Supporting Statement A for Request for Clearance:

NATIONAL AMBULATORY MEDICAL CARE SURVEY

OMB No. 0920-0234

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Supporting Statement

NCHS National Ambulatory Medical Care Survey

This request is for a revision of an approved data collection (OMB No. 0920-0234), the ongoing National Ambulatory Medical Care Survey (NAMCS), for the purpose of collecting data for the next three years. NAMCS is a national survey of patient visits to office-based physicians conducted by the National Center for Health Statistics (NCHS), one of the centers of the Centers for Disease Control and Prevention (CDC). Proposed modifications to (1) collected information, (2) instruments, and (3) sample composition are discussed below. For the remainder of this document, "core NAMCS" refers to the combined office-based physician and community health center (CHC) samples.

The following data collection activities will continue with no change at the present time:

(1) patient visits to office-based NAMCS physicians
(2) patient visits to physicians and mid-level providers at community health centers (CHCs)
(3) cervical cancer screening supplement, which examines screening practices, the use of human papillomavirus (HPV) tests, and the use of the recently approved HPV vaccine by selected physician specialties
(4) electronic medical records (EMR)/electronic health records (EHR) mail survey.

Three new/reintroduced activities are also planned during the 2009-2012 NAMCS survey period:

(1) a 2009 pretest examining laboratory values on tests commonly ordered to monitor cardiovascular fitness, diabetes management, and diabetes detection
(2) the addition of the pretested laboratory items to the 2010-2012 NAMCS Patient Record form (PRF) for office-based and CHC providers
(3) 200 oncologists will again be added to the survey's usual sample, beginning in 2010, to improve our ability to assess and monitor the quality of cancer care.

All forms used in the current core NAMCS will remain unchanged for the remainder of 2009, and only slight modifications are planned for the primary data collection instruments in 2010-2012 as documented below:

The Patient Record form (PRF) used for the remainder of 2009 will be unchanged from the form currently used in the field; however, if the 2009 pretest is successful, items to record laboratory values on cholesterol tests, and tests of cardiovascular fitness will be added to the PRF for the 2010-2012 survey period. Also, beginning in 2010, there are plans to add two new items to the PRF: (1) five distinct cancer stages under the existing cancer check box in item 5b, and (2) a check box for radiation therapy in the non-medication treatment section of the form.

Typically throughout a survey period, slight modifications to the forms are needed; therefore, in addition to the requested approval summarized above and herein, we are also requesting the ability to submit non-substantive change packages, as needed, for form modifications occurring throughout the 2010-2012 study period.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Background

NAMCS was conducted from 1973 through 1981, and in 1985, and since 1989 has been an annual survey. The breaks in data collection from 1982 through 1984 and 1986 through 1988 were due primarily to budget constraints. The survey is conducted under authority of Section 306 of the Public Health Service Act (42 USC 242k) (**Attachment A**). A 1992 study completed by the Institute of Medicine (IOM) supports the need to continue NAMCS. In the report, Toward a National Health Care Survey: A Data System for the Twenty-first Century[1], the IOM panel stated that it, "endorses the NCHS plan to conduct the provider surveys on an annual basis."

[1]Institute of Medicine. Toward a National Health Care Survey: A Data System for the Twenty-first Century. National Academy Press. Washington DC. 1992.

Core NAMCS

The specific purpose of NAMCS is to meet the needs and demands for statistical information about the provision of ambulatory medical care services in the United States, and as such, fulfills one of CDC's missions, which is to monitor the nation's health. Ambulatory services are rendered in a wide variety of settings, including physician offices and hospital outpatient and emergency departments. Since more than 80 percent of all direct ambulatory medical care visits occur in physician offices, NAMCS provides data on the majority of ambulatory medical care services. To complement these data, the National Center for Health Statistics (NCHS) initiated the National Hospital Ambulatory Medical Care Survey (NHAMCS) (OMB No. 0920-0278) in 1992 to provide data on patient visits to hospital outpatient and emergency departments.

In addition to health care provided at physician offices and outpatient and emergency departments, community health centers (CHCs) play an important role in the health care community by providing care to people who could not necessarily afford it otherwise. Specifically, CHCs are local, non-profit, community-owned health care providers which serve approximately 13 million individuals throughout the United States. Research has shown that up to 4 percent of all primary care visits, and 10 percent of all visits by uninsured patients, are made to CHCs. Prior to 2006, visits made to CHCs, although in-scope for NAMCS, have been underrepresented due to the fact that the normal sample of physicians was simply not large enough to capture many of the physicians who worked in these important locations. In an attempt to obtain a more accurate picture of health care provided in the United States, a supplemental sample of 104 CHCs was included in the 2006 NAMCS panel. There has been annual data collection since that time, and these settings will continue to be sampled in 2009-2012.

NAMCS is part of the ambulatory care component of the National Health Care Surveys (NHCS), a family of provider-based surveys that capture health care utilization from a variety of settings, including hospital inpatient and long-term care facilities. NCHS surveys of health care providers, including NAMCS, National Hospital Discharge Survey (OMB No. 0920-0212), National Nursing Home Survey (OMB No. 0920-0353), National Home and Hospice Care Survey (OMB No. 0920-0298), National Survey of Ambulatory Surgery (OMB No. 0920-0334), the National Survey of Residential Care Facilities (OMB No. 0920-0780) and NHAMCS, have been modified and expanded into this integrated NHCS.

Other justifications for conducting NAMCS include the need for more complete ambulatory medical care data that has been accentuated by increasing efforts at cost containment and health care quality improvement which require evaluating the performance of the US health care system, the rapidly aging population, the growing number of persons without health insurance, the introduction of new medical technologies, and the adoption of electronic records. As a result of these societal changes, there has been considerable diversification in the organization, financing, and technological delivery of ambulatory medical care. This diversification is evidenced by the emergence of managed care, the proliferation of insurance and benefit alternatives for

individuals, the development of new forms of physician group practices and practice arrangements, and growth in the number of alternative sites of care. Valid data are also needed on an ongoing basis to address health policy issues and to evaluate changes in the way ambulatory medical care is organized, financed, and delivered.

Cervical Cancer Screening Supplement

One of CDC's missions is to monitor the health of the nation. The core NAMCS along with various supplements carry out this mission by providing visit data from physician offices and CHCs that allow CDC and other researchers the ability to anticipate trends in diseases, health behaviors, and health care.

The Cervical Cancer Screening Supplement (CCSS) is an example of how NAMCS can monitor health by providing data through survey supplements. CCSS collects data on genital human papilloma virus (HPV) and the use of the HPV vaccine. HPV is an infection that is common among sexually active populations, and a test to detect HPV along with a vaccine to prevent the virus 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. This supplement, sponsored by the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) and initially conducted in conjunction with the 2006 NAMCS, has been in the field since then, and plans are to continue the supplement for future survey years. CCSS is used to (1) evaluate adherence to recent national testing guidelines about the use of genital human papilloma virus (HPV) testing as an adjunct to Pap testing, and for the management of patients with abnormal Pap tests, and to (2) identify determinates in practices' use of the HPV vaccine. CCSS will be administered to (1) physicians with a specialty of general/family practice, internal medicine, or obstetrics/gynecology who perform cervical cancer screening, and (2) physicians and all mid-level providers at CHCs who perform cervical cancer screening.

Electronic Medical Records Supplement

To assist in measuring the progress of meeting the President's goal for most Americans to have access to an interoperable electronic health record (EHR) by 2014, NCHS will continue to field the Electronic Medical Records Supplement (EMRS), first conducted in 2008, with a supplemental NAMCS sample of 2,000 office-based physicians. The EMRS is sponsored by the Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services (DHHS). As in 2008, this mail supplement will be used to collect information on the adoption and use of electronic medical records (EMR)/electronic health records (EHR). The questions asked in the mail supplement will be a slightly modified subset of those currently asked in the Physician Induction Interview (NAMCS-1) of the core NAMCS, which is collected via personal interview. The information collected from these additional physicians will be combined with information collected in the core NAMCS to provide more reliable estimates.

Laboratory Values

The American Heart Association (AHA) recently released a scientific statement that recommended collecting lipoproteins, blood glucose, and glycohemoglobin to track progress in meeting national goals for heart disease and stroke prevention and management. The AHA specified in its guidelines that adding these data elements to NAMCS would represent a low-cost approach to enhance national surveillance for cardiovascular disease. In their opinion, NAMCS represents a superior collection tool compared to other instruments because (1) the target population consists of all office visits within the United States made by ambulatory patients to non-Federal physicians, and (2) as mentioned earlier, 80 percent of all direct ambulatory medical care visits occur in physicians' offices. If the proposed 2009 lab value pretest is successful, the items will be added to the Patient Record form for 2010-2012.

Supplemental NAMCS Samples

A. Additional Primary Care Physicians

The NAMCS sample will be supplemented with 200 primary care physicians annually for the 2009-2012 survey period to increase the sample size of potential CCSS respondents, thereby enhancing statistical estimates. This extra sample had been included in NAMCS since 2006, and will continue to be included as funding permits.

B. Additional Oncologists.

The proposed expansion of 200 oncologists annually for the 2010-2012 survey period would build upon efforts by the National Caner Institute (NCI) to improve estimates of physician services that are needed by clinical and public policymakers to assess and monitor the quality of cancer care. With funding from NCI in 2006 and 2007, NAMCS produced the first nationally representative data from patients' medical records on the management of ambulatory cancer care. With the new data proposed to begin in 2010, variation in utilization can be analyzed by various patient and provider characteristics to answer research questions such as whether cancer treatment varies by physician specialty, physician practice characteristics, geographic region, insurance status, or patient demographics. Public use microdata files for 2006 and 2007 are being produced to expand the research base and improve the ability of researchers and policymakers to examine issues regarding the quality of cancer care. The full value of existing data will be better exploited by including a stratum of oncologists annually for the 2010-2012 survey period. Collection of data over time will permit analyses of trends in the diffusion of new treatments by type of cancer and cancer stage over time. Collection of additional years will also increase total sample sizes, permitting description of cancer care in smaller population sub-groups, such as racial and ethnic minorities and patients under age 45 years.

Privacy Impact Assessment

The substantive information required for this section is provided in detail in "Overview of Data Collection System" below. Discussion of the NAMCS website is made in the section titled "Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age."

Overview of the Data Collection System

The target universe of core NAMCS includes visits made in the United States to the offices of nonfederally employed physicians, excluding those in the specialties of anesthesiology, radiology, and pathology, who were classified by the American Medical Association (AMA) or the American Osteopathic Association (AOA) as "office-based, patient care." Second, physicians (MDs and DOs) and mid-level providers (i.e., nurse practitioners, physician assistants, and nurse mid-wives) practicing at CHCs represents the second NAMCS target universe.

For the core NAMCS, each physician/provider in private practice/CHC is asked to complete an induction form (NAMCS-1) over the telephone, and during an initial personal interview. The questions in the first-half of the NAMCS-1, which are completed over the telephone, are used to guide the field representative (FR) through the induction process and verify the physician/provider's eligibility. The second-half of the form, which is completed in person, is dedicated to obtaining information concerning selected practice characteristics and determine a sampling strategy to collect PRFs. Also, each CHC director is also asked to complete a CHC induction form during their initial personal interview. This form allows for the collection of general CHC contact information, along with the type of center, sources of revenue, and allows for the identification of sampled porviders.

The majority of the data collection occurs with the completion of PRFs by sampled physician/provider and/or office staff. A PRF is completed for each sampled patient visit and will be basically the same as the ones currently used in 2009, except that we plan to add (1) five distinct cancer stages under the existing cancer check box in item 5b, (2) a check box for radiation therapy in the non-medication treatment section of the form, and (3) a set of laboratory values on the back of the form. The NAMCS is designed for the physician to complete PRFs; however, in many cases, Census field representatives (FRs) abstract the data. The laboratory questions will be pre-tested later in 2009 using a modified PRF.

As mentioned in the previous section, we are also continuing the Cervical Cancer Screening Supplement (CCSS). This supplement is self-administered paper questionnaire intended for physicians with a specialty of general family practice, internal medicine, or obstetrics/gynecology. Regardless of their specialty, all sampled providers in CHCs also receive a CCSS.

NCHS will continue to field the EMRS with a supplementary sample of physicians. Like the CCSS, the EMRS is a self-administered paper questionnaire; however, it utilizes a mail out/mail back format.

Items of Information to be Collected

The core NAMCS collects information on a range of data on the characteristics of the users and providers of physician office-based and CHC care. Information on the sampled provider concerning selected practice characteristics such as ownership, utilization of electronic medical records, practice revenue, and basic use of the human papillomavirus vaccine (HPV) are collected. Data collected on patient visits include demographic characteristics, injury/poisoning/adverse effects, reasons for visit, continuity of care, diagnoses, vital signs, diagnostic/screening services, health education, non-medication treatment, medications, providers seen, visit disposition and time spent with provider are also collected. The laboratory values pretested in 2009, and slated for addition to the PRF in 2010 will allow researchers to better understand the extent to which ambulatory health care providers identify and control abnormal values of lipoproteins, blood sugar, and glycohemoglobin before and after diagnosis of cardiovascular disease. The CCSS contains questions on methods used to screen for cervical cancer and use of the HPV DNA test and HPV vaccine. The EMRS is conducted to help provide more reliable estimates regarding office-based physician's/CHC's adoption of EMR/EHR systems.

Information in Identifiable Form (IIF)

The core NAMCS and related supplements provide numerous and varied national estimates on provider, visit, and practice characteristics. Although a majority of the data collected are not considered personally identifiable, some fit the definition of IIF. A list of all IIF data items is highlighted below, and all were approved in past packages by OMB to be collected on survey forms. None of these data is released to the public or becomes part of public-use files.

Information in Identifiable Form Categories:

- Physician/CHC provider name
- Physician/CHC provider mailing address
- Physician/CHC provider telephone number
- Physician/CHC provider Federal Tax ID
- CHC executive director name
- CHC mailing address
- CHC contact person
- Physician office/CHC staff name
- Patient date of birth

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

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

2. Purpose and Use of Information Collected

The purpose of this study is to collect information about ambulatory patients, their problems, and the resources used for their care. The resulting published statistics and data sets help the profession plan for more effective health services, improve medical education, and assist the public health community in understanding the patterns of diseases and health conditions. In addition, policy makers use NAMCS data to identify (1) quality of care issues, (2) medical resource utilization, and (3) changes in health care over time.

If NAMCS data were not collected, there would be no national estimates on health care issues faced by office-based physicians and providers at CHCs. The patient visit data from the physician portion of the 2009-2012 NAMCS will be used in basically the same manner as data from prior surveys; however, the additional supplements will allow research to focus on the following: (1) identification of characteristics associated with visits to office-based physicians and physicians/mid-level providers practicing at CHCs; (2) cervical cancer screening practices and determinates of HPV vaccine use; (3) adoption of EMR/EHR systems; and (4) collection of laboratory values on tests commonly ordered to monitor cardiovascular fitness, diabetes management, and diabetes detection.

Privacy Impact Assessment Information

The following sections highlight the numerous components of the 2009-2012 NAMCS, and in doing so, fulfills the Office of Management and Budget's privacy impact assessment requirement. Specifically, the requirement is met by describing why NAMCS information is being collected, and the usefulness in collecting the data.

Core NAMCS

Each year, NAMCS provides a range of baseline data on the characteristics of the users and providers of physician office-based and CHC care. Data collected include the demographic characteristics of patients, reasons for visit, diagnoses, diagnostic services, medications, and disposition. These annual data, together with trend data, may be used to monitor the effects of change in the health care system, provide new insights into ambulatory medical care, and stimulate further research on the utilization, organization, and delivery of ambulatory care.

The data obtained from NAMCS are useful to managers of health care delivery systems, and others concerned with planning, monitoring, and managing health care resources. The data are valuable to those who develop and evaluate new and modified health care systems and arrangements. The continuing nature of the survey permits observation and measurement over time of different modes (e.g., examinations, imaging, procedures) for managing and treating patient problems. In addition, it provides general information on the patterns of selected conditions. NAMCS also provides valuable information about the speed and effectiveness with which certain advances in medical practice are adopted, and about the effectiveness of educational programs among office-based physician practices.

Users of NAMCS include numerous governmental agencies, state and local governments, medical schools, schools of public health, colleges and universities, private businesses, non-profit foundations, corporations, and professional associations, as well as individual practitioners, researchers, administrators and health policymakers. Uses vary from the inclusion of a few selected statistics in a large research effort, to an in-depth analysis of the entire NAMCS data set covering multiple years.

The examples listed below illustrate selected users and uses of NAMCS data.

- Researchers within and outside NCHS have published work in scholarly journals using NAMCS data:
  - Sonnenfeld N, Schappert SM, Lin SX. Racial and Ethnic Differences in Delivery of Tobacco-Cessation Services. *Am J Prev Med*. Oct 2008.
  - Olfson M, Cherry D, Lweis-Fernandez. Racial Differences in Visit Duration of Outpatient Psychiatric Visits. *Arch Gen Psychiatry*. Feb 2009.

- Staff from the Ambulatory and Hospital Care Statistics Branch presented NAMCS data on trends in visit rates for skin and soft tissue infections typical of *Staphylococcus aureus* at the 136th Annual Meeting of the American Public Health Association in 2008.

- The Department of Health and Human Services is currently using NAMCS data to evaluate certain Healthy People 2010 objectives. These objectives are designed to serve as a road map for improving the health of all people in the United States by the year 2010, and NAMCS data support efforts to quantify national improvement.

- The results of the 2003 NAMCS bioterrorism questions have been presented by Ambulatory and Hospital Care Statistics Branch staff to outside partners, such as the Association of American Medical Colleges, and decision-making components of the Department of Health and Human Services charged with bioterrorism preparedness. Combined results from the 2003 and 2004 NAMCS bioterrorism questions have been recently published in peer-reviewed journals in the primary medical care literature and as NCHS annual reports.

- The Medicare Payment Advisory Commission (MedPAC), an independent Congressional agency, is required by law to make recommendations to Congress on payment updates to Medicare providers. MedPAC uses NAMCS data in its analysis of physician services. In particular, NAMCS data provides MedPAC with information on trends in physician willingness to serve Medicare beneficiaries. MedPAC presents this indicator yearly in its public meetings and in its official reports to the Congress to help determine payment updates for Medicare services.

The addition of CHCs to the NAMCS sample has produced a better overall picture of the ambulatory care provided in the United States, and has allowed us to look at the specific utilization of health care at CHCs and how it might differ from utilization in non-CHC settings. A separate stratum of CHCs allows NCHS not only to improve our estimates of health care for the uninsured, but also to make separate estimates for providers and visits at CHCs.

Further examples of studies using NAMCS data are shown in **Attachment B**.

Cervical Cancer Screening Supplement

Collecting data from physician offices and CHCs on CCSS will allow the CDC's National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) and other researchers to examine practices regarding the provision of HPV tests for approved and non-approved uses, cervical cancer screening methods, the use of HPV tests as an adjunct to Pap testing, the use of HPV test results for managing patients with abnormal Pap tests, and the potential impact of HPV testing on lengthening Pap test screening intervals. In addition, CCSS enables researchers to identify factors used by practitioners in determining who receives the vaccine, how the vaccine is utilized, and impressions of the vaccines efficacy.

Electronic Medical Records Supplement

The EMR supplement is conducted to help provide more reliable estimates regarding the adoption of EMR/EHR systems than could be provided by core NAMCS alone. The majority of questions and the overall sample design mirror the core NAMCS. Thus, although national estimates could be produced from NAMCS or the EMRS individually, combining data from both will produce more reliable estimates. The items on EMR supplement are critical toward meeting the President's goal for having most Americans have access to an interoperable EHR by 2014. Some of the questions we hope to answer with the electronic medical record data include (1) what are the predictors of EMR/EHR adoption, (2) do physician practice characteristics (e.g., location, organization type, specialty, vulnerable population mix) and EMR/EHR functionality explain the gaps currently found in EMR/EHR adoption rates, and (3) how much progress are we making toward the national goal over time. Answers to these questions will help the Office of the National Coordinator for health Information Technology (ONC) better understand how to better meet the goal and what obstacles they must overcome for those providers reluctant to adopt such a system.

Laboratory Values

As mentioned in the last section, adding lab value items to the PRF will allow researchers to better understand the extent to which ambulatory health care providers identify and control abnormal values of lipoproteins, blood sugar, and glycohemoglobin before and after diagnosis of cardiovascular disease. There are no other surveys currently collecting these data from non-Federal, office-based physicians or CHSs.

3. Use of Improved Information Technology and Burden Reduction

Respondent burden in NAMCS data collection is minimized through sampling procedures, which are discussed in more detail in items A.5 and B.1. In general, improved information technology would not reduce the NAMCS burden because the recording-keeping systems of different physicians are too diverse to support electronic response. Attempts to implement such technology would actually increase the burden and achieve no resulting improvement to the final data.

The additional sample of physicians for the EMR supplement will use a standard mail-out/ mail-back survey design. Web collection had been used for the CCSS in earlier survey years, but was discontinued due to extremely low participation (5 percent) and high associated cost.

There are no legal obstacles to reducing the burden.

4. Efforts to Identify Duplication and Use of Similar Information

Staff of NCHS have had extensive contacts with organizations and individuals regarding survey items in both the private and public sectors who are familiar with physician utilization data, e.g., the American Medical Association. Over the 30 years since work on NAMCS began, three sources of similar data have been identified and are discussed below.

The National Health Interview Survey (NHIS. OMB No. 0920-0214) is a population-based survey in which information is obtained through household interviews. In addition to the recall problems 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 NAMCS. The NHIS can provide only counts of physician visits and general medical information.

The Medical Expenditures Panel Survey (MEPS) (Agency for Healthcare Research and Quality, OMB No. 0937-0187) is a survey of households and their members' health care providers (including physicians in office-based practice), health insurance companies, and employers. As with the NHIS, household respondents cannot supply detailed medical information. The medical information collected from physician respondents does not include detailed data on specific diagnostic services, medications, and other

therapeutic services. Both the NHIS and the MEPS also experience an unknown degree of reporting bias since it is likely that respondents may be reluctant to report medical contacts for sensitive problems, such as psychiatric disorders and sexually transmitted diseases.

IMS America, Inc., a private organization, conducts a study titled the National Disease and Therapeutic Index (NDTI) that produces data somewhat similar to those collected in NAMCS. These data are focused on the drug prescribing habits of physicians, and results are sold to drug companies for drug marketing purposes. The data collected are limited to only drug data and the corresponding patient's age, sex, and diagnosis; whereas NAMCS collects information on expected source of payment, reasons for visit, and other diagnostic and therapeutic services. Although these data are available for purchase by the government, the cost is prohibitive for most agencies. The data also have limitations that preclude their use for many purposes: data on response rates are proprietary, and may be under 50 percent, and the survey and sampling procedures are of unknown validity. Efforts to obtain such information from IMS America have been unsuccessful.

These information sources are not adequate for needs such as those described in A.2 above. NAMCS allows for greater emphasis on analysis directed toward informing physician decisions on the provision of effective health services, adoption of electronic medical technology, determination of health care workforce requirements, and the improvement of medical education. Furthermore, the depth of data collected in NAMCS about ambulatory patients allows for rich analysis regarding the principal reason for their visits and the resources used in the provision of their medical care.

Although general information is known about CHCs through the Uniform Data System (a mandatory reporting system of characteristics submitted to the Bureau of Primary Health Care at the Health Resources and Services Administration (HRSA)), the continuation of a CHC sample in NAMCS will provide details of the patient/physician encounter not collected elsewhere. Only federally qualified health centers that are funded under Section 330 of the Public Health Service Act are required to submit information to HRSA.

Advice from consultants, attendance at relevant meetings, and literature reviews have been used to identify other sources that collect practice characteristics similar to those collected by NAMCS; however, there has been no other source found that would be able to provide national estimates.

5. Impact on Small Businesses or Other Small Entities

Many NAMCS respondents are physicians in solo practices. In order to reduce respondent burden for these and 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 physician offices and community health centers (CHCs). A sample of patient visits is collected within practices and CHCs to minimize data collection workload. The data reported on each patient visit is limited to data

already obtained by the physician for the patient's medical record and is further limited to a minimum number of items which adequately describe the utilization of ambulatory medical care. The forms are designed to allow check box answers to the extent possible. In addition, the impact of NAMCS on office-based physicians is further reduced by (1) design procedures that limit participation to once every three years, and (2) for all providers, requirements that ask for the collection of forms for a designated one-week period. Because of limitations in sample size, a small number of CHCs may be included in the survey for successive years. Census field representatives (FRs) monitor reporting, and assist physicians/providers and their staff in data collection to the extent possible.

6. Consequences of Collecting the Information Less Frequently

The rapidly changing environment of ambulatory care delivery makes it important to have annual data for decision making, describing the public's use of physician services, monitoring the effects of change, and planning possible changes in payment policies. This information has become even more crucial with the need to track the effects of the health care industry's continued movement toward managed care plans by having continuous data collection before, during, and after the restructuring. To increase reliability, data from NAMCS are often analyzed by combining data across years, and less frequent collection would limit the study of rare visit characteristics. The current design asks a sampled physician/provider to participate for a 1-week period no more than once every 3 years, and only a small proportion of all physicians/providers are included in the survey each year. There are no legal obstacles to reduce the burden.

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

This request fully complies with the regulation 5 CFR 1320. There are no special circumstances affecting this survey.

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

A. Federal Register Notice

This project fully complies with all guidelines of 5 CFR 1320.8(d). The 2009-2012 NAMCS was published for public comment in the Federal Register January 30, 2009, Vol. 74, No. 19, pages 5660-5661 (**Attachment C**).

One public comment was received from the American Nurses Association (ANA) in response to the notice. Comments from the ANA are shown in **Attachment Q**. Their letter's main focus was twofold: (1) stressing the importance of expanding the NAMCS sample to include nurses, and (2) including ambulatory care settings other than physician offices where a majority of medical care is provided by nurses. In addition, this attachment has the NCHS response which was forwarded to the ANA on 4/7/2009.

B. Efforts to Consult Outside the Agency

The core NAMCS has not changed appreciably from the design and data collection summarized in the last 2007-2008 OMB package; the following consultants both within and outside CDC were instrumental at that point. The Office of the Assistant Secretary for Planning and Evaluation (OASPE) was consulted along with other government agencies, such as the Food and Drug Administration, National Institutes of Health, and Centers for Medicare and Medicaid Services. In addition, representatives from the American Medical Association and other major national medical organizations as well as private and public health services researchers were contacted for their input.

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 concerning items to add, delete, or modify on the supplement. Also during this time, considerable consultation was solicited prior to the introduction of the CHC sampling strata. First, The National Association of Community Health Centers (NACHC) worked closely with NCHS in reviewing and providing comments on all the CHC forms and procedures. A meeting was held with individuals identified as having an interest in data collection from CHCs. A total of 15 people attended whose affiliation ranged from the federal government (NCHS, HRSA and the Census Bureau) to professional association (NACHC) to academia (The Johns Hopkins Bloomberg School of Public Health). During this meeting, NCHS presented the methodological plan as well as the survey instrument for comment and discussion. Based on comments received during this meeting and those afterwards, changes were made to the CHC survey instruments. Finally, NCHS met with representatives from the Indian Health Service (IHS) to present our plan for including Indian Federally Qualified Health Centers in the CHC sample. During this meeting, NCHS explained our methodological plan and provided all forms for comment. The IHS commented on the forms and agreed to provide their list of health centers locations.

The additional NCHS sample of office-based physicians for the EMR/EHR mail survey was funded by the Office of the National Coordinator for Health Information Technology (ONC), DHHS. Both ONC and DHHS have worked closely on the development of the EMR/EHR questions currently used in the core NAMCS and used as the basis of the questions asked in the mail survey. Consultation has also taken place with experts from the Robert Wood Johnson Foundation, Massachusetts General Hospital, and The George Washington University.

NCHS will continue to work closely with these individuals and agencies as the need for consultation arises. There are no outstanding unresolved issues. A list containing the names of the consultants is provided in **Attachment D**.

9. Explanation of Any Payment or Gift to Respondents

No payments or gifts are proposed for the 2009-2012 survey. OMB will be notified of any plans to offer payment or gifts in the future.

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 (NCHS legislation),...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.”

Privacy Impact Assessment Information

A. This submission has been reviewed by Information Collection Review Office (ICRO), who determined that the Privacy Act does apply. The applicable System of Records Notice is 09-20-0167. The NCHS Privacy Act Coordinator and the NCHS Confidentiality Officer have also reviewed this package and have determined that the Privacy Act is applicable.

B. The survey is designed so that NCHS receives no identifiable patient information, such as patient names, Social Security numbers, or health identification numbers. The top section of each Patient Record form (PRF), which contains the patient's name and record number, is separated from the bottom section by a perforation running across the page. The top section remains attached to the bottom until the entire PRF is completed. To ensure confidentiality, before collecting the completed PRF, the top section is detached and given to the physician/provider or his/her staff. The field representative instructs the provider 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. Hard copies of the survey forms will be stored in a locked file cabinet in a secure building at NCHS.

Prior to 2003, NAMCS was exempted from IRB review because physician practices 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, a full review of NAMCS protocol was required by the IRB.

The NAMCS data collection plan has been approved by CDC's Institutional Review Board (Protocol #2003-5) based on 45 CFR 46. In addition, the Board has granted (1) a waiver of the requirement to obtain informed consent from the patient, (2) a waiver of the documentation of informed consent by physicians, and (3) in accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Regulation (45 CFR 164.512), a waiver of patient authorization for release of patient medical record data by health care providers.

The IRB letter granting approval for continuation of Protocol #2003-05 NAMCS for the maximum allowable period of one year is presented in **Attachment E**.

In this survey, as in others, NAMCS will include a routine set of measures to safeguard confidentiality, including the following: all staff who have access to confidential information are given instruction by NCHS staff on the requirement to protect confidentiality, and are required to sign a pledge to maintain confidentiality; only such authorized personnel are allowed access to confidential records, and only when their work requires it; when confidential materials are moved between locations, records are maintained to ensure that there is no loss in transit, and personally identifiable information is shipped separately from providers' contact information; and when confidential information is not in use, it is stored in secure conditions.

In keeping with NCHS policy, NAMCS data are made available via public-use data files to the public. Confidential data are never released to the public. All personal identifiers such as physician/provider name, address, patient date of birth, and any other specific information are removed from the public release files. All data releases are reviewed and reviewed by the NCHS Disclosure Review Board to avoid data breaches, such as release of detailed geographic information that may allow anyone to identify practices or individuals in the general population.

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

D. In the introductory letter from the NCHS director, it states that participation in the NAMCS is voluntary. There is no effect on the respondent for not participating. NAMCS data are used to monitor office-based and CHC ambulatory health care utilization. The information is not shared with anyone, although public-use data files are

available on the NAMCS website once individually identifiable information is removed. The legal authority for NAMCS data collection is Section 306 of the Public Health Service Act (42 U.S.C. 242k).

11. Justification for Sensitive Questions

No new sensitive data items are being proposed.

It is necessary for NAMCS to collect some protected and approved health information, such as date of visit, birth date, and ZIP code. These data are used internally to create certain composite variables, such as patient age, which contains 6 mutually exclusive groups. Also, in cases when the Census Bureau abstracts the data from the medical record, the patient's name or address may be viewed in the process of collecting the survey data. Strict procedures are utilized to prevent disclosure of identified NAMCS data. Individual patient names or other identifying information are not collected. At no time are the patients contacted to obtain information. After the data have been collected from the physicians/providers 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 within NCHS to match the visit data to characteristics of the patient's residential area, such as median household income or percent of the population who are high school graduates.

12. Estimates of Annualized Burden Hours and Costs

A. Burden Hours

This submission requests OMB approval for three years of NAMCS data collection. The burden for one complete survey cycle is summarized in the table below. The estimated annualized burden hours were based on previous years' experience in administering the survey, and final data from multiple components of the 2006 NAMCS. The table represents an average for one year of data collection. The average annual burden is 5,932 hours.

Table of Estimated Annualized Burden Hours

Type of Form	Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Hours per Response	Total Burden (Hours)
Core NAMCS forms	Office-based physicians/CHC providers	Physician Induction Interview (NAMCS-1)	3,657	1	28/60	1,707
	Community Health Center Directors	Community Health Center Induction Interview (NAMCS-201)	104	1	20/60	35
	Office-based physicians/CHC providers/staff	Patient Record form (NAMCS-30)	738	30	9/60	3,321
	Office/CHC staff	Pulling, re-filing Patient Record form (NAMCS-30)	650	30	1/60	325
	Office-based physicians/CHC providers/staff	Cervical Cancer Screening Supplement (NAMCS-CCS)	464	1	15/60	116
	Office-based physicians	EMR/EHR Mail Survey	1,143	1	20/60	381
Lab Values Pre-test Forms	Office-based physicians	Physician Induction Interview (NAMCS-1)	23	1	28/60	11
	Office-based physicians/staff	Patient Record form (NAMCS-30)	8	30	9/60	36
	Total					5,932

Core NAMCS

For the core NAMCS, each physician/provider in private practice/CHC is asked to complete an induction form (NAMCS-1) (**Attachment O**), while each Community Health Center director is also asked to complete a CHC induction form (NAMCS-201) (**Attachment N**) (3,657 core physicians/CHC providers, 104 CHCs).

Of the 3,657 physicians/CHC providers in the core NAMCS, an estimated 850 are anticipated to be found ineligible. Of those eligible, a majority of participants will complete Patient Record forms (NAMCS-30) (**Attachment J**) themselves (N=738), while 650 will rely on Census abstractors to complete the forms. In those cases, staff will only pull and re-file the medical records (**Attachment F**). The Patient Record form contains the laboratory data being pretested. If there is a problem, that section will be deleted. Each office submits forms on approximately 30 patients.

Using 2006 data, we estimate that approximately 464 physicians and CHC providers will be asked to complete the CCSS.

In 2008, a total of 1,143 physicians completed the NAMCS mail survey on the use of EMRs/EHRs, and therefore is used as a proxy for anticipated survey cycles.

Attachments G and **H** are instructions and reference materials that support data collection forms. Some elements of these Attachments are completed by the Census Bureau Field Representative (see cover page and page 1 of **Attachment H**), and thus do not enter into the burden calculation for respondents. Other forms are adjunctive tools for respondents (see **Attachment H**, Exhibit C, Patient Visit Worksheet), but are not used as primary data collection instruments.

Laboratory Values Pretest

For the laboratory values pretest, we present an average for one year of data collection, which means that the above estimates are based on 23 physicians (70 total physicians in pretest) who will complete the pretest Physician Induction Interview. Using 2006 data response rates, we expect eight physicians will complete PRFs (on an annualized basis).

B. Burden Cost

The cost to providers for each data collection cycle is estimated to be $335,302. The hourly wage estimates for completing the forms mentioned above in Table 1 along with pulling and re-filing PRFs are based on information from the Bureau of Labor Statistics web site (http://www.bls.gov). Specifically, we used the "May 2007 National Occupational Employment and Wage Estimates" for (1) health care practitioners and technical occupations, and (2) office administrative and support administrative support occupations. Data were gathered on mean hourly wage in 2007 for (1) physicians, mid-level providers (e.g., registered nurses), and other professionals involved in managing a private office-based practice (e.g., nurses, receptionists, etc.) as well as for (2) physicians and mid-level providers at CHCs who will complete the forms (i.e., physician assistants, nurse practitioners, and nurse midwives). The total cost estimate for office-based physicians/CHC providers includes estimates for completing the Physician Induction Interview (NAMCS-1), PRF, CCSS, and EMR/EHR mail survey. The average hourly wage for these respondents is weighted based on the final 2006 NAMCS, which showed who in the office/CHC completed each applicable form; therefore, the estimate of $56.23 is somewhat lower than the average physician salaries presented in the 2007 National Occupational Employment and Wage Estimates. The following table shows how these estimates were calculated.

Table of Annualized Respondent Cost

Type of Respondent	Response Burden (in hours)	Average Hourly Wage	Total Cost
Office-based physicians/CHC providers/staff	5,191	$56.23	$291,890
Office-based physicians, mail survey	381	$87.17	$33,212
Office/CHC staff (pulling & re-filing PRFs)	325	$25.03	$8,135
Community Health Center Directors	35	$59.00	$2,065
Total			$335,302

13. Estimates of Other Total Annual Cost Burden to Respondents or Recordkeepers

For this project there will be no annual capital or maintenance costs to the respondent resulting from the collection of information.

14. Annualized Cost to the Government

The estimate of average annual (one-data cycle) cost to the government for the 2009-2012 survey is as follows:

$3,336,412 Interagency Agreement for data collection with the Bureau of the Census
$ 386,261 Overhead
$ 22,623 Printing
$ 333,958 Contract costs for coding/keying data
$ 645,354 Staff salaries, data processing, printing, overhead, etc.

$ 4,724,608 Total cost for 12 months

15. Explanation for Program Changes or Adjustments

This revision is requesting a program change to decrease the number of hours currently approved. In September 2007, we received approval for 7,207 annual hours. The current approval is lower for three reasons: (1) a more complete review of the documents, (2) the time to complete them has changed, and (3) a slightly different calculation method that took into account the 2006 data as proxies for physician/provider responses. These have resulted in a burden that is 1,275 hours lower than the most recent cycle's estimate. The final requested annual burden is 5,932 hours for 2009-2012.

16. Plans for Tabulation and Publication and Project Time Schedule

The duration of activities for the survey will span 36 months. The timetable for key activities for the 2010 survey is as follows:

8/2009 Receive OMB clearance

9/2009	Submit data collection materials for printing
9/2009	Physician sample selection
11/2009	Begin to send out introduction letters
12/2009	Begin data collection for 2010 survey
12/2010	Formally end reporting period
4/2011	Close out field work
3/2012	End data processing
4/2012	Begin data analysis
6/2012	Publish National Health Statistics Report
7/2012	Public use data available on Internet
3/2013	Publish additional reports

Plans for types of data analyses will parallel the analyses completed for the NHAMCS because a majority of the data items from NAMCS and the outpatient department are the same. 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 the National Health Statistics Reports and Vital and Health Statistics series report. The link for an on-line copy of the 2006 NAMCS summary is http://www.cdc.gov/nchs/data/nhsr/nhsr003.pdf. In addition, a report comparing data from NAMCS and NHAMCS and combining data from both surveys has recently been published. The link for an on-line copy of the 2006 combined NAMCS and NHAMCS summary is http://www.cdc.gov/nchs/data/nhsr/nhsr008.pdf. Finally, NCHS reports examining (1) characteristics of office-based physicians and their practices (on-line copy: http://www.cdc.gov/nchs/data/series/sr_13/sr13_166.pdf) and (2) electronic medical record use by office-based physicians and their practices (on-line copy: http://www.cdc.gov/nchs/data/ad/ad393.pdf) have also been released. A more complete list of studies using NAMCS data are shown in **Attachment B**.

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

An exception for displaying the expiration date 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.