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

This request is for a revision of an approved data collection, the ongoing National Hospital Ambulatory Medical Care Survey (NHAMCS) (OMB No. 0920-0278), for the purpose of collecting data for the three years 2010, 2011, and 2012 and for the expansion of data collection to freestanding ambulatory surgery centers. The NHAMCS is a national survey of hospital ambulatory medical care conducted by the National Center for Health Statistics (NCHS), of the Centers for Disease Control and Prevention (CDC). One of the CDC's missions is to monitor health, and NHAMCS supports this mission by collecting data on patient visits to emergency and outpatient departments and ambulatory surgery centers of general and short-stay hospitals.

Approval is requested for the following ongoing data collection activities:

Continued collection of facility and patient record information from hospital emergency and outpatients departments and hospital-based ambulatory surgery centers for the years 2010, 2011, and 2012.

Continuation of the NHAMCS Cervical Cancer Screening Supplement conducted since 2006.

New data collection from freestanding ambulatory surgery centers which formerly was collected as part of a separate approved survey, the National Survey of Ambulatory Surgery (NSAS) (OMB 0920-0334).

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 cancer stages to the outpatient department Patient Record form.

Other minor adjustments to Patient Record forms, including deleting and adding items based on responses in previous survey years.

Relatively small modifications to the forms for 2011 and 2012 through the submission of OMB 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 emergency departments (EDs), outpatient departments (OPDs), and hospital-based ambulatory surgery center (ASC) utilization. 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 growing number of persons without health insurance, the introduction of new medical technologies, and the adoption of electronic health records. As a result of these societal and technological 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. Visits to freestanding ASCs increased by 300% from 1996 to 2006; therefore, these data need to be collected in an annual survey, such as NHAMCS. 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).

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 the NHAMCS is in-person visits made to EDs, OPDs, and ASCs 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. The facility-level data are collected via telephone and personal interviews with hospital staff on paper questionnaires. The patient visit data are abstracted from medical records onto paper Patient Record forms. Completed induction forms and Patient Record forms are transferred to the Washington National Records Center when 2 years old and are destroyed when 7 years old.

The Cervical Cancer Screening Supplement (CCSS), originally fielded in 2006, is sponsored by CDC's National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), and will be conducted again to evaluate adherence to recent national guidelines. It is self-administered and completed on a paper questionnaire. The impetus for this supplement was the

availability of a test to detect genital human papilloma virus (HPV) infection and the HPV vaccine which was approved, in 2006, for routine vaccination of girls 11-12 years of age. Currently, there is recognition that the availability of both the test and vaccine may require different approaches to cervical cancer screening in primary care practice, as well as new information that needs to be conveyed when counseling and educating patients and their sex partners.

Ambulatory surgery centers provide ambulatory care but have not had consistent data collected through national surveys. Nationally representative ambulatory surgery data for both hospital-based and freestanding facilities have been gathered for only 4 years, i.e., 1994-1996 and 2006, through the National Survey of Ambulatory Surgery (NSAS). The objective of NSAS was to collect data about ambulatory surgery centers, the patients served, and services delivered. In 2007, NCHS asked the Census Bureau to investigate the feasibility of expanding NHAMCS to include ASCs on a regular basis. The investigation revealed that facilities were eager to cooperate and that the data sought for NHAMCS were readily available in their data systems. In 2009, NHAMCS was expanded to include hospital-based ambulatory surgery centers. The current request seeks approval for the addition of freestanding ambulatory surgery centers to NHAMCS.

The precedence of gathering data on hospital-based ASCs through the NHAMCS allows for an easy transition into the inclusion of freestanding ASCs. Additionally, a number of data collection materials related to hospital-based ASCs, including training materials for Census Bureau field representatives and survey forms for participants, have already been approved and will require minimal modification for use with freestanding ASCs.

Items of Information to be Collected

The following facility-level data will be collected from hospitals: eligibility criteria, visit sampling information, information related to ED crowding, and information related to the use of electronic medical records. The following facility-level data will be collected from freestanding ASCs: eligibility criteria, visit sampling information, and information related to the use of electronic medical records. Patient visit data to be collected include: demographic information, reason for visit, diagnosis, diagnostic/screening services, procedures, medications, providers, and disposition. The facility-level Cervical Cancer Screening Supplement contains questions on methods used to screen for cervical cancer and use of the HPV DNA test and HPV vaccine.

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. The data are not released on public-use files.

IIF Categories:

- Facility names - hospital, ED, OPD, hospital-based ASC, and freestanding ASC
- Facility addresses – hospital, ED, OPD, hospital-based ASC, and freestanding ASC
- Patient date of birth
- Facility telephone numbers - hospital, ED, OPD, hospital-based ASC, and freestanding ASC
- Contact names - hospital, ED, OPD, hospital-based ASC, and freestanding ASC

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

An ambulatory health care data website dedicated to National Ambulatory Medical Care Survey (NAMCS) and NHAMCS (www.cdc.gov/nchs/about/major/ahcd/ahcd1.htm) describes the survey, answers questions respondents may have on why they should participate, describes how the Privacy Rule permits data collection for NHAMCS, and provides a link (www.cdc.gov/NHAMCS) to the participant website. There are no websites directed at children less than 13 years of age.

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 to provide a complete description of ambulatory health care utilization in the United States. No sensitive information will be collected. 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 National Ambulatory Medical Care Survey (NAMCS-OMB No. 0920-0234) since 1973. Although the 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 hospital EDs and OPDs, 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 2007 NHAMCS, the estimated number of U.S. hospital ED and OPD clinic visits were 116,802,000 and 88,894,000, respectively. Annual data on ED and OPD visits collected from 1992-2006 are available to the public. No sensitive information is being collected; therefore, impact on the privacy of the patient is negligible. No IIF data are shared with researchers.

NHAMCS data are cited frequently to describe the 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. 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 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. 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 and OPDs complements the current NAMCS data on office-based ambulatory care. In addition to the data uses described in A.1, 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 recent *National Health Statistics Report* (NCHS 2008), entitled "Emergency Department Visits by Persons Recently Discharged from U.S. Hospitals" reported that approximately 2.3 million ED visits (2.0%) were made by persons who had been hospitalized within the last 7 days. Ten percent of those patients had a medical or surgical complication that may have been related to their recent hospitalization. (Available at: http://www.cdc.gov/nchs/data/nhsr/nhsr006.pdf).

Example of comparative analyses: In the *National Health Statistics Report* (NCHS 2008), "Ambulatory Medical Care Utilization Estimates for 2006," data from ambulatory care visits to physician offices, OPDs, and EDs in the United States were combined to produce annual estimates of ambulatory medical care utilization. The study found that visits to physician offices were lower among patients with no insurance coverage than for patients with insurance coverage. Conversely, uninsured patients visited EDs at twice the rate of insured patients. (Available at: http://www.cdc.gov/nchs/data/nhsr/nhsr008.pdf).

Example of visit trend analyses: A study reported in *Respiratory Care* combined data from patient visits to physician offices in the NAMCS and hospital OPDs in the NHAMCS from 1994 to 2004 to derive a national estimate for visits related to chronic obstructive pulmonary disease (COPD) and compare visit trends between males and females. The analysis reported that COPD-related visits between 1994 and 2004 increased for both men and women. COPD-related visits among females surpassed visits for males, suggesting that COPD is no longer a male-dominated disease. (*Respiratory Care* 2008 Nov;53(11))

Example of facility-level data analyses: In a report entitled "Factors Associated with Ability to Treat Pediatric Emergencies in US Hospitals," published in *Pediatric Emergency Care*, data from the Emergency Pediatric Services and Equipment Supplement of the 2002-2003 NHAMCS were analyzed to examine pediatric emergency care. The study found that hospital inpatient pediatric structure was linearly related to the availability of supplies. However, inpatient structure was not associated with the presence of a pediatric trauma service or written transfer agreement. Further analyses demonstrated that pediatric volume, teaching hospital status, geographic region, and per capita income of the community were strong determinants of hospital preparedness to treat pediatric emergencies. (*Pediatric Emergency Care* 2007 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))

Ambulatory Surgery

The National Survey of Ambulatory Surgery (now being phased in over a two-year period as a component of NHAMCS) was the first and still is the only nationally representative source of clinical information on ambulatory surgery. This survey, combined with the inpatient surgery data gathered annually through the National Hospital Discharge Survey (OMB 0920-0212) provides the only national estimate of the combined inpatient and outpatient surgery. A *National Health Statistics Report*, published in 2008, entitled "Ambulatory Surgery in the United States, 2006," reported that over 60 percent of the 56 million surgery visits in 2006 were in ambulatory settings. Expansion of NHAMCS to regularly cover ambulatory surgery adds this very important data to the National Health Care Surveys. The report also stated that, of the 34.7 million ambulatory surgery visits in the U.S., 19.9 million occurred in hospitals and 14.9 million occurred in freestanding ASCs. The visits to freestanding ASCs had increased 300% from 1996 to 2006. This large and increasing number of surgeries would not be counted if NHAMCS is limited to hospital-based ambulatory surgery data. Visit data for the hospital-based ASCs, added to the NHAMCS in 2009, are not yet available.

NSAS provided data useful for a variety of planning, administrative, and evaluation activities by government, professional, scientific, academic, and commercial institutions, as well as by consumer groups and private citizens. Former and expected future users of NSAS data include

Federal agencies, such as the National Institutes of Health (NIH), the Centers for Medicare and Medicaid Services (CMS), Office of the Assistant Secretary for Planning and Evaluation (ASPE), and Agency for Healthcare Research and Quality (AHRQ); state regulatory and health care financing agencies; universities and medical schools; professional organizations, such as the American Medical Association and American Hospital Association; World Health Organization; hospitals; freestanding ASCs; medical research laboratories; pharmaceutical and medical supply manufacturers; publishing houses; market research groups; and insurance companies.

3. Use of Improved Information Technology and Burden Reduction

Record-keeping systems of different hospitals are too diverse to support electronic response to NHAMCS. NHAMCS data indicate that 61% of EDs and 51% of OPDs used a full or partial electronic medical record system in 2007; however, these systems are not uniform. Respondent burden in current data collection is held to a minimum through the use of sampling procedures at both the hospital and patient level. There are no legal obstacles to reducing the burden.

4. Efforts to Identify Duplication and Use of Similar Information

NHAMCS

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)

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.

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 emergency department visits that do not result in an admission. Information on patients initially seen in the emergency department 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 in 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.

Ambulatory Surgery

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 ASCs. 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. For a number of years SASD had data on less than one-quarter of the 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 hospital emergency service areas, OPD clinics, and ASCs. 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. The forms are designed to allow check box answers to the extent possible. Field representatives monitor reporting and assist hospital 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 ASC 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 (see Section A12a and Section B1 for details). 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 Thursday, February 5, 2009, Vol. 74, No. 23, pp. 6163-6164 (Attachment C), as required by 5 CFR 1320.8(d). No public comments were received in response to the notice.

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 D). Both NHAMCS and NSAS were also reviewed by ASPE. 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

We will conduct an experiment in 2010 to test whether or not payment affects the participation of freestanding ambulatory surgery facilities. NSAS, under its approved OMB Clearance, had authority in 1994-1996 and 2006 to pay facilities upon request as a requirement for survey participation. Our experience dating back to the original NSAS

pretest indicated that compensation would be needed to enlist the participation of some of these facilities, and in the 1994 NSAS, 40% of facilities were paid. This payment was intended to recruit facilities that otherwise would be unwilling to take on the added burden of gathering these data, and/or to pay facility staff who would then agree to abstract NSAS data on their own time. A substantial amount of work was involved when facilities participated in NSAS, including the sampling of the discharge lists, the pulling and refiling of medical records, and, in many cases, the actual abstracting of approximately 11 records for NSAS monthly. As the demands on medical records personnel increase due to administrative and legislative requirements, participation in voluntary surveys often depends on staff working overtime -- an expense which freestanding ASCs, in particular, cannot afford. Thus, to ensure participation, being able to offer compensation for these staff when necessary was allowed.

Even with payment as an option, the response rate for hospital-based ambulatory surgery facilities was lower than for the NHAMCS and National Hospital Discharge Survey (NHDS), NCHS's national survey of inpatient hospital utilization. For the 2006 NSAS the response rate was 75.1 percent for hospital-based facilities and 74.3 percent for freestanding facilities. In contrast, the hospital clinic response rate for NHAMCS was 86.7 percent, and the NHDS response rate for inpatient data was 92 percent. In the 2006 NSAS, payment was provided to 18% and 11% of the participating freestanding and hospital-based facilities, respectively.

As part of a small exploratory study conducted by Census in 2007 at NCHS's request, facilities offering ambulatory surgery were contacted to see if they would be willing and able to provide data on ambulatory surgery similar to the NSAS data through NHAMCS. This study offered some possible explanations for the lower response rate that had been previously observed in NSAS. More than half of these ASCs said that being too busy, being short staffed, having time constraints, and/or keeping up with other Medicare and state requirements were important considerations in the decision to participate in a survey of ambulatory surgery.
NHDS pays hospitals if they request it. This survey's experience has shown that paying the hospital to abstract data is considerably cheaper than having Census Bureau staff perform this activity, which in 2004 was estimated to cost $21.96 per record. The per record estimate for the Census Bureau to complete the ambulatory surgery abstract would be even higher than the NHDS cost due to additional data items in NSAS which necessitate examining the entire medical record for NSAS as opposed to only the face sheet and discharge summary for the NHDS.

In the 2010 NHAMCS, an experiment will be conducted among freestanding ASCs to determine if the response rate differs between a group that may receive payment upon request and a group that is denied payment when requested. Freestanding ASCs will be randomly assigned to one of thirteen 4-week reporting periods. When requested, payment will be provided to freestanding ASCs that fall into odd-numbered reporting periods, but denied to those participating during even-numbered periods of the 13 reporting periods. Payment for facilities will be within the same range (updated by a small amount) as was approved previously for NSAS, that is, up to $5 per record without obtaining special NCHS approval, and up to $7 with NCHS approval. If the facility just pulls the records, but does not actually do the abstracting, it will be paid $1 to $2 per

record. This payment, if requested by the facility contact person as a requirement for survey participation, will be negotiated at the time of the facility's induction. Compensation for participants will not bias the responses to data items because the data are not subjective; data are abstracted from medical records and not provided by the respondent as in a population interview survey. We will report to OMB a comparison of response rates between the groups that are and are not paid upon request.

NHAMCS has not offered payment to respondents in the past, and this practice will not change for hospital-based ASCs, OPD clinics, and emergency service areas.

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. The records are covered under Privacy Act System of Records Notice 09-20-0167, Health Resources Utilization Statistics.

b. The study is designed so that NCHS receives no identifiable patient information such as patient names, Social Security numbers, or health identification numbers. The top section

of each Patient Record form (PRF), which contains the patient's name and record number, is separated from the bottom section by a perforation running across the page. The top section remains attached to the bottom until the entire PRF is completed. To ensure confidentiality, before collecting the completed PRF, the top section is detached and given to the hospital staff. The field representatives (FRs) instruct hospital staff to keep this portion for a period of four weeks, in case it is necessary to retrieve missing information or clarify information that had been recorded. Information security procedures, including use of coded passwords and physical security of computers, prevent unauthorized access to the electronic data. Any item that could be used, either directly or indirectly, to identify hospitals or their patients is removed from public-use data files. Hard copies of the survey forms will be stored in a locked file cabinet in a secure building at NCHS.

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 4, 2008 and an amendment to add freestanding ambulatory surgery centers along with a request for the ability to offer payment to facilities if they otherwise refuse to participate was approved May 6, 2009 (Attachment E).

A routine set of measures are in place to safeguard the confidentiality of NHAMCS. 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.

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 anyone 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 hospital 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 hospital-based 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 abstracts the data from the medical record, the patient's name or address 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. Individual patient names or other identifying information are not collected. 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.

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 10,832 hours and is summarized in the table below.

Each facility will be asked to complete a Hospital Induction form or a Freestanding Ambulatory Surgery Center Induction form. Approximately 482 hospitals will be asked to complete the hospital induction questionnaire (Attachment H, NHAMCS-101). A complete induction will take one hour. This results in an overall response burden of 482 hours. Approximately 200 freestanding ASCs will be interviewed for induction (Attachment I, NHAMCS-101FS). A complete induction will take 1.5 hours. The total response burden for freestanding ASCs is 300 hours.

At each of the participating hospitals, we will then approach the ED, OPD, and any hospital-based ASCs and will induct ambulatory units from each. Ambulatory units within the ED are called emergency service areas, and within the OPD they are called clinics. Ambulatory units within hospital-based ambulatory surgery centers are referred to as ASC locations. Each ambulatory unit in the hospital will be inducted through the Ambulatory Unit Induction form (Attachment J, NHAMCS-101U), which takes one hour to complete. In 2007, a total of 1,579 ambulatory unit forms were completed in emergency services areas and outpatient clinics. In 2010, we anticipate the induction of 1,779 ambulatory units based on the number of forms in 2007 plus an additional 200 units from the hospital-based ASCs locations. Each ambulatory unit induction will take approximately 1 hour, resulting in a total annual burden of 1,779 hours.

From each department in the hospital, the participating ambulatory units will be sampled to provide a set number of Patient Record forms (PRFs) for the department. Patient Record forms will be completed by hospital staff or Census bureau staff. Approximately 100 Patient Record forms (Attachment M, NHAMCS-100(ED)) will be completed in each of the approximately 410 participating EDs. An average of approximately 225 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 2,625 hours. The remaining 185 ED forms will be abstracted by Census staff, but will require 1 minute of burden for every patient record that the hospital's medical record clerk has to pull and re-file.

In each OPD, 200 PRFs (Attachment N, NHAMCS-100(OPD)) will be completed. Among the approximately 256 outpatient departments expected in our sample, we anticipate that 128 OPDs will complete their own PRFs. Each OPD PRF will take 6 minutes to complete, and the total annual burden for the hospital staff to complete the OPD PRFs is 2,560 hours. The remaining 128 OPD PRFs 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.

Hospital-based ASCs and freestanding ASCs will each be asked to complete 100 PRFs (Attachment O, NHAMCS-100(ASC)). One form will take 6 minutes to complete, and 208 ASCs (including both hospital-based and freestanding) are expected to complete the forms without assistance. The total annual burden for the ASC staff to complete the ASC PRF is 2,080 hours. Census staff will abstract the PRFs for the remaining 112 ASCs. The burden to the medical record clerk is 1 minute per form.

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=185), OPDs (n=128), and ASCs (n=112), a total of 425 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 942 hours (Attachment P).

The Cervical Cancer Screening Supplement (CCSS) (Attachment T, NHAMCS-906) will be administered in OPD clinics with a general medicine or obstetrics/gynecology specialty only. We anticipate that 255 clinics will complete the CCSS, which takes 15 minutes to complete. The total annual response burden for the CCSS is 64 hours.

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 (NHAMCS-101)	482	1	1	482
Ancillary Service Executive	Freestanding ASC Induction (NHAMCS-101FS)	200	1	1.5	300
Ancillary Service Executive	Ambulatory Unit Induction (NHAMCS-101U)	1,779	1	1	1,779
Physician/ Registered Nurse/ Medical Record Clerk	ED Patient Record form NHAMCS-100 (ED)	225	100	7/60	2,625
Physician/ Registered Nurse/ Medical Record Clerk	OPD Patient Record form NHAMCS-100 (OPD)	128	200	6/60	2,560
Physician/ Registered Nurse/ Medical Record Clerk	ASC Patient Record Form NHAMCS-100 (ASC)	208	100	6/60	2,080
Medical Record Clerk	Pulling and re-filing Patient Records (ED, OPD, and ASC)	425	133	1/60	942
Physician/Physician Assistant/Nurse Practitioner/ Nurse Midwife	Cervical Cancer Screening Supplement (CCSS) (NHAMCS-906)	255	1	15/60	64
TOTAL					**10,832**

b. Burden Cost

The average annual response burden cost for the NHAMCS is estimated to be $491,246 for each survey year. The hourly wage estimate for the Hospital Induction interview and the Patient Record form 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 physicians (general medicine/obstetricians/gynecologists/internists), physician assistants/nurse practitioners, registered nurses, and medical secretaries published by the Bureau of Labor Statistics.

All mean hourly rates were then adjusted according to the yearly compensation inflation rates provided by the Bureau of Labor Statistics. The average annual hourly wage was determined by assuming that 10% of the Patient Record forms will be completed by physicians, 30% by nurses, and 60% by clerks.

Table 12-B. Table of Annualized Cost to Respondents:

Type of Respondent	Form Form Name	Response burden hours	Hourly wage rate	Respondent cost
Hospital Chief Executive Officer	Induction, NHAMCS-101	482	$148.82	$71,732
Ancillary Service Executive	Freestanding ASC Induction, NHAMCS-101FS	300	$72.63	$21,788
Ancillary Service Executive	Ambulatory Unit Induction, NHAMCS-101U	1,779	$72.63	$129,200
Physician/ Registered Nurse/ Medical Record Clerk	ED Patient Record, NHAMCS-100 ED	2,625	$33.62	$88,257
Physician/ Registered Nurse/ Medical Record Clerk	OPD Patient Record, NHAMCS-100 OPD	2,560	$33.62	$86,072
Physician/ Registered Nurse/ Medical Record Clerk	ASC Patient Record, NHAMCS-100(ASC)	2,080	$33.62	$69,933
Medical Record Clerk	Pulling and refiling medical records	942	$19.24	$18,292
Physician/Physician Assistant/Nurse Practitioner/ Nurse Midwife	Cervical Cancer Screening Supplement (CCSS), NHAMCS-906	64	$93.67	$5,972
TOTAL				**$491,246**

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 2010, 2011, and 2012 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)
$10,000	Freestanding ASC payment experiment

$4,473,000 Total cost for 12 months

15. Explanation for Program Changes or Adjustments

The current approved burden is 9,186 hours. With the addition of freestanding ambulatory surgery centers to the 2010 NHAMCS, and small changes to the Patient Record forms, the basic estimate of hour burden will increase by 1,646 hours from 9,186 to 10,832 hours.

16. Plans for Tabulation and Publication and Project Time Schedule

Data will be presented separately for EDs, OPDs, and ASCs. 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 *National Health Statistics Reports* and *Vital and Health Statistics Series* reports. Follow links for samples of NHAMCS summary reports (ED) **http://www.cdc.gov/nchs/data/nhsr/nhsr007.pdf** and (OPD) **http://www.cdc.gov/nchs/data/nhsr/nhsr004.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.

Data on hospital-based ASCs and freestanding ASCs from the 2010 NHAMCS will be presented in a separate report. Reports will then 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 *National Health Statistics Report* series. 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, AcademyHealth, 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 duration of survey activities will span 36 months. The timetable for key activities for the 2010 survey is as follows (data collection for 2011 begins in 12/2010 and follows a similar timeline):

8/2009	Receive OMB clearance
9/2009	Submit data collection materials for printing
12/28/2009	Begin data collection for 2010 survey
12/2010	End data collection year
4/2011	Close out field work
7/2011	End data processing by contractor
7/2011	Begin internal data editing
10/2011	End internal data editing
10/2011	Begin data analysis
4/2012	Publish first National Health Statistics Report
4/2012	Public use data available on Internet
8/2012	CD-ROM available
8/2012	Publish additional reports

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.