Supporting Statement for Request for Clearance:

NATIONAL HOSPITAL AMBULATORY MEDICAL CARE SURVEY

OMB No. 0920-0278

Contact Information:

Catharine Burt, Ed.D.
Chief, Ambulatory Care Statistics Branch
Division of Health Care Statistics
National Center for Health Statistics/CDC
3311 Toledo Road, Room 3409
Hyattsville, MD 20782
301-458-4126
301-458-4693 (fax)
cwb2@cdc.gov

June 22, 2006

SUPPORTING STATEMENT
NATIONAL HOSPITAL AMBULATORY MEDICAL CARE SURVEY

This request is for the extension with revision of an approved data collection (OMB No. 0920-0278), the National Hospital Ambulatory Medical Care Survey (NHAMCS), for the purpose of collecting data for 2007 and 2008. The NHAMCS is a national survey of patient visits to emergency and outpatient departments of general and short stay hospitals. Original clearance was approved in 2004. A subsequent request was submitted and approved on October 11, 2005 to add 25 children's hospitals to the NHAMCS sample and two separate supplements on emergency pediatric services and cervical cancer screening for the 2006 panel. The NHAMCS is conducted by the Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics (NCHS).

In addition to the annual statistics normally collected, a key focus of the 2007 and 2008 surveys will be on the prevention and treatment of selected chronic conditions with an emphasis on cancer. Additionally, the emergency department (ED) Patient Record form will be modified to add the number of past visits to the ED within the last 12 months, and changes will be made to the diagnostic and procedure checkboxes. The outpatient department (OPD) Patient Record form will have changes for diagnostic and screening checkboxes, and disposition checkboxes. Our current request is to continue to use the Cervical Cancer Screening Supplement (CCSS) from 2006 for the 2007 and 2008 panels. The Emergency Pediatric Services and Equipment Supplement (EPSES), collected in 2002, 2003 and 2006, will not be fielded in 2007 or 2008.

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 0920-0234), 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.

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.

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.

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 is 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.

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. Field representatives monitor reporting and assist hospital staff in data collection to the extent possible. Patient visit sampling is used within emergency service 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 and OPD 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 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.

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.

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. 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 Eligible	50 420	1 1	15/60 1	13 420
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).

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. 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**

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)
$2,000,000 Interagency Agreement with the Census Bureau for data collection (including induction and abstraction)

$3,463,000 Total cost for 12 months

15. Explanation for Program Changes or Adjustments

The basic estimate of hour burden decreased from 10,030 to 7,313 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.

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 Report
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.

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

Expiration date display exemption is not requested.

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.

B. Collections of Information Employing Statistical Methods

The primary goal of this study is to survey a national probability sample of visits to non-Federal, short-stay and general hospital EDs and OPDs. The NHAMCS uses a four-stage probability design with samples of geographic Primary Sampling Units (PSUs), hospitals within PSUs, OPD clinics within hospitals, and patient visits within OPD clinics and EDs. Based on data from the NHAMCS, in 2004, the estimated total number of visits to hospital EDs and OPDs was 195 million. A secondary goal is to provide estimates of characteristics of hospitals with emergency and/or outpatient departments.

1. Respondent Universe and Sampling Methods

The universe for the NHAMCS consists of non-Federal hospitals in the 50 states and the District of Columbia which have six or more beds staffed for inpatient use and are general hospitals or have an average length of stay for all patients of less than 30 days. Until 2003, the hospital sampling frame was constructed from the SMG Hospital Market Database. Beginning with 2003, the sample frame sources are the annual “Verispan Healthcare Market Index" and Verispan’s "Second Quarter, Hospital Market Profiling Solution.” The initial NHAMCS sample of hospitals was selected in 1991 from the 1991 SMG data file. According to the 1991 SMG file, there were about 6,250 NHAMCS-eligible hospitals of which about 5,600 had EDs. The universe and sample hospitals were updated for the 2004-06 NHAMCS using hospital data from Verispan, L.L.C., specifically their “Healthcare Market Index, Updated May 15, 2003” and their “Hospital Market Profiling Solution, Second Quarter, 2003.” These products were formerly known as the SMG Hospital Database. Using the 2003 data to update the sample allows for the inclusion of hospitals that had opened or changed their eligibility status since the previous sample was updated for 2001.

The NHAMCS sample design is a multi-stage design with a first stage sample of two of the four PSU panels in the 1985-94 National Health Interview Survey (NHIS), that is, the first stage sample consists of 112 PSUs. From the sample PSUs, a stratified sample of approximately 600 hospitals (representing 15 months of data collection) was selected for the NHAMCS with hospital strata defined by whether hospitals had either EDs or OPDs according to the sampling frame data. About 550 hospitals with reported EDs and/or OPDs and 50 hospitals without reported EDs or OPDs were selected. Sample hospitals are randomly assigned to 16 4-week reporting periods as described below. In 2004, the sample size was 68,000 patient visits from 464 sample hospitals.

Hospitals

Non-Federal, short-stay and general hospitals in the sample PSUs are eligible for inclusion in the sample. Hospitals are stratified by whether they have EDs and/or OPDs. Prior to sampling, hospitals are arrayed within PSUs by type of ownership (voluntary nonprofit, non-Federal government, proprietary) and size, where size is measured by combined volume of ED and OPD visits reported in the hospital sampling frame (constructed from SMG data through 2002 and from Verispan data starting in 2003). From the arrayed hospital list, five hospitals are selected in each PSU without replacement and with probability proportional to the visit volume. If there are five or fewer hospitals, then all hospitals in the PSU are selected. The hospital sample was updated in 2001 and 2004 by extending the sampling process to new hospitals as if they had been in the sampling frame in 1991, when the original NHAMCS hospital sample was selected.

A sample of 600 hospitals (representing 64 weeks [i.e., 15 months] of data collection) is randomly divided into 16 groups of hospitals (i.e., 37-38 hospitals in each group) in order to avoid hospitals participating during the same time period each year. One hospital group will be assigned to each of the four-week reporting periods during 2007 through 2008, meaning that each hospital will be inducted approximately every 15 months (i.e., about 490 hospitals will be inducted annually). Substitution of the reporting period is not permitted. The overall hospital response rate for the 2004 NHAMCS was 78%. Eighty-seven (87%) percent of eligible EDs and 69% of eligible OPDs participated.

Outpatient Clinics and Emergency Service Areas

Within the hospital's OPD, a sample of clinics is selected. Clinics are in scope if ambulatory medical care is provided under the supervision of a physician and under the auspices of the hospital. Clinics providing only ancillary services, such as diagnostic X-rays or radiation therapy, are out-of-scope. Services provided in dental or dental surgery clinics, pharmacies, or other settings in which physician services are not typically provided also are out-of-scope. In addition, freestanding clinics are out-of-scope since they are included in the NAMCS, and ambulatory surgery centers, whether in hospitals or freestanding, are also out-of-scope. The OPD clinic definition excludes the "hospital as landlord" arrangement in which the hospital only rents space to a physician group and is not otherwise involved in the delivery of services. These physicians are currently included in the office-based NAMCS. Emergency services provided under the "hospital as landlord" arrangement, however, are eligible for the study.

During the visit by a field representative to induct a hospital into the survey, a list of all outpatient clinics is obtained from the sample hospital. Hospitals may define the term "separate clinic" differently, for example, by physical location within the hospital, by staff providing the services, by specialty or subspecialty, by schedules, or by patients' source of payment. Because of these differences, "separate clinics" in the NHAMCS are defined as the smallest administrative units for which the hospital keeps separate patient volume statistics. Each clinic's function, specialty, and expected number of visits during the assigned reporting period are also collected. This clinic frame is stratified by specialty: general medicine, surgery, pediatrics, obstetrics/gynecology, substance abuse, and other clinics. For sampling purposes, clinics with very low volumes are combined to form clinic sampling units of a minimum size. If a sample hospital has more than 5 clinic sampling units, then 2 units from each of the 6 specialty strata are selected with probability proportionate to the total expected number of visits to the clinics. If there are 5 or fewer clinic sampling units, then all are included in the sample. On average, hospitals in the sample have 3.6 clinics per OPD.

Within the hospital's ED, a list of all emergency service areas (ESAs) is obtained during the hospital induction interview. ESAs are defined as the smallest administrative unit of an ED where separate patient statistics are kept. It may be located on hospital grounds or operated off site by the hospital. The ED is treated as a separate stratum and up to five ESAs within a sample hospital are included. If a sample hospital has more than 5 ESAs, then a sample is selected with probability proportionate to the total expected number of visits to the ESAs. If there are 5 or fewer ESAs, then all of the ESAs are selected on average.

Visits

Within sampling units, patient visits are systematically selected over the 4-week reporting period assigned to hospitals. A visit is defined as a direct, personal exchange between an ambulatory patient and a physician, or a staff member acting under a physician's direction, for the purpose of seeking care and rendering health services. Visits solely for administrative purposes, such as payment of a bill, and visits in which no medical care is provided, such as visits to deliver a specimen, are out of scope.

Samples of approximately 100 and 200 visits are targeted from EDs and OPDs, respectively. If there are more than five clinics in a hospital, then up to 30 visits are targeted from each clinic included in the survey. In clinics with volumes higher than these desired figures, visits are sampled by a systematic procedure which selects every nth visit after a random start. Sampling rates are determined from the expected number of patients to be seen during the reporting period and the desired number of sample records. This basic procedure is adapted, as necessary, to the record keeping systems of the particular hospitals. Previous studies found that many clinics keep their own logs which are used as the sampling frame for visits. In cases where such a log is not available, the field representative supplies the clinic with a visit log form which can be used to record patient names. The names of patients are kept confidential and forms containing names remain in the hospital.

Cervical Cancer Screening

The Cervical Cancer Screening Supplement (CCSS) sample will use a three-stage probability design with samples of geographic Primary Sampling Units (PSUs), hospitals within PSUs, general medicine and obstetrics/gynecology clinics within OPDs.

2. Procedures for the Collection of Information

Training

Training in data collection procedures is conducted at different times with four different types of staff. Census Bureau Headquarters staff are responsible for training the Regional Office staff. Regional Office staff have the primary responsibility for training the field representatives and supervising hospital data collection activities. Field representative training covers the following topics: inducting hospitals, confidentiality, Health Insurance Portability and Accountability Act (HIPAA), clinic sampling procedures, determination of the "take every" and "random start" numbers, instructing hospital staff, supervising patient visit sampling, editing completed forms, retrieving missing data, and medical record abstraction. Field representatives induct the hospitals and train the hospital staff on visit sampling and completion of the Patient Record forms. However, if hospital staff are unable to complete the forms, some field representatives abstract the data.

Census Bureau Headquarters staff are responsible for writing the field manual which contains the following: the purposes of the survey; interviewing techniques; a description of the NHAMCS induction questionnaire and related forms; and the procedures for inducting hospitals, conducting hospital visits, sampling clinics, determining the take every and random start numbers, instructing hospital staff, supervising patient visit sampling, editing completed forms, and retrieving missing data.

Initial Contact

An introductory letter is sent from the Director of NCHS (**Attachment H**) to the chief executive officer of each sampled hospital; one is for a returning hospital and the other is for a hospital new to the sample. The letter describes the purpose of the survey, the authority for data collection, that participation is voluntary and that all collected information is confidential including the identity of the hospital [308(d) confidentiality requirements]. It also covers requirements related to HIPAA. Patient names or other identifying information are not collected and at no time are the patients contacted to obtain information. Letters of endorsement by the American College of Emergency Physicians, Society for Academic Emergency Medicine, Emergency Nurses Association, American College of Osteopathic Emergency Physicians and the Surgeon General (**Attachment I**) are included in the mailing.

Hospital Induction

The introductory letter is followed by a telephone call from the field representative to verify hospital eligibility for the survey and to arrange for an appointment with the chief executive officer, directors of the ED and OPD, and whoever is designated as hospital coordinator for this

survey. During the meeting, the field representative explains the purpose of the survey, describes the data collection methods and length of data collection, and obtains both general descriptive information about the organization of the ED and OPD and specific information needed to sample clinics within the hospitals. The NHAMCS 101 Questionnaire **(Attachment J)** is administered to screen sample hospitals, verify the hospital sampling frame information, induct the sample hospitals, and obtain ED and OPD data.

The field representative explains the designated reporting period and the data collection methods which may be either prospective or retrospective. In the prospective approach to data collection, the hospital staff sample patient visits, then complete the Patient Record forms, largely through observation, during or shortly after the sample visits. In the retrospective approach, hospital staff sample visits after the patients have been seen, then complete the Patient Record forms through medical record abstraction. Since hospital staff have experience abstracting data from medical records they are encouraged to perform this task although field representatives may abstract the data if the hospital staff are too busy. Approximately 45 percent of ED records and 49 percent of OPD records require Census abstraction.

After the preliminary visit, the field representative contacts the hospital coordinator to review the sample selection and to arrange for induction of the sample ESAs and clinics and for instruction of the hospital staff.

Outpatient Department Clinic and Emergency Service Area (ESA) Induction

After the OPD clinics and emergency service areas (ESAs) are selected for each hospital, the field representative arranges for induction visits to the sampled OPD clinics and ESAs through the hospital coordinator. At these visits, the purpose and use of the survey data are explained, the visit sampling procedures and Patient Record forms are described, and an NHAMCS-101/U - Ambulatory Unit Record (**Attachment K**) is completed for each clinic and ESA selected for the sample. In some circumstances, a blank NHAMCS-103 Patient Visit Log (**Attachment L**) may be used by the hospital staff to record visits prior to sampling. In order to assure patient confidentiality, the NHAMCS-103 Patient Visit Log is not collected by the field representative, but retained by the hospital. The field representative uses the NHAMCS-124 Sampling & Information Booklet (**Attachment M**) to determine the "random start" and "take every" numbers for the clinics and emergency service areas. Hospital staff are responsible for sampling patient visits by using hospital logs or other records. The field representative assists when necessary.

Hospital staff are instructed how to complete each item by the field representative. Patient visit data are recorded for each sample visit using either the ED or OPD Patient Record form (PRF). Results of the 1992 through 2004 NHAMCS have been incorporated into the design of these forms. For detailed information on PRF question wording see **Attachments N and O**. Instructions on completing the PRFs and definitions of terms are provided in the NHAMCS-122 Emergency Service Area Instruction Booklet (**Attachment P**) and the NHAMCS-123 Outpatient Department Clinic Instruction Booklet (**Attachment Q**).

The Patient Record form for the NHAMCS routinely collects data on patient characteristics such as age, sex, race, and ethnicity, and visit characteristics such as date of visit, reason for visit in

patient's own words, physician diagnoses, medications provided or prescribed, and expected source of payment. Periodically specific items on diagnostic tests, procedures or non-medication therapies are added or deleted. Changes to the 2007-2008 ED Patient Record form include the return of the episode of care question; the deletion of pulse; and changes will be made to obtain additional information related to various diagnostic and screening services, procedures, and visit disposition. The OPD Patient Record form will be modified to change the continuity of care question from a categorical to a continuous variable; two checkboxes within diagnosis and screening services will be changed; and visit disposition will be updated to include "Left without being seen" and "No show". (See **Attachments N and O** for 2007 ED and OPD PRFs.)

Cervical Cancer Screening Supplement

A 15-minute CCSS will be added to the OPD component of the NHAMCS to collect information on cervical cancer screening practices (**Attachment R**). When NHAMCS hospitals are contacted for participation, the OPD director will be asked which of the general medicine and obstetrics/gynecology clinics selected for sample performs cervical cancer screening. OPD representatives from these sampled clinics will then be asked to complete the CCSS as a self-administered form. Upon reviewing the introductory letter and questionnaire, the OPD representative will decide which clinician would be most appropriate to complete the supplement (i.e., a person who performs Pap tests or who is involved in setting practice guidelines). The respondent will be asked to complete the CCSS at the end of the 4-week reporting period, so as not to bias the data collected on the Patient Record form.

Monitoring Data Collection and Quality Control

Census Bureau Headquarters staff from the Demographic Surveys Division, Housing Surveys Branch, is responsible for overseeing the data collection. Census Bureau Headquarters staff, Field Division, is responsible for the supervision of staff in the Bureau's 12 Regional Offices who in turn supervise the field representatives.

The field representative visits the sampled ESAs and clinics each week during the data collection period and maintains telephone contact with the hospital staff involved in the data collection effort. An essential part of this effort is quality control which focuses on the completeness of the patient sampling frame, adherence to the sampling procedures, and assurance that a Patient Record form is completely filled out for every sample patient visit. The field representative reviews the log, or other records used for visit sampling, to determine if any cases are missing and also edits completed forms for missing data. Attempts are made to retrieve both missing cases and missing data on specific cases, either by consulting with the appropriate hospital staff or, if possible, by reviewing the pertinent medical records. A record of this retrieval effort is also made.

Completed survey materials are sent on a weekly basis from the regional offices to the Census Bureau's National Processing Center (NPC) in Jeffersonville, Indiana. NPC is responsible for completing a quality control edit before packaging and shipping work to our contractor where further editing, coding and data entry are done. Keying and data entry activities are performed under contract. All medical and drug coding as well as all data entry operations are subject to

quality control procedures where a 10-percent quality control sample of survey records are independently keyed and coded. Computer edits for code ranges and inconsistencies are also performed.

For some items, missing values were imputed by randomly assigning a value from Patient Record forms with similar characteristics. For the ED data, imputation for all imputed items was based on ED volume, geographic region, immediacy with which patient should be seen, and the three-digit ICD-9-CM code for primary diagnosis. In 2004, prior to imputation, the missing values for ED data were as follows: birth year (1.6 percent), sex (0.5 percent), race (11.1 percent), and ethnicity (14.8). For 2004 OPD data the missing values prior to imputation were: birth year (3.1%), sex (2.1%), and race (12.3%), and ethnicity (12.2).

Estimation Procedures

Separate national estimates will be produced for visits to hospital EDs and OPDs. The estimation procedure has three basic components: (a) inflation by reciprocals of the sampling selection probabilities, (b) adjustments for nonresponse, and (c) calibration ratio adjustment. Beginning in 1997, the calibration ratio adjustment for OPD estimates was replaced by an adjustment that controls for effects of rotating hospital sample panels into and out of the sample each year. (The full NHAMCS hospital sample is partitioned into 16 panels that are rotated into the sample over 16 periods of 4 weeks each so that only 13 panels are used in any one year.) Also, beginning with 1997 data, the sampling weights of some OPDs were permanently trimmed to prevent single OPDs from contributing more than 15% of their region's total to OPD visit estimates. For visits to EDs, the calibration adjustments are based on current ED visit counts recorded in the Verispan Healthcare Market Index and Verispan's "Second Quarter, Hospital Market Profiling Solution" for hospitals in the NHAMCS universe. Starting in 2004, the quarter of the year in which the hospital was assigned was taken into account during the nonresponse adjustment such that the unbiased quarterly estimates were made available.

Sampling Errors

Standard errors are calculated using a first-order Taylor series approximation method as applied in SUDAAN variance software.

3. Methods to Maximize Response Rates and Deal with Nonresponse

Based on the results of the 2004 NHAMCS, the projected response rate for 2007 is approximately 87 percent for the ED and 69 percent for the OPD. Endorsements have been solicited from several prominent national organizations, including the American College of Emergency Physicians, Society for Academic Emergency Medicine, Emergency Nurses Association, American College of Osteopathic Emergency Physicians and the Surgeon General. NCHS has developed a participant web page www.cdc.gov/nhamcs, which gives a brief background on the NHAMCS, as well as provides information regarding selection and participation, confidentiality and privacy, the HIPAA Privacy Rule, new data components, data utilization and contact information.

Data collection procedures are designed to minimize response burden, a major concern and influence on response rates. This survey does require commitment from a large number of persons within each hospital, including the director, clinic and ESA directors, and medical and clerical staff. Refusals to participate may occur at any one of the stages of induction or data collection. At the time of refusal, a refusal report is completed and the Census Bureau Regional Office is notified. Reasons for refusal vary considerably, necessitating refusal conversion procedures which are flexible and responsive to individual concerns. In general, the following survey features are stressed: the data are needed by the hospital and medical professions for a variety of purposes and do not exist elsewhere; all data about hospitals, clinics, and patients are kept confidential; and every effort is made to minimize the disruption of hospital routine. Based on earlier experiences, these features are often persuasive in converting refusals.

For the first time in 2004, changes were made to the nonresponse adjustment factor to account for the seasonality of the reporting period. Extra weights for nonresponding hospitals were shifted to responding hospitals in reporting periods within the same quarter of the year. The shift in nonresponse adjustment did not significantly affect any of the overall annual estimates.

4. Tests of Procedures or Methods to be Undertaken

The focus on prevention and treatment of selected chronic conditions in ambulatory visits will be continued in 2007-08 with an emphasis on cancer. The proposed 2007 PRF questions were reviewed and will undergo further evaluation. Consultation was sought from experts within DHHS including AHRQ, ASPE, HRSA, and CDC. Experts from outside the DHHS were also consulted (**Attachment F**).

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The statistician responsible for the survey sample design is:
Iris Shimizu, Ph.D.
Mathematical Statistician
Statistical Research and Survey Design Staff
Office of Research and Methodology
National Center for Health Statistics
Telephone: 301/458-4497
Ims1@cdc.gov

The data collection agent is the Census Bureau and the contact person is:
LaTerri Bynum
Chief, Housing Surveys Branch
Demographic Surveys Division
Bureau of the Census
Telephone: 301/763-3858
laterri.d.bynum@census.gov

The data will be analyzed under the direction of:

Catharine Burt, Ed.D.
Chief, Ambulatory Care Statistics Branch
Division of Health Care Statistics
National Center for Health Statistics
Telephone: 301/458-4126
cwb2@cdc.gov

ATTACHMENTS

A. Public Health Service Act, Section 306

B. List of NHAMCS Publications

C. Bioterrorism and Mass Casualty Preparedness in Hospitals: United States, 2003

D. Use of Computerized Clinical Support Systems in Medical Settings: United States, 2001-03

E. 60-day Notice in Federal Register

F. List of Consultants for the 2005-07 NHAMCS

G. CDC #2003-06 IRB Approval for Continuation of Protocol

H. Introductory Letters to NHAMCS Hospitals

I. NHAMCS Endorsing Letters

J. NHAMCS-101 Hospital Induction Form

K. NHAMCS-101/U Ambulatory Unit Record

L. NHAMCS-103 Patient Visit Log

M. NHAMCS-124 Sampling & Information Booklet

N. NHAMCS Emergency Department Patient Record form

O. NHAMCS Outpatient Department Patient Record form

P. NHAMCS-122 Emergency Service Area Instruction Booklet

Q. NHAMCS-123 Outpatient Department Clinic Instruction Booklet

R. NHAMCS-906 Cervical Cancer Screening Supplement