Supporting Statement A. for Request for Clearance:

NATIONAL HOSPITAL AMBULATORY MEDICAL CARE SURVEY

OMB No. 0920-0278

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2nd Revision

SUPPORTING STATEMENT
NATIONAL HOSPITAL AMBULATORY MEDICAL CARE SURVEY

Revised:

This request is for the revision of an approved data collection (OMB No. 0920-0278 - expiration date August 31, 2009), the National Hospital Ambulatory Medical Care Survey (NHAMCS), for the purpose of adding ambulatory surgery data for 2009. The NHAMCS is a national survey of patient visits to emergency and outpatient departments of general and short stay hospitals. Original clearance was approved on August 8, 2006. Changes were approved on September 11, 2007 and January 11, 2008. We propose to revise NHAMCS in 2009 for the purpose of collecting hospital-based ambulatory surgery data which formerly was collected as part of a separate approved survey, the National Survey of Ambulatory Surgery (NSAS) (OMB 0920-0334 -clearance expires 11/30/2008). We propose, in this package, to first add the collection of data from hospital-based ambulatory surgery centers for hospitals already gathering other data for NHAMCS in 2009. For the 2010 NHAMCS we will request, in a full OMB package, the addition of the rest of the providers covered in the NSAS survey, that is, the free-standing ambulatory surgery centers. I

In addition, in this package some other some minor changes to the NHAMCS forms are described in detail in revised section B.2 of this document. Also, the NHAMCS Pandemic and Emergency Response Preparedness Supplement, which was approved in September 2007 for data collection in 2008 and 2009, will not be collected in 2009 due to lack of funding. That approval is not discussed in this package.

This package is the original 2006 clearance package with changes for 2009. All substantive changes to this package will be clearly marked “revised” and be located at the end of specific sections. Some sections have no revisions.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The need for more complete ambulatory medical care data has been driven by changes in diversification of the healthcare system which in turn is influenced by factors such as increasing efforts at cost containment, the rapidly aging population, the growing number of persons without health insurance, and the introduction of new medical technologies. As a result of these changes, there has been considerable diversification in the financing, organization, and delivery of ambulatory medical care. This diversification is evidenced 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 genetics and pain management. Valid data are needed to address health policy issues and to evaluate changes in the way ambulatory medical care is organized, financed, and delivered.

The National Hospital Ambulatory Medical Care Survey is part of the ambulatory care component of the National Health Care Survey, which is a family of provider-based surveys that captures health care utilization from a variety of settings including hospital inpatient and long-term care facilities. For the last ten years, the NCHS surveys of health care providers, including the National Ambulatory Medical Care Survey (NAMCS) (OMB 0920-0234), the National Hospital Discharge Survey (OMB 0920-0212), the National Nursing Home Survey (OMB 0920-0353), the National Health Provider Inventory (OMB 0920-0267), the National Home and Hospice Care Survey (OMB 0920-0298), the National Survey of Ambulatory Surgery (OMB 0920-0334), and the National Hospital Ambulatory Medical Care Survey (OMB 0920-0278), have been modified and expanded into an integrated National Health Care Survey. The NHAMCS is a major component of the NHCS. Both the NAMCS and NHAMCS are conducted under authority of Section 306 of the Public Health Service Act (42 USC 242k) **(Attachment A).**

The Cervical Cancer Screening Supplement (CCSS), originally fielded in 2006, is sponsored by the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), and was conducted in conjunction with the NHAMCS. A test to detect genital human papilloma virus (HPV) infection is now available for clinicians to use. Currently, there is recognition that this new information 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. The cervical cancer screening supplement will be used again in 2007 and 2008 to evaluate the adherence to recent national guidelines.

Revised:

Nationally representative ambulatory surgery data for both hospital-based and free-standing facilities have been gathered for only 4 years, i.e.,1994-1996 and 2006, through the National Survey of Ambulatory Surgery (NSAS) (approved under OMB No. 0920-0334). The objective of this survey was to collect data about

ambulatory surgery centers, the patients they serve, and the services they deliver. After the 1994-1996 NSAS, funds were not available to gather this important, and much sought after, data until 2006. Funds are again a problem.

To establish a mechanism for the collection of the ambulatory surgery data on an annual basis, and in a manner which we believe will be less costly, we plan to phase-in the addition of both the hospital-based and the free-standing ambulatory surgery centers to NHAMCS over a two-year period. For the first year, which is covered in this request, the 2009 NHAMCS will be expanded to include hospital-based ambulatory surgery facilities. Later, for the 2010 NHAMCS data collection, we plan to seek OMB approval in a full package to also add free-standing ambulatory surgery facilities to NHAMCS. Cost savings should occur because the hospital-based surgery centers to be sampled will be those in hospitals already sampled for NHAMCS. This OMB revision package is to request approval to add to NHAMCS the collection of data from hospital-based ambulatory surgery facilities.

In 2007, NCHS asked the Census Bureau to investigate the expansion of NHAMCS to include ambulatory surgery centers (ASCs) and the affordability of collecting NSAS data on a regular basis. Census field representatives conducted a semi-structured interview with representatives from 3 NHAMCS-participating hospitals in three separate Census Regions to gather information about whether the hospital would agree to provide ASC data on a sample of visits during the 4-week reporting period that was assigned for NHAMCS, and if their medical records contained the information needed for this annual survey. The results were encouraging. These facilities recognized the need for data of this type, and its inherent value, and said they would participate so long as the burden on them was minimized. They also indicated that the type of data we would need to collect is available in their systems.

Lower costs and increased efficiency are expected to result from gathering hospital-based ambulatory surgery data through NHAMCS rather than in a separate NSAS. In addition to saving induction costs, since the NHAMCS hospitals are already inducted, money should be saved in training costs since NHAMCS abstractors may have already worked on NSAS and the data gathered for the two surveys are similar. Reduced costs for data collection are expected to occur due to the fact that the number of months from which records are sampled from each facility will be lower using the NHAMCS design. Also, ongoing, annual data collection is cheaper than the periodic data collection since intermittent collection requires substantial start-up costs each time the survey is fielded. From the decreased costs, and other money from NCHS or from external funding sources, we anticipate that annual ambulatory surgery data collection will be possible.

Although for 2009 only hospital-based ASC data will be collected, there are plans to revise NHAMCS in 2010 to include the rest of the ASCs covered by NSAS, that is, the free-standing ASCs.

2. Purpose and Use of Information Collection

NHAMCS data have been used extensively for medical care research, education, and administration, as well as public policy decision making. The NHAMCS was initiated to learn more about how ambulatory care was rendered in hospital emergency and outpatient departments in the United States. Ambulatory medical care is the predominant method of providing health care services in the United States. Since 1973, data on ambulatory patient visits to physicians' offices have been collected through the National Ambulatory Medical Care Survey (NAMCS). The NAMCS provides a wide range of data describing the public's use of physician services. The NAMCS is limited to patient visits to office-based physicians, thus omitting visits to hospital emergency departments and outpatient departments which represent a significant segment of total ambulatory medical care. Together the NAMCS and NHAMCS comprise the ambulatory care component of the National Health Care Survey. 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 medical care costs, and to plan for the provision of ambulatory medical care. NHAMCS is an ongoing survey initiated in 1992 with continuous data collection since that time. Data are currently available to the public for the ED and OPD visits for 1992 through 2004. According to the 2004 NHAMCS, the estimated number of hospital ED and OPD clinic visits were 110,216,000 and 84,994,000, respectively.

The CDC plays an essential role in controlling infectious diseases and investigating disease outbreaks, as well as preventing violence and unintentional injury. NHAMCS data are cited frequently to describe the quality of medical care provided in the ED and to assess ED utilization. Recent journal articles using NHAMCS data have been published on the following topics: hospital and outpatient adverse drug reactions; racial and ethnic disparities in outpatient care; and emergency department visits for suicide and self-inflicted injury. In addition to the sample 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 topics such as Bioterrorism and Mass Casualty Preparedness and Emergency Pediatric Services and Equipment.

Users of NHAMCS data include Congress and federal government agencies, e.g., the Government Accountability Office; 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, National 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: HIV infection; differences in antibiotic prescribing among physicians, residents, and non-physician clinicians; screening and counseling associated with pediatric obesity diagnosis; and hip fractures **(see**

Attachment B for more details).

The information collected in the national survey of patient visits to hospital EDs and OPDs complements the current NAMCS of office-based ambulatory care. In addition to the data uses described in A.1. that are enhanced by the more complete database, four other general types of uses are possible for the hospital ambulatory medical care data: (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 and (d) analyses of facility–level data.

Example of descriptive analyses: According to an article published in *Annals of Emergency Medicine*, Analysis of Ambulance Transports and Diversions among US Emergency Departments, patients arrived by ambulance at 16.2 million ED visits (14.2%) in 2003. Of ambulance-related visits, 39% were made by seniors, 68% were triaged as emergent or urgent, and 37% resulted in hospital admission.

Example of comparative analyses: Information on the use of electronic clinical systems to support patient care in physician offices and hospital emergency and outpatient settings were published in the *Advance Data from Vital and Health Statistics*, Use of Computerized Clinical Support Systems in Medical Settings: United States 2001-03. This study found that electronic clinical systems were not widely adopted in the U.S. in 2001-2003 (**Attachment D**).

Example of visit trend analyses: Trends in OPD visits will be published in *Advance Data from Vital and Health Statistics*, National Hospital Ambulatory Medical Care Survey: 2004 Outpatient Department Summary. From 1994 through 2004, increasing trends in OPD visit rates were found for age groups under 21 years: children 1-12 years (up by 34%); infants under 1 year (up by 37%); and adolescents 13-21 years (up by 27%).

Example of facility-level data analyses: In a report entitled Bioterrorism and Mass Casualty Preparedness in Hospitals 2003, published in *Advance Data from Vital and Health Statistics,* data from the NHAMCS bioterrorism supplement were used to analyze the content of hospital terrorism preparedness emergency response plans. Results showed that almost all hospitals have plans for responding to natural disasters (97.3%). About three quarters of hospitals were integrated into communitywide disaster plans. Less than half reported written memoranda of understanding with other facilities to accept patients during a declared disaster. The percentage of hospital staff training varied from 92.1 % for nurses to 49.2% for medical residents (**Attachment C**).

Additional examples of uses of NHAMCS data are as follows:

- For the 2002 and 2003 NHAMCS, HRSA requested NCHS to conduct the Emergency Pediatric Services and Equipment Supplement. Data presented in a recent report entitled *Advance Data from Vital and Health Statistics*, Availability of Pediatric Services and Equipment in Emergency Departments: United States 2002-03, conclude

that half of hospitals admitted pediatric patients but did not have a specialized inpatient pediatric ward. One-quarter of EDs had 24/7 access to a board-certified pediatric emergency medicine attending physician and only 5.5 percent had all recommended pediatric supplies.

- For the 2003 and 2004 NHAMCS, NCHS fielded supplements to obtain information on the impact of ED overcrowding on patients; to determine the number and type of inpatient beds available; and to obtain data on the frequency and proportion of ambulance diversion, reasons for the diversion, and who in the hospital ordered the diversion. Analysis of these data revealed that approximately one-half million ambulances may have been diverted in 2003. Among hospitals that had any diversion, about 3 percent of operating time was spent in diversion status.

Revised:

The National Survey of Ambulatory Surgery (now to be 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 complements the inpatient surgery data obtained through the National Hospital Discharge Survey, and expands the regular coverage of the National Health Care Surveys. NSAS provides 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 the 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, the American Hospital Association, and the World Health Organization; hospitals; free-standing ambulatory surgery centers; medical research laboratories; pharmaceutical and medical supply manufacturers; publishing houses; market research groups; and insurance companies.

More detail about the purposes and uses of the NSAS data were included in the NSAS Supporting Statement.

3. Use of Improved Information Technology and Burden Reduction

Record-keeping systems of different hospitals are too diverse to support electronic response to the NHAMCS. Data from the report *Advance Data from Vital and Health Statistics*, Use of Computerized Clinical Support Systems in Medical Settings: United States 2001-03, indicate that only 31% of EDs and 29% of OPDs have electronic medical records. Respondent burden in this collection is held to a minimum through the use of sampling procedures. There are no legal obstacles to reducing the burden.

Respondents will have the option to complete the Cervical Cancer Screening Supplement (which is not based on medical record data) using a paper questionnaire or via Census Taker. The Census Bureau's Census Taker service provides a standardized system for collecting survey and census information by means of encrypted web page (HTML) forms. All user supplied information is encrypted both in transport and when saved. In combination, the system hardware, operating system, web server, and application software are configured to make Census Taker a highly secure system. The respondent's name will not be collected, but instead a unique ID number and password will be entered.

Revised:

The Census Taker option for respondents to the Cervical Cancer Screening Supplement is no longer being used. Respondents preferred to complete the questionnaire.

4. Efforts to Identify Duplication and Use of Similar Information

Based on previous work at NCHS and discussions with other government and professional organizations, four sources of related data have been 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	NCHS
Medical Expenditure Panel Survey (MEPS)	0937-0187	Agency for Healthcare Research and Quality

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. 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. The DAWN sample of hospitals now represents the entire U.S. In 2003, there were 518 hospitals in sample.

The Consumer Product Safety Commission (CPSC) operates the National Electronic Injury Surveillance System (NEISS) in 100 hospital EDs in the U.S. 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 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 the Agency for Healthcare Research and Quality (AHRQ) and co-sponsored by the National Center for Health Statistics, Centers for Disease Control and Prevention (NCHS/CDC). Since its inception in 1996, the MEPS Household Component has been a continuous on-going survey of the U.S. civilian non-institutionalized population. Unlike the NHIS, the 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.

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 surveys described. NHIS and MEPS are population- instead of provider-based surveys. Consequently, the information available from these systems is not adequate for needs such as those described earlier, and cannot be used as an alternative to the proposed data collection.

Revised:

More detail on the limited ambulatory surgery data gathered to date by government and private organizations has been included in the Supporting Statement for the National Survey of Ambulatory Surgery. For that reason only a summary of the some of these efforts will be repeated in the following two paragraphs.

Individual states have made varying progress in recent years in collecting ambulatory surgery data. States are more likely to maintain extensive data bases on inpatient data

rather than on ambulatory surgery data. Also, if they do collect any ambulatory surgery data, states are more likely to collect data on hospital-based ambulatory surgery rather than free-standing ambulatory surgery center data. The format and data elements used in different states vary. Some states only collect 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 the Health Care Utilization Project (HCUP) in the Agency for Healthcare Research and Quality, includes ambulatory surgery data from some states which have been put together in a uniform data format. For a number of years SASD has data on less than one-quarter of the states, and even with the state data they have, there are serious gaps. Many SASD states only provide hospital-based ambulatory surgery data. The gaps in, questionable quality of, and problems with individual state's 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 who 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 of the respondents are small hospitals. 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 and OPD clinics and in ambulatory surgery centers. Field representatives monitor reporting and assist hospital staff in data collection to the extent possible. Patient visit sampling is used within emergency service, and ambulatory surgery, areas and clinics to minimize data collection workload. The data collected on each patient visit is limited to a minimum number of items which adequately describe the utilization of hospital ambulatory medical care. The forms are designed to allow check box answers to the extent possible.

6. Consequences of Collecting the Information Less Frequently

The rapidly changing environment in hospital ambulatory medical care delivery makes it important to have annual data for decision making, for describing the public use of hospital ED, OPD, and ASC services, for monitoring the effects of change, and for 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 movement toward managed care plans, by having continuous data collection before, during, and after the 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 antibiotic use, preventive services, or any of the other analytic examples presented in the package. Respondents will be asked to respond to the data collection every 15 months (see Section A12A for details). There are no legal obstacles to reduce

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. The agency's 60-day notice for NHAMCS appeared in the Federal Register Thursday**,** January 12, 2006, Vol. 71, No. 8, pp. 2045-2046 (**Attachment E**), as required by 5 CFR 1320.8(d). No public comments were received in response to the notice.

B. From 2003-2005, numerous individuals, both within and outside CDC were consultants on the 2005 and 2006 and 2007 and 2008 NHAMCS (**Attachment F**). In the Summer of 2005, experts from Batelle and the University of California – San Francisco were consulted to review the CCSS questionnaire and provide recommendations of items to add, delete, or modify on the supplement. NCHS will continue to work closely with these individuals and agencies. There are no outstanding unresolved issues.

Revised:

A. The NSAS was granted a three-year clearance on November 30, 2005 because of the possibility that the survey would continue for multiple years beginning in 2006, and so its OMB approval is still current. The NSAS 60-day public comment notice was published in the Federal Register, Volume 70, Number 46, pages 11985-11986, on March 10, 2005, and the 30-day notice was published in the Federal Register on November 3, 2005 in Volume 70, Number 212, pages 66837-66838. No public comments were received. Because the public had the opportunity to comment upon the NSAS in these two public notices, OMB determined that only a 30-day notice is required for the revision combining hospital-based NSAS data collection with NHAMCS for the one-year period in 2009.

B. An expert technical advisory panel was convened before the NSAS was first conducted in 1994 to provide guidance during the development of the data collection instruments. The list of the individuals who were on that technical advisory panel, and the organizations they represented, were included in the NSAS Supporting Statement.

Since over 10 years had passed since the first NSAS technical advisory panel, NCHS consulted a wide range of experts in ambulatory surgery before the 2006 NSAS survey to be sure that the NSAS data collection instruments still contained items of interest, to determine if any items should be added or deleted, and to ensure that NSAS still covered the areas that health care providers, researchers and policy makers considered valuable.

Included among the outside groups contacted for input were the Federated Ambulatory Surgery Association, the American Academy of Ophthalmology, the American College of Surgeons, the Society for Ambulatory Anesthesiologists, the Joint Commission on the

Accreditation of Hospitals, and the American Association of Ambulatory Surgery Centers. We also consulted experts (see below) from within other government agencies (e.g. CMS, ASPE, AHRQ) which have provided input to NSAS since its inception.

Included among the individuals consulted were:

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9. Explanation of Any Payment or Gift to Respondents

No payment or gift will be provided to respondents.

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."

The study is designed so that NCHS receives no identifiable patient information such as patient names, Social Security numbers, or health identification numbers. The records are covered under Privacy Act System of Records 09-20-0167, Health Resources Utilization Statistics. 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.

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, IRB or Privacy Board review is needed 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 Institutional Review Board (Protocol #2003-6) based on 45 CFR 46. In addition, the Board 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 21, 2005 **(Attachment G).**

11. Justification for Sensitive Questions

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 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 two NHAMCS data collections: one that will be initiated in 2007, and one that will be initiated in 2008. These data collections will occur within the context of ongoing data collection activities (OMB #0920-0278). The burden for one complete survey cycle is summarized in the table below. Two complete data collection cycles will be conducted during this 3-year clearance period.

Each institution that is asked to complete a Hospital Induction Form (NHAMCS-101) is considered a respondent. The number of eligible hospital respondents (N=420) is based on the number of hospitals that were in-scope or eligible for the survey in 2004 (N=420). In 2004, 50 hospitals were found to be ineligible.

The 400 participating Emergency Departments (EDs) and the 250 participating Outpatient Departments (OPDs), described in more detail below, are operating units within the set of 420 participating hospitals/respondents.

A. 12-A. (Original) 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 Medical Officer	Hospital Induction (NHAMCS-101)				
	Ineligible	50	1	15/60	13
	Eligible	420	1	1	420
Ancillary Service Executive	Ambulatory Unit Induction (ED) (NHAMCS-101/U)	400	1	1	400
Ancillary Service Executive	Ambulatory Unit Induction (OPD) (NHAMCS-101/U)	250	4	1	1,000

Physician/ Registered Nurse/Medical Record Clerk	ED Patient Record form NHAMCS-100 (ED)]	220	100	6/60	2,200
Medical Record Clerk	Pulling and re-filing ED Patient Record	180	100	1/60	300
Physician/ Registered Nurse/Medical Record Clerk	OPD Patient Record form [NHAMCS-100 (OPD)]	125	200	6/60	2,500
Medical Record Clerk	Pulling and re-filing OPD Patient Record	125	200	1/60	417
Physician	Cervical Cancer Screening Supplement (CCSS) (NHAMCS-906)	200	1	15/60	50
Physician Assistant/Nurse Practitioner/ Nurse Midwife	Cervical Cancer Screening Supplement (CCSS) (NHAMCS-906)	50	1	15/60	13
TOTAL					7,313

It is estimated that 400 hospitals will have an eligible ED and will complete the required induction form for the ED (NHAMCS-101/U). The average number of Patient Record forms (PRFs) completed by the hospital per ED will be 100 (see NHAMCS-100(ED). Approximately 220 of the 400 hospitals will complete the PRFs without assistance from a Census Bureau representative. Burden to hospital staff who complete the NHAMCS-100(ED) is estimated to be 6 minutes per form. However, in approximately 180 hospitals, the NHAMCS-100(ED) form will be completed by a Census Bureau representative. In these cases, the only burden to hospital staff is the burden associated with pulling and re-filing the patient record, which is estimated to be one minute per form. Table A.12-A does not include the Census Bureau representative's effort for completing NHAMCS-100(ED) forms.

It is estimated that 250 hospitals will have eligible OPDs. Each clinic within the OPD completes a separate induction form; the average number of clinics per OPD is four (see NHAMCS-101/U). The average number of Patient Record forms (PRFs) completed by the hospital per OPD will be 200 (see NHAMCS-100(OPD)). Approximately half of the hospitals (125 out of the 250) will complete the PRF without assistance from a Census Bureau representative. Burden to hospital staff who complete the NHAMCS-100(OPD) is estimated to be 6 minutes per form. For the remaining 125 hospitals, the NHAMCS-100(OPD) form will be completed by a Census Bureau representative, and the only burden to hospital staff is the burden associated with pulling and re-filing the patient record, which is estimated to be one minute per form. Table A.12-A does not include the Census Bureau representative's effort for completing NHAMCS-100(OPD) forms. The CCSS forms are also completed in the OPD.

The total number of annual responses (92,120) was calculated by multiplying the number of respondents by the number of responses per respondent, then adding those values. The hour burden estimates were based on previous years' experience in administering the survey.

Note: Three forms included in this OMB submission do not as appear as line-item elements of Table A.12-A. These forms are adjunctive tools or references that support the completion of primary data collection instruments. The burden for reviewing or completing each adjunctive form is thus included in the burden estimate for the primary data collection instrument with which it is associated. See: 1) NHAMCS-103 (**Attachment L**), associated with NHAMCS-100 (**Attachments N and O**); 2) NHAMCS-122 (**Attachment P**), associated with NHAMCS-101/U (**Attachment K**); and 3) NHAMCS-123 (**Attachment Q**), associated with NHAMCS-101/U (**Attachment K**).

Revised:

Out of the 470 selected NHAMCS hospitals, 195 are anticipated to have participating hospital-based Ambulatory Surgery Centers (ASCs) for 2009. The added burden for this ASC data gathering is included in the table below labeled Revised.

A. 12-A. Revised 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 Medical Officer	Hospital Induction (NHAMCS-101)	470	1	55/60	431
Ancillary Service Executive	Ambulatory Unit Induction (NHAMCS-101/U)	845	2	1	1690
Physician/ Registered Nurse/Medical Record Clerk	ED Patient Record form NHAMCS-100 (ED)]	220	100	7/60	2,567
Medical Record Clerk	Pulling and re-filing Patient Records	393	132	1/60	865

Physician/ Registered Nurse/Medical Record Clerk	OPD Patient Record form [NHAMCS-100 (OPD)]	125	200	6/60	2,500
Phys./Phys. Assistant/Nurse Practitioner/ Nurse Midwife	Cervical Cancer Screening Supplement (CCSS) (NHAMCS-906)	250	1	15/60	63
Physician/ Registered Nurse/Medical Record Clerk	ASC Patient Record Form NHAMCS-100 (ASC)	107	100	6/60	1,070
TOTAL					9,186

Revised:

It is estimated that 195 hospitals will have an eligible ASC and will complete the required induction form for the ASC portion of the 2009 NHAMCS (revised NHAMCS-101-**Attachment J**) and the ambulatory unit induction record (revised NHAMCS-101/U **Attachment K)**. The average number of Patient Record Forms (PRFs) completed by the hospital per ASC will be 100 (see NHAMCS-100ASC-**Attachment T**). The NHAMCS-126 (**Attachment U**) Instruction Booklet is provided to each ASC unit and is associated with ambulatory unit induction record NHAMCS-101/U. It is estimated that the majority of hospital ambulatory units will complete the PRFs without assistance from a Census Bureau representative. Burden to hospital staff who complete the NHAMCS-100(ASC) is estimated to be 6 minutes per form. However, in about 393 hospital ED, OPD, and ASC units, the NHAMCS-100 will be completed by a Census Bureau representative. In these cases, the only burden to hospital staff is the burden associated with pulling and re-filing the patient record, which is estimated to be one minute per form (procedure described on pages 5-7 of Attachment U).

Burden to hospital staff who complete the revised NHAMCS-100(ED) is increased from 6 to 7 minutes per form to include minor revisions described in section B.2.

B. Burden Cost

The average annual response burden cost for the NHAMCS is estimated to be $288,904 for each survey year (i.e., 2007 and 2008). The hourly wage estimate for the Hospital Induction interview and the Patient Record form for hospital executives was based on the 2005 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 for 2004 published 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. The following table shows how the respondent cost was calculated:

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

Type of Respondent	Form	Response burden hours	Hourly wage rate	Respondent cost
Hospital Chief Medical Officer	Induction(NHAMCS-101) Ineligible Eligible	13 420	$125.00 $125.00	$ 1,625 $ 52,500
Ancillary Service Executive	Ambulatory Unit Induction -ED (NHAMCS-101/U)	400	$61.00	$ 24,400
Ancillary Service Executive	Ambulatory Unit Induction - OPD (NHAMCS-101/U)	1,000	$61.00	$ 61,000
Physician/ Registered Nurse/Medical Record Clerk	Emergency Dept. Patient Record (NHAMCS-100)	2,200	$28.24	$ 62,128
Medical Record Clerk	Emergency Dept. Patient Record (NHAMCS-100)	300	$16.31	$ 4,893
Physician/ Registered Nurse/Medical Record Clerk	Outpatient Dept. Patient Record (NHAMCS-100)	2,500	$28.24	$ 70,600
Medical Record Clerk	Outpatient Dept. Patient Record (NHAMCS-100)	417	$16.31	$ 6,801
Physician	Cervical Cancer Screening Supplement (CCSS) (NHAMCS-906)	50	$89.00	$ 4,450
Physician Assistant/Nurse Practitioner/ Nurse Midwife	Cervical Cancer Screening Supplement (CCSS) (NHAMCS-906)	13	$39.00	$ 507
	TOTAL			$288,904

Revised:

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

Type of Respondent	Form	Response burden hours	Hourly wage rate	Respondent cost
Hospital Chief Medical Officer	Induction(NHAMCS-101)	431	$125.00	$53,875
Ancillary Service Executive	Ambulatory Unit Induction (NHAMCS-101/U)	1,690	$61.00	$103,090
Physician/ Registered Nurse/Medical Record Clerk	ED Patient Record (NHAMCS-100 ED)	2,567	$28.24	$ 72,492
Medical Record Clerk	Pulling and Refiling medical records	865	$16.31	$ 14,108
Physician/ Registered Nurse/Medical Record Clerk	OPD Patient Record (NHAMCS-100 OPD)	2,500	$28.24	$ 70,600
Physician	Cervical Cancer Screening Supplement (CCSS) (NHAMCS-906)	50	$89.00	$ 4,450
Physician Assistant/Nurse Practitioner/ Nurse Midwife	Cervical Cancer Screening Supplement (CCSS) (NHAMCS-906)	13	$39.00	$ 507
Physician/ Registered Nurse/Medical Record Clerk	ASC Patient Record – NHAMCS-100(ASC)	1070	$28.24	$30,217
	TOTAL			$349,339

With the above revisions the average annual response burden cost for the NHAMCS is estimated for 2009 to be $349,339.

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

There will be no new 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 2007 and 2008 NHAMCS assuming no increase in sample size 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
$ 416,000 Contract (to conduct receipt and control operations, medical coding, data entry, and keying/coding quality control)
$3,000,000 Interagency Agreement with the Census Bureau for data collection (including induction and abstraction)

$4,463,000 Total cost for 12 months

Revised costs for 2009:

The added cost will be $500,000 for the ASC Add-on; this includes a $400,000 Interagency Agreement with the Census Bureau for data collection (including induction and abstraction) and $100,000 for a contract for medical coding and data processing

$4,463,000 – NHAMCS costs
$ 500,000 – ASC add-on

$4,963,000 - NHAMCS Total cost for 12 months (2009) including revision

15. Explanation for Program Changes or Adjustments

The basic estimate of hour burden decreased from 10,030 to 7,313 hours due to a recalculation of the burden to respondents to take into account that fact that 45% of ED and 49% of OPD records are abstracted by the Census. The burden also decreased due to the removal of the time previously allocated for the EPSES, which will not be fielded in 2007 or 2008. Additionally, there was an increase in PRF completion time from five to six minutes to account for the time to pull medical records and the increased length of the form.

Revised:

The current approved burden is 7,312 hours (the amount was decreased by 1 hour during the 2007 OMB approval as needed to upload the changes to the system). With the addition of the collection of hospital-based ambulatory surgery data items to the 2009 NHAMCS, and changes to the ED patient record, the basic estimate of hour burden will increase by 1,874 hours from 7,312 to 9,186 hours.

16. Plans for Tabulation and Publication and Project Time Schedule

The duration of activities for survey will span 36 months. The timetable for key activities

for the 2007 survey is as follows (data collection for 2008 begins in 12/2007 and follows a similar timeline):

6/2006	Receive OMB clearance
8/2006	Submit data collection materials for printing
1/2007	Begin data collection for 2007 survey
12/2007	End data collection
2/2008	Close out field work
7/2008	End data processing
10/2008	Begin data analysis
12/2008	Publish first Advance Data
12/2008	Public use data available on Internet
3/2009	Publish additional reports
4/2009	CD-ROM available
6/2009	Publish additional reports

Data will be presented separately for EDs and OPDs. Plans for data analysis will parallel the analysis completed for the NAMCS. 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 Advance Data from Vital and 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/ad/ad358.pdf** and (OPD) **http://www.cdc.gov/nchs/data/ad/ad366.pdf .** In addition, there are plans to produce reports comparing data from the NAMCS and NHAMCS and combining data from both surveys.

Revised:

The timetable for key activities for the 2009 ambulatory surgery add-on to NHAMCS is as follows:

9/2008	Receive OMB clearance
12/29/08	Begin data collection for 2009 survey
12/2009	End data collection
3/2011	Publish first National Health Statistics Report (replacing Advance Data series)
3/2011	Public use data available on the Internet
6/2011	Publish additional reports

6/2011	CD-ROM available

Data on hospital-based ASCs from the 2009 NHAMCS will be presented in a separate report. Beginning in 2010, we plan to add free-standing ASCs to NHAMCS thereby making the ASC data comparable to what was gathered in NSAS in 2006. Reports would then be published containing both hospital-based and free-standing 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 a National Health Statistics Report series which replaces the Advance Data 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. Some selected articles and reports which used data from the earlier NSAS surveys were included in the NSAS Supporting Statement.

Annual 2009 public use NHAMCS files containing the hospital-based ambulatory surgery data will be available on CD-ROMS and on our website. Beginning with the 2010 NHAMCS, we hope to have public use files with both hospital-based and free-standing ambulatory surgery data.

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

Expiration date display exemption is not requested.

Revised:

An exemption from the requirement of displaying the OMB expiration date on the forms for 2009 was granted by OMB on 1/31/08.

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.