Frequently

The rapidly changing environment in hospital ambulatory health care delivery and the current interest in health care reform lend importance to having annual data for decision making; describing the use of hospital ED, OPD, and ASL services; monitoring the effects of change; and planning possible changes in payment policies. This information has become even more crucial with the need to track the effects of the health care industry's evolution, by having continuous data collection before, during, and after policy change and possible restructuring. Since data from the surveys are often analyzed by combining data across years, the potential consequence of less frequent data collection is loss of ability to study issues such as ED crowding, antibiotic use, preventive services, or any of the other analytic examples presented in the package. Respondents will be asked to participate in data collection every 15 months. There are no legal obstacles to reducing the burden.

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

There are no special circumstances applicable to this survey.

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

Agency

a. Federal Register Notice

The agency's 60-day notice for NHAMCS appeared in the Federal Register Wednesday**,** June 29, 2011, Vol. 76, No. 125, pp. 38180-38181 (Attachment C), as required by 5 CFR 1320.8(d).

One nonsubstantive comment was received in response to the notice and shown in Attachment D. The following CDC response was forwarded to the individual providing the comment:

> Thank you for your comments concerning the CDC 60 Day Federal Register Notice for OMB No. 60-Day 11-0278, National Hospital Ambulatory Medical Care Survey. We have given the concerns you described careful consideration. For further information regarding the unique mission of CDC, please refer to our website at www.cdc.gov.

b. Efforts to Consult Outside the Agency

As NHAMCS is an ongoing survey, experts are consulted on survey advice as needed. Because the survey is fairly consistent from year to year, consultants are not solicited for every survey year, but are contacted when major changes are made to the survey. Numerous individuals both within and outside CDC have consulted on the NHAMCS (Attachment E). NHAMCS was also reviewed by ASPE.

NCHS, along with the Assistant Secretary for Preparedness Response, convened a meeting of the Working Group on the Role of the Emergency Department under Health Reform on January 31, 2011. The meeting's goal was to obtain feedback from national experts regarding the use of NCHS' provider-based surveys to better monitor the role of the EDs as health reform progresses (see Attachment E). Specific objectives were to identify gaps in data and routine analysis, and to obtain work group members' perspectives on priorities for filling these gaps. The group consisted of representatives from the health care community, academia, and federal agencies. The meeting identified priorities and possible ways to expand the utility of NHAMCS to monitor the role of the EDs as health reform progresses, including increasing sample hospitals in order to make state-based estimates on ED characteristics. As a result of these discussions, it was decided to add a sample of 167 hospitals to the 2012 sample in order to make state-based estimates of the care provided in EDs for the five most populous states - California, Texas, New York, Florida, and Illinois.

Preliminary work to develop a colonoscopy supplement was sponsored by the National Cancer Institute (NCI), National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP). A panel of experts in the field of colorectal cancer screening was held at NCHS to develop the priorities and questions for the supplement on October 27, 2010 (see Attachment E). The panel consisted of representatives from the health care community, academia, and federal agencies. The panel will be consulted regularly in the development of the supplement.

NCHS will continue to work closely with these individuals and agencies. There are no outstanding unresolved issues.

9. Explanation of Any Payment or Gift to Respondents

NHAMCS will not offer a payment or gift to respondents for participation.

10. Assurance of Confidentiality Provided to Respondents

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:

> "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 (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 5 years, or fined not more than $250,000, or both.”

<u>Privacy Impact Assessment Information</u>

a. This submission has been reviewed by the NCHS Privacy Act Coordinator and the NCHS Confidentiality Officer who determined that the Privacy Act does apply. The applicable System of Records Notice is 09-20-0167 Health Resources Utilization Statistics.

b. The automation of the survey will eliminate the need to record potentially identifiable information on paper. Medical record numbers will be entered into the computerized instruments but will only be used for survey operations purposes. The medical record number will aid field representatives in abstracting data from the various record systems in the facility. The medical record number may also be used during reabstraction efforts to verify the quality of initial abstraction. Once the case is complete and the data are ready to be transmitted to NCHS, medical record number will be wiped from the dataset and will not be retained beyond that time.

   An assurance of confidentiality is provided to all respondents as described earlier in this section. In the past, the NHAMCS was exempted from IRB review because hospitals were not considered to be

human subjects, the medical record data already existed, and no patient identifiers were collected. However, with the implementation of the Privacy Rule mandated by the Health Insurance Portability and Accountability Act (HIPAA) in April, 2003, Institutional Review Board (IRB) approval has been required to obtain a waiver of authorization of patient consent for hospitals to release protected health information from the medical record in certain circumstances. The NHAMCS data collection plan was approved by CDC's IRB (Protocol #2003-06) based on 45 CFR 46. In addition, the IRB granted (1) a waiver of the requirement to obtain informed consent from the patient, and (2) 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. A "Request for Continuation Approval of Protocol" to conduct the NHAMCS was approved on December 23, 2010 and approval to automate survey instruments was approved through an amendment on May 31, 2011. (Attachment F).

A routine set of measures are in place to safeguard the confidentiality of NHAMCS. Confidential data will be treated in a secure manner and will not be disclosed. All staff with access to confidential information are given instruction by NCHS staff on the requirement to protect confidentiality, and are required to sign a pledge to maintain confidentiality. Only such authorized personnel are allowed access to confidential records, and only when their work requires it. When confidential materials are moved between locations, records are maintained to ensure that there is no loss in transit, and personally identifiable information is shipped separately from providers' contact information. When confidential information is not in use, it is stored in secure conditions. Automation of the survey in 2012 will greatly decrease the risk of losing confidential information, as all survey data will be collected on a laptop and will always be encrypted before transmittal.

In keeping with NCHS policy, NHAMCS data are made available via public-use data files to the public. Confidential data, however, are never released to the public. All personal identifiers such as hospital name, address, and patient date of birth, are removed from the public release files. Outside researchers have access to items not available on the public use files through the Research Data Center, including zip code linked income, education, or urbanicity status. Users are not allowed to remove data files and cannot use data to identify patients or providers. All data releases are reviewed and approved by the NCHS Disclosure Review Board to avoid data breaches, such as release of detailed geographic information that may allow sponsors to identify individuals in the general population.

c. The IRB granted a waiver of the requirement to obtain informed consent from the patient.

d. In the introductory letter from the NCHS director, the facility administrator is informed that participation in the NHAMCS is voluntary. There is no effect on the respondent for not participating. NHAMCS data are used to monitor ambulatory health care utilization. The information is not shared with anyone, although public-use data files are available on the NHAMCS website once individually identifiable information is removed. The legal authority for NHAMCS data collection is Section 306 of the Public Health Service Act (42 U.S.C. 242k).

11. Justification for Sensitive Questions

In order for some key analyses to be possible, it is necessary for the NHAMCS to collect some protected health information, such as date of visit, birth date, and zip code. Also, in some cases when the Census Bureau Field Representative (FR) abstracts the data from the medical record, the patient's name may be disclosed to the FR in the process of collecting the survey data. Strict procedures are utilized to prevent disclosure of identified NHAMCS data. At no time are the patients contacted to obtain information.

After the data are collected from the facilities and processed, a file of the sample visits will be sent to NCHS. The only identifiable elements on the file are date of visit, zip code, and birth date. For the public use files, date of visit is converted to month and day of week, birth date is converted to patient's age; and zip code is deleted. Patient's zip code is used internally to match the visit data to characteristics of the patient's residential area, such as median household income or percent of population who are high school graduates.

Medical Record Number

Starting in 2012, we will be collecting medical record number for internal survey operations purposes. The medical record number will be collected in the Patient Record form instrument to aid the field representative in abstracting data from the various record systems in the facility. Some facilities maintain patient visit information in more than one electronic or paper system, and the medical record number would help the field representative to ensure that they are abstracting data for the correct patient. After the case is transmitted and the medical record number is no longer necessary, the medical record numbers will be deleted from the dataset. NCHS will never receive any medical record number.

In plans for the future, medical record number will also be used for reabstraction efforts, where a second field representative would revisit sampled hospitals and FS-ASCs to reabstract patient visit information to check data quality. In such a situation, medical record number will be used in identifying the exact patient visits that were originally abstracted. Medical record numbers will be maintained by the contractor on a separate file to facilitate record selection. Plans for reabstraction are forthcoming, and we will submit an OMB nonsubstantive change request for approval once plans are finalized.

12. Estimates of Annualized Burden Hours and Cost

a. Burden Hours

This submission requests OMB approval for three years of NHAMCS data collection. The burden for one complete survey cycle is 10,348 hours and is summarized in the table below.

Each hospital will be asked to complete a Hospital Induction Interview. Approximately 482 hospitals will be asked to complete the hospital induction questionnaire (Attachment I). A complete induction will take one and a half hours. This results in an overall response burden of 723 hours.

An additional 167 hospitals will be also interviewed, but will only answer the general hospital induction questions and questions pertaining to the emergency department (Attachment J). This additional sample of hospitals will be added under an agreement sponsored by ASPR to make state-based estimates of ED characteristics. Because the sponsor is only interested in ED-level data, these hospitals will not be asked to complete the outpatient department and ambulatory

surgery induction questions. The induction interview for these hospitals will take 30 minutes, for an overall burden of 84 hours.

Approximately 200 freestanding ASCs will be interviewed with the FS-ASC Induction Interview (Attachment K). A complete induction will take 30 minutes. The total response burden for freestanding ASCs is 100 hours.

At each of the participating hospitals in the original sample, we will then approach the ED, OPD, and any hospital-based ASLs and will induct ambulatory units from each. For the new sample of 167 hospitals, we will only approach the ED. Ambulatory units within the ED are called emergency service areas (ESAs), and within the OPD they are called clinics. Ambulatory surgery units within hospitals are referred to as ASLs. Each unit in the hospital will be inducted through the Ambulatory Unit Induction form (Attachment L), which takes fifteen minutes to complete. In years past, NHAMCS has typically had approximately 1779 ambulatory units. With the addition of the 167 hospitals, we anticipate an average of one ESA per hospital. In 2012, we anticipate the induction of 1,946 ambulatory units, with a total annual burden of 487 hours.

From each department in the hospital and within each FS-ASC, a set number of PRFs will be targeted for abstraction. Patient Record forms will be completed by Census bureau staff or facility staff on a computerized Patient Record form. The information collected in the computerized instrument will be identical to that collected in the former paper-based Patient Record forms.

Approximately 100 ED PRFs (Attachment M) will be targeted for completion in each of the approximately 617 participating EDs. We anticipate that 75% of EDs will allow a Field Representative to abstract the patient record data. In the 463 EDs where the Field Representative abstracts the data, a burden of 1 minute will be incurred by the hospital for every patient record that the hospital's medical record clerk has to pull and re-file (including in line 7 of table). An average of approximately 154 EDs will complete their own forms, which take 7 minutes to complete. The total annual burden for the hospital staff to complete the ED PRFs is 1,797 hours.

In each OPD, 200 PRFs (Attachment N) will be targeted. Among the approximately 310 outpatient departments expected in our sample, we anticipate that 78 OPDs will complete their own PRFs. Each OPD PRF will take 14 minutes to complete, and the total annual burden for the hospital staff to complete the OPD PRFs is 3,640 hours. The PRFs from the remaining 233 OPDs will be abstracted by Census staff, but will require 1 minute of burden for each patient record that the hospital's medical record clerk has to pull and re-file (included in line 7 of table).

Hospitals and freestanding ASCs with participating ASLs will be asked to complete approximately 100 PRFs for ambulatory surgery visits (Attachment O). One form will take 7 minutes to complete, and 108 ASLs (including both hospital-based and freestanding) are expected to complete the forms without assistance. The total annual burden for the staff to complete the AS PRF is 1,260 hours. Census staff will abstract the PRFs for the remaining 323 ASLs. The burden to the medical record clerk is 1 minute per form (included in line 7 of table).

As noted, a portion of the Patient Record forms will be abstracted by Census staff. The burden to Census staff is not included in the burden table. The burden to the respondent will be 1 minute per PRF, as the medical record clerk will have to pull and re-file the records for abstraction. For the

EDs (n=463), OPDs (n=233), and ASLs (n=323), a total of 1018 medical record clerks will have to pull and re-file an average of 133 PRFs. At an average of 1 minute per record, the total annual burden to medical record clerks is 2,257 hours (Attachment P).

Table 12-A. Annualized Burden to Respondents

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Response Burden (in hours)
Hospital Chief Executive Officer	Hospital Induction	482	1	1.5	723
Hospital Chief Executive Officer	Hospital Induction (new sample)	167	1	30/60	84
Ancillary Service Executive	Freestanding ASC Induction	200	1	30/60	100
Ancillary Service Executive	Ambulatory Unit Induction	1,946	1	15/60	487
Physician/ Registered Nurse/ Medical Record Clerk	ED Patient Record form	154	100	7/60	1,797
Physician/ Registered Nurse/ Medical Record Clerk	OPD Patient Record form	78	200	14/60	3,640
Physician/ Registered Nurse/ Medical Record Clerk	AS Patient Record Form	108	100	7/60	1,260
Medical Record Clerk	Pulling and re-filing Patient Records (ED, OPD, and AS)	1,018	133	1/60	2,257
				Total	10,348

13. Estimates of Other Total Annual Cost Burden to Respondents and Record keepers

There are no annual capital or maintenance costs to the respondent resulting from the collection of information for this project.

14. Annualized Cost to the Government

The estimate of average annual cost for the 2012, 2013, and 2014 NHAMCS is as follows:

$ 609,000	Staff salaries (for editing, monitoring of data collection, analyzing data, producing reports, responding to data requests, and providing technical assistance to researchers)
$ 383,000	Overhead
$ 55,000	Printing of public relations materials and reports
$ 800,000	Contract (to conduct receipt and control operations, medical coding, data entry, and keying/coding quality control)

$3,800,000	Interagency Agreement with the Census Bureau for data collection (including induction and abstraction)
$ 385,000	Additional of 167 new hospitals
$6,032,000	Total cost for 12 months

15. Explanation for Program Changes or Adjustments

The current approved burden is 12,194 hours. The automation of data collection will greatly decreased burden, and despite the increase in hospitals samples and the addition of supplement, the overall burden will decrease by 1,846 hours to 10,348 hours in 2012.

16. Plans for Tabulation and Publication and Project Time Schedule

Data will be presented separately for ED visits, OPD visits, and ambulatory surgery visits. Plans for data analysis will parallel the analysis completed for the NAMCS because the data elements in the OPD and NAMCS are similar. For example, data will be presented in the following tables: patient visits by age, sex, and race; expected source(s) of payment; principal reason for visit; primary diagnosis; diagnostic service; disposition; and provider type seen. NCHS plans to publish the data in its *Data Brief* reports. Follow links for samples of NHAMCS reports (ED) **http://www.cdc.gov/nchs/data/databriefs/db43.htm and (OPD) http://www.cdc.gov/nchs/data/databriefs/db47.pdf.** In addition, there are plans to produce reports comparing data from the NAMCS and NHAMCS and combining data from both surveys. A list of selected NHAMCS publications can be found in Attachment B.

NHAMCS collection of ambulatory surgery data began in 2009, and analysis of the data is forthcoming. Reports will be published containing both hospital-based and freestanding NHAMCS ambulatory surgery data. The types of reports and tables will be similar to the OPD report referred to above. Data will be published in NCHS's *Data Brief* report. Data will be presented on the type, number, and rate of surgeries by age and sex, and by expected source of payment. In addition, data on diagnostic categories for surgery patients by age and sex will be included. Plans are to prepare articles for professional journals, special reports, and presentations for meetings and conferences of professional organizations, such as the American Public Health Association, Academy Health, the Ambulatory Surgery Center Association, and the Society for Ambulatory Anesthesia.

Annual public use NHAMCS files containing the ambulatory surgery data will be available on CD-ROMS and on the NCHS website: **http://www.cdc.gov/nchs/nhamcs.htm.**

The timetable for key activities for the 2012 survey is as follows:

Time after clearance	
--	Receive OMB clearance
Immediate	Begin data collection for 2012 survey
2 months	Begin internal data editing

12 months	End data collection year
15 months	Close out field work
17 months	End data processing by contractor
17 months	End internal data editing
18 months	Begin data analysis
20 months	Publish first NCHS Data Brief
2 years	Public use data available on Internet

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

N/A

18. Exceptions to Certification for Paperwork Reduction Act Submissions

The data encompassed by this project will fully comply with all guidelines of 5 CFR 1320.9 and no exception is requested to certification for Paperwork Reduction Act Submission.