

Supporting Statement A for Request for Clearance:  
NATIONAL AMBULATORY MEDICAL CARE SURVEY  
SUPPLEMENT on Culturally and Linguistically Appropriate Services

OMB No. 0920-NEW

Contact Information:

Carol DeFrances, Ph.D.  
Chief, Ambulatory and Hospital Care Statistics Branch  
Division of Health Care Statistics  
National Center for Health Statistics/CDC  
3311 Toledo Road  
Hyattsville, MD 20782  
301-458-4440  
301-458-4032 (fax)  
[csd0@cdc.gov](mailto:csd0@cdc.gov)

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## Supporting Statement

### National Ambulatory Medical Care Survey Supplement on Culturally and Linguistically Appropriate Services

- Goal of the study: To describe cultural and linguistic competency and the provision of the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (the National CLAS Standards) among office-based physicians regionally and nationally in the United States. Culturally and linguistically appropriate services (CLAS) are respectful of and responsive to individual cultural health beliefs and practices, preferred languages, health literacy levels, and communication needs.
- Intended use of the resulting data: To help medical school educators, physicians, health care organizations, researchers and policymakers understand cultural and linguistic competency, CLAS adoption, and associated system characteristics as well as progress towards OMH program goals measurement.
- Methods to be used to collect data: Data will be collected directly from a sample of office-based physician respondents through a self-administered web questionnaire, self-administered paper questionnaire or telephone interview.
- Subpopulation to be studied: Non-federally employed office-based physicians.
- How data will be analyzed: Data will be weighted to provide regional and national estimates.

The Centers for Disease Control and Prevention’s (CDC) National Center for Health Statistics (NCHS) is requesting approval to conduct a new information collection, the National Ambulatory Medical Care Survey Supplement on Culturally and Linguistically Appropriate Services (NAMCS CLAS). Although this will be a component of the ongoing National Ambulatory Medical Care Survey (NAMCS) (OMB No. 0920-0234, Expires 12/31/17), the NAMCS CLAS will have its own clearance and sample. This submission represents a new information collection request package for 1 year of OMB approval to cover data collection.

## **A. Justification**

### **1. Circumstances Making the Collection of Information Necessary**

#### Background

The Centers for Disease Control and Prevention’s (CDC), National Center for Health Statistics, is requesting approval from OMB to collect information on cultural competence and the awareness of the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (the National CLAS Standards) within non-federal physicians’ offices. Culturally and linguistically appropriate services are respectful of and responsive to individual cultural health beliefs and practices, preferred languages, health literacy levels, and communication needs. The project is sponsored by the Office of Minority Health (OMH), Office of the Secretary (OS), Department of Health and Human Services (HHS).

The National CLAS Standards in Health and Health Care were established in 2000 by the OMH to advance health equity, improve quality, and eliminate health care disparities. In 2013, OMH published the enhanced National CLAS Standards in order to reflect advancements made since 2000 release, expand their scope and improve their clarity to ensure better understanding and implementation. Although there has been increased awareness and efforts to train culturally and linguistically competent health care providers, there has not been a nationally representative data collection to capture the level of adoption or implementation of the National CLAS Standards among this group. Due to the limited understanding of how the Standards are adopted and implemented it is difficult to know what goals have been achieved and which need more work. The NAMCS CLAS will be the first to collect these data elements to yield national and regional estimates. The data elements have been developed with NCHS and OMH advisors.

We are requesting approval to:

- Collect 2016 data on CLAS from a national sample of office-based physicians.
- Submit a revision for subsequent data collection if funding allows and there is sufficient justification.

A one-year clearance is requested. 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 one year study period.

Authorization:

Section 306 of the Public Health Services Act (41 U.S.C. 242) authorizes the collection of these data. Please see **Attachment A** for a copy of this legislation.

## **2. Purpose and Use of Information Collection**

The general purpose of this study is to collect information about the provision of culturally and linguistically appropriate services among office-based physicians. The resulting published statistics and data sets will help medical school educators, physicians, health care organizations, researchers and policymakers understand cultural and linguistic competency, CLAS provision, and associated characteristics as well as progress towards OMH program goals.

The target universe of NAMCS CLAS will include non-federally employed physicians who were classified by the American Medical Association (AMA) or the American Osteopathic Association (AOA) as providing “office-based, patient care” or by AMA as being “hospital employed.” Physicians in the specialties of anesthesiology, radiology, and pathology will be excluded.

The NAMCS CLAS will be a self-administered web questionnaire, self-administered paper questionnaire or telephone interview. Recruitment will be by mail and telephone. Telephone interviews will be the follow-up alternative for non-respondents.

Eligibility will be determined based on responses to screening questions that the physician currently practices in an office-based setting (question 3) and typically provides care to the most patients in a solo or group practice, freestanding clinic or urgent care center, community health center, mental health center, non-federal government clinic, family planning clinic, health maintenance organization or faculty practice plan (question 4). The respondent is asked to select all settings that apply in question 4.

A description of the Information to be collected

The NAMCS CLAS will collect information to describe the provision of culturally and linguistically appropriate services among ambulatory care physicians. The specific data that will be collected on the NAMCS CLAS include:

- Demographics & Practice characteristics
  - Number of years the physician has provided direct patient care (includes residency)
  - Specialty
  - Sex
  - Ethnicity
  - Race
  - Email address
  - County, state and zip code of primary setting
  - Primary practice setting (e.g. solo or group practice, community health center, etc.)
- Training & Policy
  - Cultural competency training (e.g. frequency, motivation for training, topics covered)

- Practice policy regarding culturally and linguistically appropriate services
- Services provided & Practice climate regarding CLAS
- Free language-assistance, use of interpreters, materials in languages other than English or for limited English literacy
  - Record of language or cultural characteristics of patients
  - Consideration of patient cultural characteristics during diagnosis, treatment, and health education
  - Factors that aid or impede provision of culturally and linguistically appropriate services
- National CLAS Standards
- Familiarity with National CLAS Standards
  - Practice adoption of National CLAS Standards

No individual patient data will be collected.

Please see **Attachment C** for a list of questions that will be used for data collection and **Attachment D** for the phone script.

The collected information will have multiple applications. It will be used to describe cultural and linguistic competency, CLAS adoption and associated system characteristics as well as progress towards achievement of OMH program goals. The information collected from this project will also be used to identify strengths and areas of improvement for policy surrounding the Standards themselves, and will inform future promotion and dissemination of the Standards to medical school educators, physicians, health care organizations, researchers and policymakers. Information from this assessment will also be used to contribute to the body of literature in the field of cultural and linguistic competency and about the National CLAS Standards.

Without this data collection, questions regarding the regional and national adoption and implementation of the National CLAS Standards could not be answered. This would make it difficult to describe cultural and linguistic competency and understand health disparities in office-based care in the United States.

### **3. Use of Improved Information Technology and Burden Reduction**

The 2016 NAMCS CLAS will use self-administered web questionnaire, self-administered paper questionnaire or telephone interview for modes of data collection. Participation via the web questionnaire is the only mode offered in the first survey invitation; the web questionnaire will be available during the complete data collection period. The paper questionnaire will only be offered after non-response to the web questionnaire. Burden will be minimized by using sampling procedures designed to prevent overlap of the 2016 NAMCS CLAS sample and samples for all other physician surveys fielded by NCHS (2014—2016 NAMCS (OMB No. 0920-0234, Expires 12/31/17), National Electronic Health Records Survey (NEHRS) (OMB No. 0920-1015, Expires 04/30/17), AHRQ Feasibility Study, NAMCS Supplement of Primary Care Policies(OMB No. 0920-1063, Expires 05/31/17) in the past two years. There are no known legal obstacles to reduce the burden.

#### **4. Efforts to Identify Duplication and Use of Similar Information**

NCHS and OMH staff have reviewed the literature and consulted individuals and organizations with expertise in the National CLAS Standards for Health and Healthcare to identify other data collection sources similar to what is proposed for NAMCS CLAS. Although there have been numerous studies on cultural competency training of healthcare providers, few have comprehensively focused on office-based physicians and none have been able to provide regional and national estimates.

#### **5. Impact on Small Businesses or Other Small Entities**

Many respondents will be physicians in solo practices that may qualify as a small business or small entity. In order to reduce respondent burden for these and all respondents, the survey procedures provide that only a sample of physicians will be contacted, the sample will not overlap samples used for any other NAMCS data collection in the past two years, and data topics will be kept to the minimum necessary for the study.

#### **6. Consequences of Collecting the Information Less Frequently**

This is a single data collection with the potential of future data collections if funding and proper justification allows. Without this data collection, questions regarding the regional and national adoption and implementation of the National CLAS Standards could not be answered.

#### **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 & Efforts to Consult Outside the Agency**

##### **A. Federal Register Notice**

A 60-day Federal Register Notice was published in the Federal Register on Friday, August 28, 2015, Vol. 80, No. 167, pages 52291-52292. The Federal Register Notice can be found in **Attachment B**. CDC did not receive any comments from the public related to this notice.

##### **B. Efforts to Consult Outside the Agency**

NCHS and OMH staff have reviewed the literature and consulted individuals and organizations with expertise in the National CLAS Standards to identify other data collection sources similar to what is proposed for NAMCS CLAS. Although there have been numerous studies on cultural competency training of healthcare providers, few have comprehensively focused on office-based physicians and none have been able to provide regional and national estimates.

A list of individuals consulted for this project is provided in **Attachment E**.

## **9. Explanation of Any Payment or Gift to Respondents**

NAMCS CLAS will not offer a monetary incentive or gift to respondents for participation.

## **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:

"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.”

### Information in Identifiable Form (IIF)

The NAMCS CLAS will provide national estimates on provider characteristics. NAMCS CLAS will collect the following indirect identifiable information: sex, race, ethnicity, length of time in years (including residency) the physician has provided direct care in an office-based setting, county, state and zip code of the practice. Although the majority of the data that will be collected is not considered personally identifiable, some fit the definition of information in



identifiable form (IIF). The survey will collect personal identifiable information for analysis purposes and to facilitate contacting physicians for potential NAMCS CLAS follow-up surveys. A list of all IIF data items is highlighted below. All were approved by OMB for the NAMCS Information Collection (0920-0234). None of this data will be released to the public.

#### Information in Identifiable Form Categories:

##### Obtained from the sample file

- Physician name

##### Obtained or verified in the survey

- Practice mailing address: county, state, and zip code
- Physician e-mail address

This survey will include a routine set of measures to safeguard confidentiality, including the following: all staff (NCHS and contractual staff) who have access to confidential information take the NCHS confidentiality training, and are required to sign a non-disclosure affidavit 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 will be maintained to ensure that there is no loss in transit; and when confidential information is not in use, it is stored in secure conditions.

After data are entered from paper survey forms, the data will be combined with telephone interview data to create a final file. The contractor will upload the data file to CDC's Secure Access Management Services Partner Portal (SAMS) to be retrieved by NCHS. SAMS provides a secure data transfer service along with a strong suite of security controls to host applications and exchange data between CDC programs and public health partners while providing a high level of data integrity, confidentiality, reliability, and security. This meets NCHS/CDC policies for data transmission via the Internet. Users accessing systems protected by SAMS are required to adhere to the identity verification and authentication requirements for the Electronic Authentication Assurance Level (EAAL) of the protected system. SAMS provides system monitoring on a 24/7 basis, data redundancy features, and disaster recovery features for select information systems.

Once the data files are finalized, the survey forms will be destroyed. NCHS will retain and destroy records in accordance with the applicable CDC Records Control Schedule.

In keeping with NCHS policy, data will be made available via public use files or the Research Data Center. Confidential data will never be released to the public. All personal identifiers such as physician name, address, and any other specific information will be 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 a person to identify practices or individuals in the general population.

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

The NAMCS CLAS data collection plan has been approved by CDC’s Research Ethics Review Board (ERB) (Protocol #2016-08, **Attachments G**) based on 45 CFR 46. In addition, the Board has granted a waiver of the documentation of informed consent by physicians.

The Research Ethics Review Board’s letter granting approval of Protocol #2016-08 for the maximum allowable period of one year is presented in **Attachment G**.

There are no sensitive questions captured in this data collection effort.

## 12. Estimates of Annualized Burden Hours and Costs

### A. Burden Hours

This submission requests OMB approval for one year of NAMCS CLAS data collection. The burdens for one complete survey cycle are summarized in the tables below. The NAMCS CLAS will sample approximately 2400 physicians, all of whom will be asked to complete a 15 minute questionnaire. With an estimated 62% response rate, 912 non-respondents will be contacted by telephone. The total estimated annual burden is 676 hours.

Table of Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (Hours)	Total Burden (Hours)
Office-based physicians	NAMCS CLAS questionnaire	2400	1	15/60	600
Office-based physicians (non-respondents)	NAMCS CLAS Phone Script	912	1	5/60	76
<b>Total</b>					676

### B. Burden Cost

The average annual cost to providers for the survey is estimated to be \$61,671. The hourly wage estimates for completing the forms mentioned above in the burden hours table are based on information from the Bureau of Labor Statistics web site (<http://www.bls.gov>). Specifically, we used the "May 2014 National Occupational Employment and Wage Estimates United States" for “physicians and surgeons, all other.” The only cost to physicians is their time to participate.

Table of Annualized Burden Cost

Type of Respondent	Form Name	Total Burden Hours	Average Hourly Wage	Total Respondent Costs
Office-based physicians	NAMCS CLAS questionnaire	676	\$91.23	\$61,671
<b>Total</b>				\$61,671

### **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**

We estimate the average annual cost to the government for the 2016 NAMCS CLAS is \$300,000, which was transferred to NCHS from OMH. The contractor will receive \$179,226 for planning, printing of survey materials, mailing and postage for survey materials, data collection (web, paper and telephone), telephone follow-up, coding, processing, data entry, analysis, file release and report. The remaining \$120,774 will be used by NCHS to cover the salaries of government employees involved in the survey for survey design, sampling, evaluation, quality control, analysis, weighting, estimation, and the cognitive testing of the questions by the NCHS Center for Questionnaire Design and Evaluation Research (CQDER).

### **15. Explanation for Program Changes or Adjustments**

This is a new data/information collection.

### **16. Plans for Tabulation and Publication and Project Time Schedule**

**The timetable for key activities for the 2016 survey is:**

Printing of materials for initial letters	1 week after OMB approval
Begin data collection	2 weeks after OMB approval
Complete data collection	6 months after OMB approval
Produce final file	8 months after OMB approval
Analysis	15 months after OMB approval
Publish reports and make data available	15 months after OMB approval

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

The display of the OMB expiration date is not inappropriate.

### **18. Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification.