Supporting Statement: Part A

National Ambulatory Medical Care Survey (NAMCS) Supplement of Primary Care Policies (NSPCP) for Managing Patients with High Blood Pressure, High Cholesterol, or Diabetes

OMB No. 0920-NEW

Contact Information:

Christine A. Lucas, MPH, MSW
Ambulatory and Hospital Care Statistics Branch
National Center for Health Statistics
Centers for Disease Control and Prevention
3311 Toledo Road, Room 3317
Hyattsville, MD 20782
Voice: 301-458-4071
clucas3@cdc.gov

May 1, 2015

Table of Contents

A. JUSTIFICATION

- Goal of the study: To help CDC learn about the current state of primary care management policies in physician practices in the United States. Policies of interest are those aimed at management of adult patients with high blood pressure, high cholesterol, or diabetes. CDC and its partners want to better support primary care physicians and their medical practices in reducing mortality and morbidity due to these chronic conditions.
- Intended use of the resulting data: To assess (1) the extent to which primary care physicians deliver care in ways that have been shown to improve health outcomes and (2) the extent to which the ways they deliver care are established policies in their practices. CDC and its partners will then develop materials in support of such delivery methods. The survey will yield both national and regional estimates, providing practices with information to compare with their own management policies.
- Methods to be used to collect data: Data collection will consist of a one-time mail survey of a national representative sample of primary care physicians whose specialties are Internal Medicine (IM) and Family Practice (FP). Methods include a telephone screening and telephone follow-up of non-respondents.
- Subpopulation to be studied: Primary care physicians whose specialties are Internal Medicine (IM) and Family Practice (FP).
- How data will be analyzed: Data will be obtained to permit both physician level and practice level estimation.

Supporting Statement

The National Ambulatory Medical Care Survey (NAMCS) Supplement of Primary Care Policies (NSPCP) for Managing Patients with High Blood Pressure, High Cholesterol, or Diabetes.

The Centers for Disease Control and Preventions' (CDC) National Center for Health Statistics (NCHS) is requesting approval to conduct a new information collection, the NAMCS Supplement of Primary Care Policies (NSPCP) for Managing Patients with High Blood Pressure, High Cholesterol, or Diabetes. Working in partnership with the CDC's Division for Heart Disease and Stroke Prevention (DHDSP), NCHS' goal with this survey is to help CDC learn about the current state of primary care management policies in physician practices in the United States. Policies of interest are those aimed at management of adult patients with high blood pressure, high cholesterol, or diabetes. CDC and its partners want to better support primary care physicians and their medical practices in reducing mortality and morbidity due to these chronic conditions.

In 2011, the DHDSP developed what was then referred to as "The National Survey of Primary Care Policies for Managing Patients with High Blood Pressure, High Cholesterol, or Diabetes (NSPCP)" in collaboration with a number of other CDC units, including the Division of Diabetes Translation, the Office on Smoking and Health, and the Division of Nutrition, Physical Activity, and Obesity. Initially, that survey was cognitively tested with six primary care physicians. The testing was an important step towards revising the survey's questions in terms of clarity, use of terms and definitions, and response options. That version of the NSPCP was submitted to the Office of Management and Budget (OMB) in 2011.

When OMB reviewed the NSPCP questionnaire it was determined that there were a number of duplicate questions with the National Ambulatory Medical Care Survey (NAMCS), a national survey of patient visits to office-based physicians conducted by NCHS (OMB No. 0920-0234) (expires 12/31/2017). Eventually, it was decided that the survey questions should be placed at NCHS as a NAMCS supplement. In turn, the project was transferred to NCHS and the original OMB package was withdrawn.

Together, NCHS and DHDSP decided that the original NSPCP questions would be refined to conform to the NAMCS style of questioning and administered as a separate physician mail survey supplement to NAMCS using similar methods already developed by NCHS. The new project hereafter referred to as The National Ambulatory Medical Care Survey Supplement of Primary Care Policies for Managing Patients with High Blood Pressure, High Cholesterol, or Diabetes (NAMCS NSPCP) probes for further data on clinical decision supports and protocols, on the sources of clinical guidelines used by the respondent's practice, and on the use of multidisciplinary teams in respondents' offices. Data collected from the NAMCS NSPCP will

be consistent with the NAMCS and, consequently, the questions in the NAMCS NSPCP are expected to inform future revisions of the core NAMCS survey items.

For this OMB package, approval is requested to first cognitively test the NAMCS NSPCP with up to thirty physicians. The purpose of the testing is to refine the survey instrument further to make sure that the revised NSPCP, according to the NAMCS style, retains its meaning and comprehension to physicians. Next, a one-time mail survey of a national representative sample of primary care physicians whose specialties are Internal Medicine (IM) and Family Practice (FP) will be conducted. Methods include a telephone screening and telephone follow-up of non-respondents. NAMCS participants will be excluded from participation in the NAMCS NSPCP.

CDC will use the NAMCS MSPCP survey data to assess (1) the extent to which primary care physicians deliver care in ways that have been shown to improve health outcomes and (2) the extent to which the ways they deliver care are established policies in their practices. CDC and its partners will then develop materials in support of such delivery methods. The survey will yield both national and regional estimates, providing practices with information to compare with their own management policies.

We are requesting approval to:

- Conduct cognitive testing on the NSPCP survey questions
- Conduct a one-time, mail-based survey of a national sample of physicians, including a telephone screening and telephone follow-up of non-respondents

In this application, we are requesting two years of OMB approval to cover both the cognitive testing of the instrument and the field data collection.

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

Background

One of the strategic priorities of the CDC National Center for Chronic Disease Prevention and Health Promotion is to promote social, environmental, policy, and systems approaches that support healthy living for individuals, families, and communities. To support this priority, in 2005 the Division for Heart Disease and Stroke Prevention (DHDSP) began developing evaluation indicators that reflect evidence-based outcomes from policy and systems changes for heart disease and stroke prevention. The ultimate goal of developing these indicators is to provide common measures for the Centers for Disease Control and Prevention (CDC), CDC-funded state Heart Disease and Stroke Prevention programs, and other partners to monitor outcomes in heart disease and stroke prevention and control efforts.

Many DHDSP indicators that reflect intermediate and long-term behavioral and health outcomes have known data sources that can be used to monitor them at the national and state levels. However, having an existing data source was not a criterion used to decide whether an indicator would be included in the DHDSP indicators. As a result, many of the indicators that reflect outcomes of short-term policy and systems changes do not have readily available data sources. This is particularly true for outcomes related to health care systems changes.

The proposed NAMCS NSPCP will provide much needed data on existing policies and systems in primary care physician practices related to chronic disease management for high blood pressure, high cholesterol, and diabetes. These data will provide in-depth information on the existence of evidence-based systems changes, including multidisciplinary team approaches for chronic disease treatment, electronic health records with features appropriate for treating patients with chronic disease (e.g., clinical decision supports), and patient follow-up mechanisms.

In addition to providing CDC with crucial information about the prevalence of evidence-based approaches to managing chronic illnesses, the survey will also aid CDC in supporting primary care practices to better serve their patients. CDC can better serve its partners through development of translation pieces or technical assistance aids that address gaps in the use of evidence-based interventions identified by the NAMCS NSPCP.

Most importantly, the NAMCS NSPCP will provide knowledge about primary care practices that can inform guidelines for managing patients with chronic conditions and to improve the quality of care delivered. Published manuscripts will add depth to the peer-reviewed scientific literature with regard to the extent that evidence-based policies have been adopted into practice.

Authorization:

Section 306 of the Public Health Services Act (41 U.S.C. 242) authorizes the collection of these data. Please see **Attachment 1** for a copy of this legislation.

2. Purpose and Use of Information Collection

With data collected from the NAMCS NSPCP, CDC can better assist primary care practices in managing chronic illnesses and reduce patient morbidity and mortality due to heart disease, stroke, and diabetes. CDC grantees in state health departments are charged with implementing policy and system changes in the health care arena. Many of the recommended strategies are being assessed in the NAMCS NSPCP. Additionally, the Patient Protection and Affordable Care Act (ACA) calls for the creation of "health homes" (ACA §2703). Many components of the health home, also known as the medical home, are part of the NAMCS NSPCP, such as the use of EHRs, registries, multidisciplinary teams, and clinical decision supports. The results of this survey are also aligned with several of the goals of the National Strategy to Improve Health Care Quality (ACA §3011) such as monitoring and evaluating clinical preventive services for prevention and treatment of the Nation's major causes of death and disability: heart disease and stroke. Although NAMCS asks questions about medical homes, the NAMCS NSPCP will probe for further information about components within physician practices that define them as medical homes.

Because of a paucity of existing data sources for monitoring short-term policy and system changes, CDC is unable to effectively gauge how it can best support health care delivery. This is particularly true for outcomes related to health care systems for managing chronic illnesses. Without data sources to monitor the use of evidence-based health care delivery systems, CDC cannot provide effective technical assistance for health systems change. This particularly affects CDC's ability to support public health initiatives at the state and local levels. Up-to-date information on physician practices' use of evidence-based health care delivery systems will allow CDC to guide state and community health care initiatives to improve support for identified gaps.

Cognitive Testing: Prior to fielding the NAMCS NSPCP, survey questions will undergo pretesting with up to 30 respondents (Attachment 4a) before the instrument is fielded in its final form with 3,000 physicians. The purpose of the testing is to refine the survey instrument to make sure it asks valid questions and is understandable to physicians. Pretesting will consist of cognitive testing that will either be in-person or a telephone interview. To assure recruitment of the desired number and mix of physicians in terms of specialty type and size and type of practice, the maximum number of screenings will be 50. It is anticipated that any resulting changes based on the cognitive testing to the data collection instrument will be minor.

The contractor will place an advertisement on LinkedIn to recruit physicians to participate in cognitive testing. The ad will be targeted to LinkedIn members that list themselves as physicians and that are local to the DC/Rockville area. Additional recruiting techniques will include requests for assistance from organizations such as the Medical Group Management Association and large health systems, and the distribution of recruiting flyers (Attachment 4d). Respondents are recruited by expressing their personal willingness to participate. Thus, participation is strictly voluntary and respondents are not chosen randomly. In addition to answering the survey questions, respondents will be asked open-ended probes intended to assess whether they understood the questions as intended and how easily they arrived at their answers. While the cognitive testing results will be used to refine the survey instrument items and procedures, the answers will not be incorporated into the main study. (Please see Statement B, P. 12 for more information on how results of the cognitive testing will inform the mail-based survey.)

Mail Survey: The NAMCS NSPCP will collect information about physicians and practice policies regarding the use of evidence-based systems, including multidisciplinary team approaches for chronic disease treatment, electronic health records (EHRs) with features appropriate for treating patients with chronic disease (e.g., clinical decision supports, patient registries), and patient follow-up mechanisms. The NAMCS NSPCP will be a mail-based survey of a national sample of physicians. Physicians will be screened by telephone (Attachment 3a) to confirm eligibility and correct contact information. Each eligible physician will receive a survey instrument by mail **(**Attachment 3b). After three mail requests, respondents who have not completed the survey will be called and asked to participate.

Respondent contact and eligibility information and survey completion status will be tracked by a Study Management System developed by the contractor overseeing the data collection effort. They will conduct the majority of tasks associated with this data collection effort, including recruiting participants through the telephone, sending reminder letters to participants, designing, printing and mailing the survey instrument, collecting and safeguarding data, and performing data cleaning and rudimentary analysis. The contractor's staff will sign nondisclosure affidavits and will be subject to the terms of the Designated Agent Agreement (DAA) with NCHS. With all of the data collection systems described below, once the data collection is complete for this survey, the contractor will send all survey data to NCHS including audiotapes. All data (including PII) will then be destroyed by the contractor and a certificate of destruction will be provided to NCHS documenting the destruction. Hard copies of the screening survey forms will be stored in a locked file cabinet at NCHS. If for some reason the original hard copies are to be retained, they will be marked for destruction within 2 years.

Mail Survey Screening Component: For the telephone screener, up to 4 contact attempts will be made with each the potential respondent. During the telephone screener, the physician or a representative of their practice will be asked about the following items of information:

- Whether the selected physician has a specialty of either Family Medicine or Internal Medicine;
- Whether the physician sees adult ambulatory patients;
- Whether the physician sees patients only in a hospital emergency or out-patient department, urgent care facility, Federal facility, nursing home, rehabilitation center, or correctional facility.
- Whether the name and contact information for the physician is correct.

If there is no success in contacting the potential respondent, they will be mailed the survey. (See Attachment 3a for the screening instrument). Information collected during the screener will be stored for 6 months after data collection in the contractor's Study Management System and then it will be destroyed. The contractor will send a certificate of destruction to NCHS.

Full Mail Survey Component: The mail-based NAMCS NSPCP will be mailed to all those confirmed to be eligible during the telephone screener and to the entire fielded sample for whom screener information was not successfully obtained. The survey (**Attachment 3b**) will collect information about the policies and systems used by eligible physicians. The respondent's name and contact information will be maintained separately from survey response data.

Survey completion will be linked to screener information through the Study Management System in order to facilitate reminder mailings and phone calls. De-identified survey data and screener data will be linked in the data delivery to NCHS.

<u>Items of Information to be Collected</u>

- Physician characteristics (e.g., specialty, practice type, patient setting, practice policies)
- Clinical decision supports and protocols when treating patients for high blood pressure, high cholesterol or diabetes
- Clinical guidelines used (e.g., NHLBI JNC 7)
- Use of multidisciplinary teams
- Patient registry systems (e.g., registry of patients with high blood pressure)
- Electronic functions
- Methods for patient follow-up
- Patient education and self-management (how does the provider educate patients)

3. Use of Improved Information Technology and Burden Reduction

Only a sample of physicians will be included in this study. NAMCS participants will be excluded from participation in the NAMCS NSPCP. Further, respondent burden is reduced through the prescreening process. Physicians that can be identified as non-eligible during the screening phone call will not be sent a questionnaire or receive any follow-up phone calls. This will ensure that no burden is placed on physicians who are not the target of this study. This is a one-time data collection, so once a respondent has completed the instrument, he/she will not be contacted again for this survey nor the NAMCS.

There are no legal obstacles to reducing the burden.

4. Efforts to Identify Duplication and Use of Similar Information

Extensive literature and internet searches were conducted by the DHDSP project staff to assess if information regarding prevalence of the uptake of evidence-based health care systems had been previously collected. Additionally, DHDSP project staff conferred with CDC colleagues from the Division of Diabetes Translation, as well as colleagues from the Bureau of Primary Care at the Health Resources and Services Administration. There are currently no known efforts to collect chronic disease-specific information in the health care systems arena that is nationally representative. DHDSP is developing a simple checklist that can be used by individual physicians to assess whether they are using evidence-based practices. This checklist is not a survey and does not involve CDC's collection of data. It is a template that can be used by States for physician practices that are interested in conducting a self-assessment of their use of evidence-based practices. Although surveys assessing the use of Electronic Health Records have been conducted such as the National Electronic Health Records Survey, none of these studies were detailed or precise enough to provide information related to treatment of specific chronic diseases.

5. Impact on Small Businesses or Other Small Entities

Although some physician practices are large and have multiple sites, some practices may comprise just a few physicians and thus may be considered small entities. The mail instrument will be designed to minimize respondent burden, including an easy-to-read format. Time-to-complete the mailed instrument is estimated at 20 minutes or less.

6. Consequences of Collecting the Information Less Frequently

Respondents will only be asked to participate once in the survey.

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 regulations 5 CFR 1320.5.

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

A. Federal Register Notice

A 60-day Federal Register Notice was published on June 19, 2014, Vol. 79, No. 118, pages 35164 35165. See Attachment 2b for a copy of the 60-day FRN.

One public comment (see attachment 2c) was received and the standard CDC response was sent:

B. Consultations Outside the Agency

DHDSP project staff consulted with CDC colleagues from the Division of Diabetes Translation, and the Division for Cancer Prevention and Control, as well as colleagues from the Bureau of Primary Care at the Health Resources and Services Administration (Attachment 7).

9. Explanation of Any Payment or Gift to Respondents

Payment for participating in an interview or survey is standard practice when seeking participation of professionals such as physicians. The incentive payment is an effective method of drawing physicians' attention to the study and gaining their cooperation in completing the questionnaire. It is not intended to be a payment for their time, but an incentive to increase response rate. Historically, physicians are one of the most difficult populations to survey, partly because of the number of surveys they receive, as well as the demands on their professional time. Consequently, incentives assume an even greater importance with this group.

Cognitive testing: Participants for the survey pretesting information collection will be physicians who will likely have demanding schedules with limited time for pretesting activities. All the participants in the 1.25 hour interview will be given an incentive of $150.00. This amount is consistent with current pretesting incentives offered by the data collection contractor to senior healthcare professionals (in the past two years, incentives for this population have usually ranged from $100 to $200 (see Table A12-2).

Full Mail Survey: There is no incentive planned for the mail survey.

10. Assurance of Confidentiality Provided to Respondents

The confidentiality of participant information is protected by section 308(d) of the Public Health Service Act (42 USC 242m), which states:

"No information, if an establishment or person supplying the information or described in it is identifiable, obtained in the course of activities undertaken or supported under section...306,...may be used for any purpose other than the purpose for which it was supplied

unless such establishment or person has consented (as determined under regulations of the Secretary) to its use for such other purpose and (1) in the case of information obtained in the course of health statistical or epidemiological activities under section...306, such information may not be published or released in other form if the particular establishment or person supplying the information or described in it is identifiable unless such establishment or person has consented (as determined under regulations of the Secretary) to its publication or release in other form..."

In addition, legislation covering confidentiality is provided according to section 513 of the Confidential Information Protection and Statistical Efficiency Act (PL 107-347) which states:

"Whoever, being an officer, employee, or agent of an agency acquiring information for exclusively statistical purposes, having taken and subscribed the oath of office, or having sworn to observe the limitations imposed by section 512, comes into possession of such information by reason of his or her being an officer, employee, or agent and, knowing that the disclosure of the specific information is prohibited under the provisions of this title, willfully discloses the information in any manner to a person or agency not entitled to receive it, shall be guilty of a class E felony and imprisoned for not more than 5 years, or fined not more than $250,000, or both."

The following assurance of confidentiality will be on any new paper or electronic forms:

"All information which would permit identification of an individual, a practice, or an establishment will be held confidential, will be used only for statistical purposes by NCHS staff, contractors, and agents only when required and with necessary controls, and will not be disclosed or released to other persons without the consent of the individual or establishment in accordance with section 308(d) of the Public Health Service Act (42 USC 242m) and the Confidential Information Protection and Statistical Efficiency Act (PL-107-347)."

Data will be treated in a confidential manner. The process of informing respondents of the procedures used to keep information confidential begins with the telephone screener and will carry through to the interviewer and all communications with potential respondents. Materials will include all elements of informed consent, including the purpose of the data collection, the voluntary nature of the study, audio recording of the interview, and the effect upon the respondent for terminating the interview at any time.

A number of procedures will be implemented to safeguard respondent identity and they will be explained to respondents. Participants in the cognitive testing information collection will be advised of safeguards in writing through the consent form (**Attachment 4c**) if the interview is to be conducted in-person. If the interview is to take place over the phone, information about safeguards will be confirmed orally prior to the start of the interview. Mail survey participants will be advised of safeguards in writing through the invitation letters/emails (**Attachments 5a and 5b**).

The contractor's staff will sign nondisclosure affidavits and will be subject to the terms of the Designated Agent Agreement (DAA) with NCHS. The contractor provides all safeguards mandated by the Privacy Act to protect privacy of data gathered for this study. The data collection contractor's data security procedures comply fully with procedural safeguards for computerized records as outlined in the U.S. Department of Health and Human Service's *General Administrative Manual* under "Safeguarding Records Contained in Systems of Record" and specified by the National Institute of Standards and Technology Federal Information Processing Standards.

IRB Approval

The NCHS Ethics Review Board has granted approval for Protocol #2015-03 through 10/23/16 (**Attachment 6a**). Information will be provided on a voluntary basis only. There are no adverse effects if the respondent chooses not to participate. Respondents will be informed of the voluntary nature of their responses in all cover letters and in the consent form prior to pretesting.

Cognitive testing: At the beginning of each in-person interview, respondents will review and sign a consent form (**Attachment 4c**) if the interview is in person. The form will also ask for permission to audio record the interview. If any telephone interviews are conducted as part of the pretesting, the interviewer will convey the information in the consent form over the telephone and ask for consent to participate in the interview and to have it audio recorded. If the respondent consents to the audio recording the interviewer will ask for consent again after turning on the recorder (see the introductions for both the in-person and telephone interviews in **Attachment 4a**). The respondent may refuse recording or may stop the recording at any time, and the interviewer will turn off the machine. If the respondent decides to stop recording, the interviewer will ask for consent to retain the portion already recorded. Once the data collection is complete for this survey, the contractor will send all survey data to NCHS including audiotapes. All data (including PII) will then be destroyed by the contractor and a certificate of destruction will be provided to NCHS documenting the destruction. Hard copies of the screening survey forms will be stored in a locked file cabinet at NCHS. If for some reason the original hard copies are to be retained, they will be marked for destruction within 2 years.

These data may be used internally to further analyze the data for publication. At no time are the physicians contacted to obtain further information.

Privacy

The interview will be conducted in a closed office. NCHS is required by law to tell the respondent how the recorded interview will be used and how their privacy will be protected.

Audio recordings are stored in a locked room or secured by a password. All recordings are labeled by a code number, date, time, and project title. The recording is never labeled with the respondent's name or other personal facts.

Full Mail survey: Information about the study and use of the information will be included in mailed cover letters accompanying the survey (**Attachment 5a**). Completion of the survey is considered to be consent to participate. No changes in disclosure or data use will be permitted without explicit consent from each survey respondent.

Furthermore, employees from the data collection contractor will be required to sign a Designated Agent Agreement with NCHS, which include affidavits of non-disclosure. It states that the signer will not disclose confidential information, either while an agent or after, contained in data files, lists, or reports created using NCHS data, as specified under Section 308(d) of the Public Health Service Act and under penalties set for in 513 of the Confidential Information and Protection and Statistical Efficiency Act of 2003 (PL 107-347, title V).

This study has also been reviewed and approved by the contractor's IRB. See **Attachment 6b** for their approval letter.

10.1 Privacy Impact Assessment Information

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

The survey collects personal identifiable information for analysis purposes. Hard copies of the survey forms will be stored in a locked file cabinet at NCHS. Personally Identifiable Information (PII) will be secured using password-protected networks, system firewalls, and key cards/identification badges for all physical locations. Data are maintained in a secure database, and information will be secured using all applicable National Institute of Standards and Technology security controls. Information will be secured on the system through access controls; personnel security awareness and training; regular auditing of information and information management processes; careful monitoring of the information system; control of changes to the system; appropriate handling and testing of contingencies and contingency planning; proper identification and access authorization for all users; properly maintaining the system and regulating the environment the system operates in; controlling media; evaluating risks and planning for information management and information system operations. These steps ensure that the system and any exchange of information are protected, and that the integrity of the system and the information stored in it are maintained.

Overview of the Data Collection Security System

Cognitive testing: Respondent contact information (including name, telephone number, medical practice name and address) will be collected as part of the recruitment process for the cognitive testing **(Attachment 4b**). This information will be maintained in an electronic file on a secure project directory at the contractor's site until the data collection effort has been completed. Thereafter the information will be transferred to NCHS. As stated previously in this document, the contractor's staff will sign nondisclosure affidavits and will be subject to the terms of the NCHS Designated Agent Agreement. The interviews will be audio recorded with the recordings maintained in either a locked file cabinet (if cassette) or within the data collection contractor's secure firewall (if digital) until the data collection has been completed. Thereafter the information will be transferred to NCHS.

Mail Survey Screening: Information collected during the screening telephone call is intended to: 1) confirm contact information; 2) determine the eligibility of the physician; and 3) assess nonresponse bias. Personnel working on the survey will be granted rights to the information in the system by the project director, who will determine need to know based on the activity the person is doing and the particular requirements of the tasks assigned to that person. Specified contractor staff will need to have access to this information in order to mail reminder letters and conduct follow-up phone calls. The PII collected will be restricted to the respondent's contact information at the participating practice.

Full Mail Survey: No additional PII will be collected by the survey. Surveys will be tracked using a Respondent ID number and will not include any names, addresses or telephone numbers.

As stated previously, once the data collection is complete for this survey, the contractor will send all survey data to NCHS including audiotapes. All data (including PII) will then be destroyed by the contractor and a certificate of destruction will be provided to NCHS documenting the destruction. Hard copies of the screening survey forms will be stored in a locked file cabinet at NCHS. If for some reason the original hard copies are to be retained, they will be marked for destruction within 2 years. These data may be used internally to further analyze the data for publication. At no time are the physicians contacted to obtain further information.

11. Justification for Sensitive Questions

This survey will not include questions of a personally sensitive nature. However, respondents will be asked to share information about the policies and systems in place at their practices for treating patients with high blood pressure, high cholesterol, and diabetes. Respondents may assume that their answers reflect the quality of care provided by their practice. Therefore, the survey questions may be perceived as organizationally sensitive. Respondents will be informed of safeguards that insure their data are not identifiable by NCHS and information will be maintained in a secure manner.

12. Estimates of Annualized Burden Hours and Costs

Cognitive testing. Prior to administration of the baseline survey, cognitive testing (Attachments 4a-c) will be conducted with up to 30 physicians providing primary care and with a specialty of either family practice (FP) or internal medicine (IM). To assure recruitment of the desired number and mix of physicians in terms of specialty type and size and type of practice, the maximum number of 5-minute screenings will be 50. The contractor will place an advertisement on LinkedIn to recruit physicians to participate in cognitive testing. The ad will be targeted to LinkedIn members that list themselves as physicians and that are local to the Washington, D.C./Rockville, MD area.

Additional recruiting techniques will include requests for assistance from organizations such as the Medical Group Management Association and large health systems, and the distribution of recruiting flyers.

The purpose of the testing will be to further refine the survey instruments. Any resulting changes to the data collection instrument are anticipated to be either cuts or minor wording changes. We anticipate each cognitive interview to take 1.25 hours. With this two-year period, the annualized number of respondents for the cognitive testing information collection is 15 respondents and the annualized burden is 19 hours.

Mail Survey Screening. The telephone screener will be administered to the individual who answers the phone at the selected practice (**Attachment 3a**). We anticipate that this will likely be an office assistant or medical secretary. The primary purpose of the screener is to ensure correct contact information for the physician, so we anticipate that an office assistant or medical secretary will be able to answer the screener questions in a short amount of time. We have estimated 10 minutes per response. Screening will involve approximately 3,000 respondents, Over the two-year period of this information collection request, the annualized number of respondents for the screening information collection is 1,500 respondents, and the annualized burden is 250 hours.

Full Mail Survey. The target for the mail survey is the selected physician. The estimated burden per response is 20 minutes. Approximately 945 respondents are expected to complete the NAMCS NSPCP questionnaires. Over the two-year period of this information collection request, the annualized number of respondents for the mail-based NAMCS NSPCP information collection is 473 respondents, and the average annualized burden is 158 hours.
This is a one-time data collection, so once a respondent has completed the instrument, he/she will not be contacted again. Table A12-1 below summarizes the expected number of respondents and the estimated burden hours. The total estimated annualized burden hours over the 2-year period are 429.

Table A12-1: Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in Hours)	Total Burden (in Hours)
Physician	Cognitive Testing Screener	25	1	5/60	2
Physician	Cognitive Testing Protocol	15	1	1.25	19
Medical Secretary	NAMCS NSPCP Screener	1,500	1	10/60	250
Physician	NAMCS NSPCP	473	1	20/60	158
Total					429

B. Table A12-2 summarizes the estimated cost to respondents. The hourly wages reflect the mean hourly earnings reported by the National Compensation Survey[1]. The hourly wages for the physician are those of family and general practitioners. The total estimated annualized cost to respondents is $20,092.50.

Table A12-2: Estimated Annualized Cost to Respondents

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Physician	Cognitive Testing Screener	2	$90.00	$180.00
Physician	Cognitive Testing Protocol	19	$90.00	$1710.00
Medical Secretary	NAMCS NSPCP Screener	250	$15.93	$3,982.50
Physician	NAMCS NSPCP	158	$90.00	$14,220.00
Total				$20,092.50

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

There are no capital or start-up costs, and there are no costs to the respondents or record keepers for operation and maintenance of services.

[1] National Compensation Survey, All United States, May 2013. *Table 4: Full-time private industry workers: Mean and median hourly, weekly and annual earnings and mean weekly and annual hours.* Bureau of Labor Statistics, US Department of Labor.

14. Annualized Cost to the Government

The data collection contractor will conduct the majority of tasks associated with this data collection effort, including recruiting participants through telephone, sending reminder letters to participants, designing, printing and mailing the survey instrument, collecting and safeguarding data, and performing data cleaning and rudimentary analysis. Costs to the government also include NCHS and CDC time and effort for selecting the physician sample, overseeing the contract, providing technical expertise, and answering questions posed by the contractor. CDC estimates personnel time as 15% FTE (5% time for three individuals @ GS-13 with $101, 914 used as the estimated average per annum rate (Table A14-1). The total estimated annual cost to the government is $197,595.

Table A14-1: Annualized Cost to Government

	Annualized Cost
CDC total	$15,287
Contractor total	$182,308
Total	$197,595

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Testing of the NAMCS NSPCP questionnaire will start 1 month after OMB approval is obtained and data collection will start 3 months after approval (Table A16-1) and full data collection will start 6 months after OMB approval.

Table A16-1: Project Time Schedule

Study Activity	Time Schedule
Conduct cognitive testing	1-3 months after OMB approval
Screening telephone calls	4-6 months after OMB approval
Invitation letter sent to respondents	7 months after OMB approval
Surveys sent via mail to physicians	8-9 months after OMB approval
Reminder phone calls	10 months after OMB approval
Data collection complete	11 months after OMB approval
Data cleaning and weighting	11 12 months after OMB approval
Analyses (baseline data collection)	12-18 months after OMB approval
Publication	18-20 months after OMB approval

Once data cleaning and weighting is complete, analysis will begin. Basic univariate and bivariate frequencies will be analyzed and displayed as percents with 95% confidence intervals (Table A16-2). Data for each domain will be analyzed by specialty type (Family Practitioners, Internal Medicine), US census region (northeast, midwest, south, west), and practice size as appropriate.

Sample Table Shells for Publication

Table A16-2: Percent of Private Physician Practices with Family Practitioners and/or Internal Medicine Specialists with Evidence-based Systems for Managing Patients with High Blood Pressure, High Cholesterol, and Diabetes

Characteristics	**Electronic Health Records % (CI)**	**Clinical Decision Supports % (CI)**	**Multidisciplinary Teams % (CI)**	**Specialized Chronic Care Clinics % (CI)**
Total				
Specialty Family Practitioners Internal Medicine				
Region Northeast Midwest South West				
Practice Size 1 physician 2-5 physicians 5 or more physicians				

Table A16-3: Estimated Percent Distributions of Targeted Physicians using Sources of Clinical Guidelines for Managing Patients with High Blood Pressure, High Cholesterol, and Diabetes

Characteristics	National Organization % (CI)	State-specific Guidelines % (CI)	Affiliated Health System % (CI)	Practice-specific Guidelines % (CI)
Total				
Specialty Family Practitioners Internal Medicine				
Region Northeast Midwest South West				
Practice Size 1 physician 2-5 physicians 5 or more physicians				

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

The expiration date for OMB approval of data collection will be displayed as required.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement.