

Supporting Statement A for Request for Clearance:
NATIONAL AMBULATORY MEDICAL CARE SURVEY

OMB No. 0920-0234
(Expires 3/31/2019)

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November 21, 2018

Table of Contents

A. Supporting Statement A.....	5
1. Circumstances Making the Collection of Information Necessary.....	5
2. Purpose and Use of the Information Collection.....	6
3. Use of Improved Information Technology and Burden Reduction.....	8
4. Efforts to Identify Duplication and Use of Similar Information.....	9
5. Impact on Small Businesses or Other Small Entities.....	11
6. Consequences of Collecting the Information Less Frequently.....	11
7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5.....	11
8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency.....	12
9. Explanation of Any Payment or Gift to Respondents.....	12
10. Protection of the Privacy and Confidentiality of Information Provided by Respondents.....	12
11. Institutional Review Board (IRB) and Justification for Sensitive Questions.....	14
12. Estimates of Annualized Burden Hours and Cost.....	15
13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers.....	21
14. Annualized Cost to the Federal Government.....	21
15. Explanation for Program Changes or Adjustments.....	22
16. Plans for Tabulation and Publication and Project Time Schedule.....	22
17. Exceptions to Certification for Paperwork Reduction Act Submissions.....	23

List of Attachments

NAMCS = National Ambulatory Medical Care Survey

CHC = Community Health Center

A. Applicable Laws and Regulations

B. 60-day Federal Register Notice

C1. 2019 NAMCS-1 List of All Proposed Questions for Traditional Office-based Physicians

C2. 2018 Induction Sample Card for Traditional Office-based Physicians

C3. 2019 Induction Sample Card for Traditional Office-based Physicians

C4. 2019 NAMCS-1 List of All Proposed Questions for CHC Providers

C5. 2018 NAMCS-1 Induction Sample Card for CHC Providers

C6. 2019 NAMCS-1 Induction Sample Card for CHC Providers

D. Consultants for 2019-2021 NAMCS

- E1. 2019 NAMCS-201 CHC Service Delivery Site Induction Interview
- E2. 2019 NAMCS-201 CHC Service Delivery Site Induction Interview Sample Card
- F1. 2019 Patient Record Form Sample Card
- G. 2018 NAMCS Reabstraction Study Screenshots
- H. 2018 IRB Continuation of Protocol Approval Letter
- I. 2018-2019 NAMCS Patient Record Form (PRF): Pulling and Re-filing Medical Records
- J. 2018 NAMCS Reabstraction Study: Pulling and Re-filing Medical Records
- K1. 2018 NAMCS Advanced Letters
- K2. 2019 NAMCS Advance Letters
- L. NAMCS Brochure
- M. NAMCS Endorsing Organizational Letters
- N. 2019 NAMCS-PFI MU Physicians
- O. Detailed Description of Burden Row Calculations
- P. 2019 ERB Burden Abstract
- Q. 2019-2021 NAMCS Reinterview Study Questionnaire
- R. 2018 NAMCS FAQs

Supporting Statement

National Center for Health Statistics National Ambulatory Medical Care Survey

- Goal of the study: To assess the health of the population through patient use of physician offices and community health centers (CHCs) and to monitor the characteristics of physician practices.
- Intended use of the resulting data: These data are used to monitor public health, used by DHHS for program planning and to inform national policies, and used by health care researchers, medical schools, policy analysts, congressional staff, the news media, and many others to improve our knowledge of medical practice patterns and patients.
- Methods to be used to collect: A stratified randomized list of sampled providers is generated from a universe of physicians. Basic practice characteristics are collected and these sampled providers are then assigned a pre-determined 7-day reporting period to collect cross-sectional patient visit medical record data.
- The subpopulation to be studied: The subpopulation includes both sampled physicians in private practice and sampled providers who work in CHCs, and patient visits seen by these physicians and providers.
- How data will be analyzed: NAMCS data are weighted and analyzed using appropriate statistical approaches. Public-use files will be made available where possible. Findings will be released in NCHS reports, journal articles, and research papers, as well as released to researchers for analysis.

The National Center for Health Statistics (NCHS) requests approval for a revision of an approved data collection, the ongoing National Ambulatory Medical Care Survey (NAMCS) (OMB No. 0920-0234: Exp. Date 03/31/2019). A revision was approved on 03/14/2016. A non-substantive change was approved on 03/07/2017. The non-substantive approval included the addition of 1,000 physicians who prepare and transmit electronic health records (EHRs) to fulfill Meaningful Use (MU) requirements (i.e., Onboarding) in 2017, and the use of field representatives to abstract all office-based and CHC patient visit data for non-MU participants. The current 3-year request is for the purpose of:

- Continuing survey activities for the 3 years of 2019, 2020, and 2021.
- Discontinuing the prevention and treatment of sexually transmitted infections (STIs) and HIV (STD/PrEP) prevention questions.
- Discontinuing the culturally and linguistically appropriate service questions.
- Discontinuing the alcohol and substance abuse screening and brief intervention questions.
- Increasing the number of office locations sampled physicians' report where they work during their pre-determined sample week (from 5 offices to 10 offices).

- Modifying existing questions for clarification and to keep up-to-date with current medical practice and terminology.
- Deleting a majority of electronic health record (EHR) questions on the physician induction interview and CHC service delivery site induction interview.
- Updating how race and ethnicity are asked of physicians on the NAMCS induction forms, to follow the Department of Health and Human Services guidance on data collection standards for race and ethnicity for self-identification.
- Continue to include the supplemental sample of Meaningful Use (MU) physicians, and increase the sample size for survey years 2020 and 2021.
- Discontinue reabstraction of patient visits (office-based NAMCS physicians/CHC providers); however, we will continue 2018 reabstraction of physicians into the 2019 survey period.
- Conduct a reinterview study for 2019-2021 (office-based NAMCS physicians/CHC providers).

NAMCS is a national survey of both provider characteristics and patient visits to office-based physicians conducted by the Centers for Disease Control and Prevention's National Center for Health Statistics. NAMCS will produce estimates for four Census regions and nine Census divisions. The projected annualized 2019-2021 NAMCS sample size for traditional office-based physicians, MU physicians, and CHC providers is 5,312.

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 2019-2021 study period.

A. Supporting Statement A

1. Circumstances Making the Collection of Information Necessary

Background

The National Ambulatory Medical Care Survey (NAMCS) was conducted intermittently from 1973 through 1985, and annually since 1989. The survey is conducted under authority of Section 306 of the Public Health Service Act (42 USC 242k) (**Attachment A**). A copy of the most recently published Federal Register notice announcing the 60-day public comment period along with public comments can be found in **Attachments B**.

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 include NAMCS, the National Hospital Ambulatory Medical Care Survey (NHAMCS) (OMB No. 0920-0278, Exp. Date 06/30/2021), the National Hospital Care Survey (OMB No. 0920-0212, Exp. Date 01/31/2019), and National Study of Long-term Care Providers (OMB No. 0920-0943, Exp. Date 05/31/2019).

An overarching 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; this fulfills one of NCHS missions, to monitor the nation's health. In addition, NAMCS provides ambulatory medical care data to study: (1) the performance of the U.S. health care system, (2) care for the rapidly aging population, (3) changes in services such as health insurance coverage change, (4) the introduction of new medical technologies, and (5) the use of EHRs. Ongoing societal changes have led to considerable diversification in the organization, financing, and technological delivery of ambulatory medical care. This diversification is evidenced by the proliferation of insurance and benefit alternatives for individuals, the development of new forms of physician group practices and practice arrangements (such as office-based practices owned by hospitals), and growth in the number of alternative sites of care.

Ambulatory services are rendered in a wide variety of settings, including physician offices and hospital outpatient and emergency departments. Since more than 80% of all direct ambulatory medical care visits occur in physician offices, NAMCS provides data on the majority of ambulatory medical care services.

In addition to health care provided in 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 might not be able to afford it otherwise. CHCs are local, non-profit, community-owned health care settings, which serve approximately 23 million individuals throughout the United States. Prior to 2006, visits made to CHCs, although captured

in NAMCS, were not purposely included in the sampling plan; at that time, CHCs did not represent a separate NAMCS stratum. In an attempt to obtain a more accurate picture of health care provided in the United States, a sample of 104 CHCs was included in the 2006 NAMCS panel. There has been annual data collection from CHCs since that time, and these settings will continue to be sampled in 2019-2021.

A major issue that continues to affect NAMCS is the declining participation rate over a number of years. Starting in 2016, some physicians could electronically submit patient data to NCHS. This new data submission method is referred to as “Onboarding.” To encourage the use of Electronic Health Records (EHRs), the government provides financial incentives to physicians and hospitals (providers) who adopt certified EHRs and meet specific reporting objectives (termed Meaningful Use [MU]) through the Medicare and Medicaid Incentive Program. Providers may submit electronic health data to the National Health Care Surveys, including NAMCS, and receive MU credit. The ability to receive MU credit is a major incentive and recruitment tool for NAMCS. Any physician may register with NCHS to receive MU credit and must demonstrate the ability to electronically submit EHR data. Since 2016, many physicians have approached NCHS with an interest in participating in NAMCS using this method. We are proposing to continue to allow physicians to submit electronic data through Onboarding; however, a contractor will now oversee data collection. Transmission of NAMCS MU data will be directly sent to NCHS via Secured File Transmission Protocol (SFTP) through the Secure Access Management Services (SAMS). SAMS is accessed through a website and will provide secure transmission for the NAMCS data submissions.

Beginning in 2018, the Centers for Medicaid and Medicare Services (CMS) concept of Meaningful Use (MU) is now referred to as the Promoting Interoperability (PI) Program but will continue to be referenced as MU for the remainder of this package.

2. Purpose and Use of the Information Collection

The general purpose of this study is to collect information about physician practices, CHCs, 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 CHC providers. The additional items on the NAMCS-1 , the physician interview, will allow research to focus on the following: (1) measurement of electronic health record (EHR) system use and associated system characteristics, (2) adoption rates of financial incentives for the meaningful use (MU) of certified EHR technology to improve patient care, and (3) characterization of the physician workforce including staffing composition of office-based practice, autonomy of advance practice providers, and coordination of care.

NAMCS Office-based Physicians and CHC Providers

Each year, NAMCS provides a range of baseline data on the characteristics of the users and providers of office-based and CHC care. Data collected include the demographic characteristics of patients, reasons for visit, diagnoses, diagnostic services, medications, and visit 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 and CHCs.

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 in-depth analyses of the entire NAMCS data set covering multiple years.

The examples listed below illustrate selected users and uses of NAMCS data, and an extensive list can be found at https://www.cdc.gov/nchs/data/ahcd/namcs_nhamcs_publication_list.pdf.

Selected Journal Articles Using NAMCS Data

- Barnett ML, Linder JA, Clark CR, Sommers BD. Low-Value Medical Services in the Safety-Net Population. *JAMA Intern Med.* 2017 Apr 10. doi: 10.1001/jamainternmed.2017.0401.
- Mafi JN, Wee CC, Davis RB, Landon BE. Association of Primary Care Practice Location and Ownership With the Provision of Low-Value Care in the United States. *JAMA Intern Med.* 2017 Apr 10. doi: 10.1001/jamainternmed.2017.0410.
- Pemberton MR, Bose J, Kilmer G, Kroutil LA, Forman-Hoffman VL, Gfroerer JC. Comparison of NSDUH Health and Health Care Utilization Estimates to Other National Data Sources. *CBHSQ Data Review.* Rockville (MD): Substance Abuse and Mental Health Services Administration (US); 2012-.
- Lau DT, McCaig LF, Hing E. Toward a More Complete Picture of Outpatient, Office-Based Health Care in the U.S. *Am J Prev Med.* 2016 Apr 5. pii: S0749-3797(16)30003-4. doi: 10.1016/j.amepre.2016.02.028.
- Dieleman JL, Baral R, Birger M, Bui A. et al. US Spending on Personal Health Care and Public Health, 1996-2013. December 27, 2016. *JAMA.* 2016;316(24):2627-2646. doi:10.1001/jama.2016.16885

Conferences/Presentations Using NAMCS Data

- Akinseye A, Cherry D. Understanding and Analyzing Ambulatory Health Care Data: The NAMCS & NHAMCS. Presentation at the 2018 Academy Health Annual Research Meeting Pre-Conference Seminar.
- George Washington University, Milken Institute School of Public Health/NCHS U.S. Health Surveys of Households and Care Providers lecture series session for students: “Ambulatory Care: National Ambulatory Medical Care Survey Care Survey (NAMCS) and National Hospital Ambulatory Medical Care Survey (NHAMCS).”

Other Publications Using NAMCS Data

- The Department of Health and Human Services is currently using NAMCS data to evaluate certain Healthy People 2020 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 2020, and NAMCS data support efforts to quantify national improvement.
- 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, such as 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 traditional office-based, physician-only NAMCS sample has produced a better overall picture of the ambulatory care provided in the United States. The traditional office-based physician NAMCS and CHC NAMCS allow us to compare the delivery of health services at non-CHC and CHC settings to understand utilization differences across ambulatory care settings. Also, 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.

Although the 2016-2017 MU data is still in the process of being edited within NCHS and is currently not in a format suitable for data release, the plan is to eventually combine MU visit data (from EHR systems) with its abstracted visit data counterpart from traditional physicians. Combining this data will provide a more analytically rich data set for researchers within both NCHS and those wishing to access the data at our Research Data Center.

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 section A12.

Electronic Data Collection

A move to electronic collection has significantly reduced the burden for NAMCS respondents

when answering both the NAMCS-1 and CHC induction interview questions. Using a computer-assisted interviewing instrument for the induction interview allows the U.S. Census Bureau field representatives (FRs) to automatically skip unnecessary questions, reduce incorrect or inconsistent entries, and reduce the need for paper flashcards that highlight item choices. The end result is that the time that a respondent spends during the induction interview is reduced.

Use of a computerized data entry system for the patient record form (PRF) significantly simplifies the data collection activities by reducing data entry errors and omissions, as well as providing on-screen look-up tables for items such as reason for visit, diagnosis, and medications. Overall, using a computerized data entry system reduces FR and respondent burden, and ultimately improves overall data quality. In addition, collecting the data electronically speeds up editing, transmission, and processing, thereby making release of the yearly data files and statistics more timely.

Meaningful Use NAMCS Participation

Since 2016, physicians have been given the option to submit electronic health record patient data to NCHS. This new data submission method is referred to as “Onboarding.” To encourage the use of EHRs, the federal government provides financial incentives to physicians and hospitals who adopt certified EHRs and meet specific reporting objectives (i.e., meaningful use [MU]) through the Centers for Medicare and Medicaid Services’ (CMS) EHR Incentive Program. Physicians and hospitals may submit electronic health data to the National Health Care Surveys, including NAMCS, and receive MU credit from CMS. The ability to receive MU credit is a major incentive and recruitment tool for NAMCS. Any physician may register with NCHS to receive MU credit. After a physician registers, a determination will be made by NCHS staff as to whether the physician is part of the NAMCS sample or not. To successfully complete participation, sampled physicians must demonstrate the ability to electronically submit EHR data. Non-sampled physicians are not asked to submit EHR data. Data elements about the physician and facility are requested of sampled physicians. In addition, all sampled physicians will be invited to a testing and validation stage, and ultimately to submit EHR data. All MU registered sampled physicians will be asked to provide data on all patient visits for a designated reporting week. Data received from sampled physicians will be evaluated, and if acceptable, will be added to the NAMCS data set. For eligible non-sampled physicians, receiving their EHR data will be dependent on NCHS data storage capabilities; however, it is anticipated that in time NCHS will accept data from all eligible non-sampled physicians who register with NCHS for MU credit.

While sampled and non-sampled physicians are asked to participate in NAMCS, they will be informed about Health Insurance Portability and Accountability Act (HIPAA) research disclosure requirements. Physicians or groups expressing interest in submitting data will be provided with guidance on how to submit the data. The guidance will include explicit statements that the data submitted to NCHS will be used for research purposes, and they will need to include NAMCS in the list of research disclosures provided to their patients (if requested). Physicians or groups submitting data will be asked to remove all direct personal identification information (PII) (e.g., patient name, address, cell phone, work phone, home phone, and e-mail) prior to

transmitting the data to NCHS. If removal of the direct PII is too burdensome for the physicians, NCHS will remove it upon receipt.

It is anticipated that 33% of sampled NAMCS physicians will participate in this new program. There are no legal obstacles to reducing the burden. Justification for including and increasing the MU physician component for the 2020-2021 NAMCS samples is presented in Supporting Statement B, section B.1.

4. Efforts to Identify Duplication and Use of Similar Information

NCHS staff have had extensive contacts regarding survey items with organizations and individuals in both the private and public sectors who are familiar with physician utilization data (e.g., the American Medical Association). Over the 40 years since NAMCS began, three sources of similar data have been identified and are discussed below.

The National Health Interview Survey (NHIS; OMB No. 0920-0214, Exp. Date 12/31/2020) 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. NHIS can provide only counts of physician visits and general medical information.

The Medical Expenditures Panel Survey, or MEPS (Agency for Healthcare Research and Quality, OMB No. 0935-0118, Exp. Date 12/31/2018), is a survey of households and their members' health care providers (including physicians in office-based practice), health insurance companies, and employers. As with 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 NHIS and 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 or 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 NDTI 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 the survey and sampling procedures are of unknown validity. Efforts to obtain such information from IMS America, Inc. have been unsuccessful.

These data sources are not adequate for needs such as those described in section 2 above. NAMCS allows for greater emphasis on analysis of the provision of effective health services, adoption of electronic health technology, determination of health care workforce requirements,

and improvement of medical education. Furthermore, the depth of data collected in NAMCS about ambulatory patients allows for rich analysis regarding the principal reason for patients' 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

A number of NAMCS respondents are physicians in solo practices. In order to reduce respondent burden for these and all respondents, several data collection methods are used. These methods are designed to be flexible to meet the varied reporting and record-keeping situations found in physician offices and CHCs. Only 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 that s/he recorded on the patient's medical record, and is further limited to a minimum number of items which adequately describe the utilization of ambulatory medical care. In addition, the impact of NAMCS on office-based physicians is further reduced by: (1) design procedures that limit participation to no more than once every three years, and (2) for all providers, requirements that ask for the collection of abstracted patient record form (PRF) (**Attachment F1**) data for a designated one-week period. Because of limitations in population size, a small number of CHCs may be included in the survey for successive years. U.S. Census Bureau field representatives (FRs) complete abstraction themselves in order to further minimize burden.

A reduction in NAMCS respondent burden is further noted for office-based MU physicians. Specifically, we estimate that 90% of MU physicians work in large medical conglomerates and will not be personally involved in submitting a NAMCS Physician Facility Interview (PFI) (**Appendix N**) or EHR visit data. Further, we estimate that the remaining MU physicians work in small medical practices and will submit data themselves; however, they will only need to complete a NAMCS-PFI and identify, prepare, and transmit EHR for a specified week of practice. Even in these cases, we expect that many MU physicians in small practices will have their staff work on NAMCS tasks.

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 changing arrangements for delivering care, 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. 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 three 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 1320.5.

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

Federal Register Notice

This project fully complies with all guidelines of 5 CFR 1320.8(d). A 60-day Federal Register Notice was published in the Federal Register on XX, 2018 (**Attachment B**).

Efforts to Consult Outside the Agency

Within the past 4 years, the following consultants both within and outside CDC were instrumental to the development of NAMCS. The Health Resources and Services Administration (HRSA) reviewed the CHC facility and provider induction questions, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) was consulted along with other government agencies, such as the Centers for Medicare and Medicaid Services (CMS) and, NCHS also collaborated with the U.S. Census Bureau to implement various components of the computerized data collection instruments.

NCHS will continue to work closely with these individuals and agencies as the need for consultation arises. Currently, there are no outstanding unresolved issues. A list containing the names of the consultants for 2019-2021 is provided in **Attachment D**.

9. Explanation of Any Payment or Gift to Respondents

NAMCS will not offer a payment or gift to respondents for participation. Any future plans to offer payment or gifts would be submitted to OMB for review and potential approval.

10. Protection of the Privacy and Confidentiality of Information

Provided by Respondents

This submission has been reviewed by Information Collection Review Office (ICRO), who determined that the Privacy Act does apply. The NCHS Privacy Act Coordinator and the NCHS Confidentiality Officer have also reviewed this package and have determined that the Privacy Act is applicable because this study includes the collection of information in identifiable form. The applicable System of Records Notice is 09-20-0167 Health Resources Utilization Statistics.

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:

“We take your privacy very seriously. All information that relates to or describes identifiable characteristics of individuals, a practice, or an establishment will be used only for statistical purposes. NCHS staff, contractors, and agents will not disclose or release responses in identifiable form without the consent of the individual or establishment in accordance with section 308(d) of the Public Health Service Act (42 U.S.C. 242m(d)) and the Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA, Title 5 of Public Law 107-347). In accordance with CIPSEA, every NCHS employee, contractor, and agent has taken an oath and is subject to a jail term of up to five years, a fine of up to \$250,000, or both if he or she willfully discloses ANY identifiable information about you.

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.”

Information in Identifiable Form (IIF)

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 information in identifiable form (IIF). A list of all IIF data items is highlighted below, and all were approved by OMB in the previous packages to be collected on survey forms. None of these data are released to the public or become part of public-use files. All forms are automated for data collection by the FR or sampled physician.

The automation of the survey eliminates the need to record potentially identifiable information on paper. Medical record numbers are entered into the computerized instruments, but will only be used for survey operations purposes. The medical record number will aid Census FRs in

abstracting data from the various record systems in the facility. The medical record number may also be used during reabstraction efforts (2018 carry-over fieldwork) to verify the quality of initial abstraction and assure interviewer verity. Once the case is complete and the data are ready to be transmitted to NCHS, the medical record number will be wiped from the dataset and will not be retained beyond that time.

Information in Identifiable Form Categories:

- Physician/CHC provider name
- Physician/CHC provider mailing address
- Physician/CHC provider telephone number
- Physician/CHC provider National Provider identifier (NPI)
- Physician/CHC provider Federal Tax ID/EIN
- CHC executive director name
- CHC mailing address
- CHC contact person
- Physician office/CHC staff name
- Patient medical record number
- Patient date of birth

NAMCS will include a routine set of measures to safeguard confidentiality, including the following: all staff, including contractors at the U.S. Census Bureau and other contractors, 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; and only such authorized personnel are allowed access to confidential records, and only when their work requires it. When confidential information is not in use, it is stored in secure conditions. The FR enters patient medical record data directly into his or her assigned laptop alone and nowhere else. Once the data collection is completed, the FR electronically transmits the data onto a secure server and the data are wiped from the FR's laptop. As mentioned earlier, transmission of NAMCS MU data will be directly sent to NCHS via Secured File Transmission Protocol (SFTP) through the Secure Access Management Services (SAMS). SAMS is accessed through a website and will provide secure transmission for the NAMCS data submissions.

In keeping with NCHS policy, NAMCS data are made available via public-use data files on the NAMCS website once individually identified information is removed. 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 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.

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

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

The NAMCS data collection plan has been approved by NCHS's Research Ethics Review Board (ERB) (Protocol #2016-03) 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. In the introductory letter from the NCHS Director, it states that participation in NAMCS is voluntary; there is no effect on the respondent for not participating. The Research Ethics Review Board's letter granting approval for continuation of Protocol #2016-03 NAMCS for the maximum allowable period of one year is presented in **Attachment H**.

While there are some personally identifiable information collected within this survey, none of the questions are of a sensitive nature.

12. Estimates of Annualized Burden Hours and Cost

Burden Hours

This submission requests OMB approval for three years of NAMCS data collection, 2019-2021. The annualized burden for one complete survey cycle (plus the completion of 2018 data collection) is summarized below in Table 1. Continuing from past submissions, NAMCS activities were divided into office-based physicians and CHCs. As described earlier, the office-based physicians have a subgroup of MU physicians, those who submit a modified induction instrument and patient visit data through their EHR system. In this submission, we are increasing the number of MU physicians for survey years 2020-2021. Burden associated with a newly proposed reinterview study has been added to the end of Table 1.

Several assumptions related to response rates are made for Table 1 calculations, and since these assumptions are relatively stable across survey years, some were replicated from past OMB packages. Specifically, the modifications factored into the table are based on: (1) assumptions from the last approved 2016-2018 non-substantive OMB change package, (2) 2013 NAMCS survey data, and (3) recent correspondence from our data collection agent, the U.S. Census Bureau.

Rows indicating 2018 survey year forms (and associated burden) are included in Table 1 below because it is estimated that about one-third of the 2018 survey activities will continue into the first quarter of 2019. The assumptions for determining 2018 row burdens are the same as 2019 burden assumptions described below. For these 2018 cases, we are assuming the continued activities to include the following participants (annualized): (1) 333 traditional office-based physicians (3,000 physicians * .333; 999 physicians/3 years), (2) 12 CHC sites (104 CHC sites * .333; 35 CHCs/3 years), (3) 36 CHC providers (12 CHC sites * 3 CHC providers), and (4) 10 physicians/CHC providers anticipated for reabstraction (10 providers/3 years).

General Background on Expected 2019-2021 Participation

Office-based/MU Physicians

Approximately 3,000 traditional office-based physicians will be selected into the sample annually. However, due to changes in physician practices between the time the sample was drawn and data collection, we estimate that only 62% of these physicians will remain eligible for the survey. Further, previous NAMCS data suggests that 59% of eligible physicians will complete the NAMCS-1 (**Attachment C1**), but not necessarily complete patient record forms (PRFs) (**Attachment F1**), as a physician can complete a NAMCS-1 without necessarily submitting PRFs. The proposed burden associated with answering the NAMCS-1 (30 minutes) has been reduced from 45 minutes due to the removal of three question blocks as described earlier in this package. General assumptions for traditional physicians include the following:

- Three-year sample average: 3,000 for traditional physicians.
- Assume 62% of average number of traditional physicians will be eligible: $62\% * 3,000 = 1,860$.
- Assume 59% of eligible traditional physicians (based on 2013 NAMCS response rate) will complete NAMCS-1 induction interviews: $59\% * 1,860 = 1,097$.
- Assume 48% of eligible traditional physicians (based on 2013 NAMCS response rate) will participate and provide at least one PRF that will be pulled and re-filled by their staff: $48\% * 1,860 = 893$. (Within the burden table, the pulling of the PRFs for office-based physicians represents 447 hours.)
- Assume FRs abstract 100% of PRFs for traditional physicians: 893.
- Assume 25% of sampled physicians will complete a NAMCS-1 themselves; 75% of sampled physicians will have their staff complete the NAMCS-1. Only staff will pull and re-file PRFs for abstraction.

NAMCS proposes to increase the sample size of physicians who have registered to participate in the Meaningful Use program in hopes of improving the response rate. We plan to sample the following MU physicians (by sample year): 2019-0 physicians, 2020-3,000 physicians, and 2021-3,000 physicians. MU physician staff will complete the NAMCS-PFI, a reduced induction questionnaire similar to the NAMCS-1 referenced above (**Attachment N**). The burden associated with completing the NAMCS-PFI for an annual average of 2,000 physicians is 45 minutes. The only other burden associated with submitting visit data will be preparing and transmitting electronic health record (EHR) files (60 minutes total for staff associated with each sampled MU physician). General assumptions for MU physicians include the following:

- Three-year MU sample average: 2,000 physicians.
- Assume 100% of MU physicians will be eligible and agree to participate in NAMCS.
- Assume 10% of MU physicians work in small medical practices, and 90% will work in large medical conglomerates. In both cases, we are further presume that none of the sampled MU physicians will be personally involved in submitting either a NAMCS-PFI induction or EHR visit data; all burden associated with MU participation will be with their staff.

Community Health Centers

It is anticipated that approximately 104 CHC service delivery sites will be asked to participate, and historically most executive/medical directors have completed the induction interview for the service delivery site (NAMCS-201) (**Attachment E1**). Up to 3 providers can be sampled at each CHC site, and for this package, we are assuming all 3 will be selected and complete the induction interview designed specifically for CHC providers (NAMCS-1) (**Attachment C4**). This interview will take about 30 minutes for the 312 physicians. General assumptions for CHC sites and providers include the following:

- Three-year sample average: 104 CHC service delivery sites.
- Assume 100% response rate of all sampled CHC service delivery sites executive/medical directors will complete a NAMCS-201 induction interview= 104.
- Assume 3 CHC providers (out of 3 maximum) per CHC sampled site choose to participate and complete NAMCS-1 induction interviews = $3 * 104 = 312$.
- Assume FRs abstract 100% of PRFs from CHC providers = 312.
- The staff of the CHC providers will pull and refill approximately 30 PRFs each (156 hours).
- All sampled CHC providers will complete the NAMCS-1 themselves.

Medical Record Abstractions

Once the office-based physician and community health center provider interviews are completed, they will be asked to draw and provide a sample of visits from medical records that will be abstracted by the NCHS contractor, the U.S. Census Bureau. It is estimated that approximately 48%, or 893 eligible office-based physicians and 312 CHC providers will agree to have their staff pull and re-file records for 30 patients annually (**Attachment I**). It is anticipated that each file takes about one minute to locate and pull. There is no burden to the physician or CHC provider for the actual work of abstracting, as that is being completed by the Census field representatives (FRs).

Reinterview Study

Beginning in 2019 and continuing through 2021, approximately 100 physicians and CHC providers combined will be asked to participate yearly in a newly developed NAMCS reinterview study that will be replacing the current reabstraction study. This study will use the Data Retrieval Adobe Management System (DReAMS). This proposed system is semi-automated and is currently used for many of the Census Bureau's smaller surveys, where the cost for a fully automated reinterview process is not within budget. Mathematical statisticians within Census' Demographic Statistical Methods Division (DSMD) are going to develop the tool using MS Access that will utilize contact information from the current FR production instrument and generate a form in the instrument that clerks in the Census ROs will use to conduct the reinterview. The currently proposed questions asked would be based on the standard reinterview questions Census uses for all surveys (**Attachment Q**) and modified based on the NAMCS/NHAMCS goals.

Census will use this information for two main purposes. The first is to generate some very basic reports, created on a quarterly basis by DSMD to provide the team at Census and at NCHS with general results highlighting any gross inconsistencies. A more thorough, analytical report would then be created at the end of each survey year. The second use of the data at Census will be to assess and then follow-up on Census FR falsification. This process is being developed at Census, however, they are proposing to do reinterview on one case per NAMCS FR per year.

The major benefit to implementing reinterview for NCHS is that the process will hopefully guard against interviewer falsification. Currently, NAMCS and NHAMCS are the few remaining Census computerized surveys that do not have such a check. Reinterview means Census can continue to have a quality assurance process around NAMCS and NHAMCS data collection, and do so within the budget for the 2019-2021 panels.

A portion of the 2018 reabstraction study will continue into the 2019 survey year. There should be no burden for these sampled providers because only their staff will pull and re-file approximately ten medical records each (**Attachment J**).

In total, the estimated annualized burden for the NAMCS data collection activities is 5,039 hours. As mentioned earlier, several assumptions were made for the burden calculations in Table 1.

Description of Each of the Rows in the Newly Proposed Table 1 Burden

The numbers indicated below represent an estimated annualized average for survey years 2019-2021.

Row 1. Data collection for 122 traditional physicians (or staff) from the 2018 sample will continue into 2019, and they will complete the 2018 NAMCS-1 induction questions (61 hours) (**Attachment C2**).

Row 2. 1,097 traditional physicians (or staff) will complete the NAMCS-1 induction questions (549 hours) (**Attachment C1**).

Row 3. Staff from 99 offices sampled in 2018 will pull and re-file records into 2019 so the data collection agent can continue to abstract (50 hours) (**Attachment I**).

Row 4. Staff from 893 offices will pull and re-file records for the data collection agent to abstract (447 hours) (**Attachment I**).

Row 5. 2,000 staff associated with sampled MU physicians will complete the NAMCS-PFI induction questions (1,500 hours) (**Attachment N**). The anticipated burden per respondent associated with the completion of the MU physician induction interview (NAMCS PFI: 45 minutes) is slightly longer than the time to complete the more detailed induction interview by traditional office-based physicians (NAMCS1: 30 minutes). This difference is assumed to be attributed to the fact that in most MU cases, a representative of the sampled MU physician will

be completing the NAMCS-PFI, and this person will most likely need to do some research before answering the questions.

Row 6. Staff from 2,000 offices (representing MU physicians) will pull and re-file EHRs that will be sent to NCHS (2,000 hours) (**Attachment P**).

Row 7. Data collection for 12 CHC administrators from the 2018 sample will continue into 2019, and they will complete the 2018 NAMCS-201 induction questions (6 hours) (**Attachment C5**).

Row 8. 104 CHC executive/medical directors will complete the NAMCS-201 induction questions (52 hours) (**Attachment E1**).

Row 9. Data collection for 36 CHC providers from the 2018 sample will continue into 2019, and they will complete the 2018 NAMCS-1 induction questions (18 hours) (**Attachment C5**).

Row 10. 312 CHC providers will complete the NAMCS-1 induction questions (156 hours) (**Attachment C4**).

Row 11. CHC staff associated with 36 CHC providers from the 2018 sample will pull and re-file records into 2019 so the data collection agent can continue to abstract (18 hours) (**Attachment I**).

Row 12. CHC staff associated with 312 CHC providers will pull and re-file records that the data collection agent will abstract (156 hours) (**Attachment I**).

Row 13. Staff from the offices of 3 physicians from the 2018 sample will continue into 2019 to pull and re-file records that the data collection agent will reabstract for the Reabstraction Study (1 hour) (**Attachment I**).

Row 14. Staff from the offices of 100 physicians and CHC providers will complete a brief series of follow-up questions for the Reinterview Study (25 hours) (**Attachment Q**).

Table 1-Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)
Traditional Office-based Physicians or Staff	2018 Physician Induction Interview (NAMCS-1)	122	1	30/60	61
	2019+ Physician Induction Interview (NAMCS-1)	1,097	1	30/60	549
	2018 Pulling, re-filing medical record forms (FR abstracts)	99	30	1/60	50

	2019+ Pulling, re-filing medical record forms (FR abstracts)	893	30	1/60	447
MU Office-based Physician Staff	2019+ MU Physician Induction Interview (NAMCS-PFI)	2,000	1	45/60	1,500
	2019+ Pulling, re-filing medical record forms (MU Onboarding)	2,000	1	60/60	2,000
Community Health Center Executive/Medical Directors	2018 Induction Interview – service delivery site (NAMCS-201)	12	1	30/60	6
	2019+ Induction Interview – service delivery site (NAMCS-201)	104	1	30/60	52
Community Health Center Providers	2018 Induction Interview – Providers (NAMCS-1)	36	1	30/60	18
	2019+ Induction Interview – Providers (NAMCS-1)	312	1	30/60	156
Community Health Center Provider Staff	2018 Pulling, re-filing medical record forms (FR abstracts)	36	30	1/60	18
	2019+ Pulling, re-filing medical record forms (FR abstracts)	312	30	1/60	156
Traditional Physician Office-based and Community Health Center Staff	2018 Pulling, re-filing medical record forms (FR abstracts) for the Reabstraction Study	3	10	1/60	1
Traditional Physician Office-based and Community Health Center Staff	2019+ Reinterview Study	100	1	15/60	25
Total					5,039

Burden Cost

The cost to providers for each data collection cycle is estimated to be \$185,977. This is a slight decrease of \$39,437 from the current estimate of \$225,414 that was submitted in the last non-substantive OMB change package. The decrease in annualized cost is due to a slightly more conservative set of calculations of who will complete the NAMCS forms. The hourly wage

estimates for completing various NAMCS forms and activities used in the table below are based on information obtained from the Bureau of Labor Statistics (BLS) web site (<http://www.bls.gov>). Specifically, we used the "May 2017 National Occupational Employment and Wage Estimates" for the categories including (1) management occupations, (2) healthcare practitioners and technical occupations, and (3) office and administrative support occupations.

Data were gathered on mean hourly wages in 2017 for (1) physicians, (2) advanced practice providers (i.e., physician assistants, nurse practitioners, and nurse midwives) providing care at CHCs, and (3) other professionals involved in managing either a private office-based practice or a CHC (e.g., nurses, receptionists, etc.). The total cost estimate for NAMCS is detailed by the type of respondent who will complete the associated components of the survey. Specifically, the respondent costs include estimates for completing the physician induction interview items (NAMCS-1 & NAMCS-PFI), CHC facility induction items (NAMCS-201), and pulling and re-filing medical records/submitted EHR files.

Overall, the average hourly wages presented in Table 2 were averaged across different specialties, and who may complete each applicable form. The numbers indicated below represent an estimated annualized respondent cost for survey years 2019-2021. Please see **Attachment O** for a detailed description (by row) of how each average hourly wage for each respondent was determined.

The following table shows the breakdown of the total annual respondent cost.

Table 2-Annualized Respondent Cost

Type of Respondents	Form Name	Total Burden Hours	Average Hourly Wage Rate	Total Respondent Costs
Traditional Office-based Physicians	Physician Induction Interview (NAMCS-1)	152	\$103.65	\$15,755
Traditional Office-based Physician's Staff	Physician Induction Interview (NAMCS-1)	458	\$32.16	\$14,729
Traditional Office-based Physician's Staff	Pulling, re-filing medical record forms (FR abstracts)	497	\$32.16	\$15,984
MU Physician's Staff	Physician Induction Interview (NAMCS-PFI) & Prepare and transmit EHR visit data	3,500	\$32.16	\$112,560
Community Health Center Executive/Medical Directors	Induction Interview – service delivery site (NAMCS-201)	58	\$90.52	\$5,250
Community Health Center Providers	Induction Interview – Providers (NAMCS-1)	174	\$87.74	\$15,267
Community Health Centers Provider Staff	Pulling, re-filing medical record forms (FR abstracts)	174	\$32.16	\$5,596
Traditional Physician Office-based and Community Health Center Staff	Pulling, re-filing medical record forms (FR abstracts) for the Reabstraction Study	1	\$32.16	\$32
Traditional Physician Office-based and Community Health Center Staff	Reinterview study	25	\$32.16	\$804
Total				\$ 185,977

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

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 Federal Government

The estimate of average annual (one-data cycle) cost to the government for the 2019-2021 survey is \$9,313,341.

Expense Description	Total Cost
Interagency Agreement for data collection with the U.S. Census Bureau	\$5,000,000
Printing	\$10,901
Contract costs for coding and keying data	\$500,000
Contract costs for collecting and processing MU data	3,000,000
Sponsoring agency expenses: Staff salaries, benefits, other miscellaneous costs	\$802,440
Total cost for 12 months	\$ 9,313,341

15. Explanation for Program Changes or Adjustments

The increase in sample size, specifically MU physicians, and the inclusion of a reinterview study will increase the requested burden by 2,370 hours from the 2,669 total hours reported in the most previously approved non-substantive change package. The total NAMCS burden will now equal 5,039 hours.

16. Plans for Tabulation and Publication and Project Time Schedule

The duration of activities for core NAMCS (traditional office-based physicians and CHCs) will span 12 months. The desired timetable for key activities for the 2019 survey is as follows:

Steps	Timeline	Activity
1	Within one month of OMB approval	Begin data collection for 2019 survey
2	One year after OMB approval	Formally end reporting period
3	Three months after reporting period ends	Close out fieldwork
4	One year and five months after OMB approval	Begin cleaning and weighting
5	One year and six months after OMB approval	Begin data analysis

6	Two years after OMB approval	Public-use data available on Internet Publish reports and on-line data summary tables
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Plans for types of data analyses will parallel the analyses completed for the NHAMCS. For example, data will be presented in the following tables: patient visits by age, sex, and race/ethnicity; expected source(s) of payment; principal reason for visit; primary diagnosis; diagnostic service; disposition; and provider type seen. The National Center for Health Statistics (NCHS) publishes the data on the Internet and in various *NCHS Data Briefs* and other reports.

The most recent NAMCS *Data Brief* titled “Mental Health-related Physician Office Visits by Adults Aged 18 and Over: United States, 2012-2014” can be found on-line at: <https://www.cdc.gov/nchs/data/databriefs/db311.pdf>

Highlights from each new survey year of NAMCS and NHAMCS data are featured in the *NCHS Data Brief* series, which can be found on-line at: <https://www.cdc.gov/nchs/products/databriefs.htm>.

The standard tables from the traditional summaries, referred to as *Summary Tables*, will continue to be produced in PDF format on the web. The NAMCS 2015 *Summary Tables* are available at: https://www.cdc.gov/nchs/ahcd/web_tables.htm#2015.

Other tables are also available, some combining data across surveys or across years. Finally, NCHS reports examining (1) characteristics of visits to primary care physicians by adults diagnosed with hypertension (available at: <https://www.cdc.gov/nchs/data/nhsr/nhsr106.pdf>) and (2) “Characteristics of Primary Care Physicians in Patient-centered Medical Home Practices: United States, 2013” (available at: https://www.cdc.gov/nchs/data/nhsr/nhsr101_table.pdf) have also been released.

17. 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.