**DEPARTMENT OF HEALTH & HUMAN SERVICES** **Public Health Service**

Centers for Disease Control and Prevention

### National Center for Health Statistics

#### 3311 Toledo Road

### Hyattsville, Maryland 20782

April 10, 2015

Margo Schwab, Ph.D.

Office of Management and Budget

725 17th Street, N.W.

Washington, DC 20503

Dear Dr. Schwab:

The staff of the NCHS Questionnaire Design Research Laboratory (QDRL) (OMB No. 0920-0222, exp. 06/30/2015) plans to conduct an evaluation of questionnaire items on the 2016 NAMCS Culturally and Linguistically Appropriate Services (CLAS) Supplement which is a supplemental survey to the ongoing National Ambulatory Medical Care Survey (NAMCS, OMB #0920-0234).

 We propose to start recruiting for volunteer participants as soon as we receive clearance and to start testing as soon as possible after that.

Background Information about Cognitive Testing of Questionnaires

 The methodological design of this proposed study is consistent with the design of typical cognitive testing research. As you know, the purpose of cognitive testing is to obtain information about the processes people use to answer survey questions as well as to identify any potential problems in the questions. The analysis will be qualitative.

Proposed project: 2016 NAMCS Culturally and Linguistically Appropriate Services (CLAS) Supplement Evaluation

The purpose of the 2016 NAMCS CLAS supplement will be to assess physicians’ training, awareness, and provision of culturally and linguistically appropriate services.

The 2016 NAMCS CLAS supplement will be a national survey of office-based physicians conducted by the NCHS Division of Health Care Statistics (DHCS). The 2016 NAMCS CLAS supplement is sponsored by the Office of Minority Health (OMH), Department of Health and Human Services (DHHS). The National Standards for CLAS in Health and Health Care were established in 2000 by the OMH to advance health equity, improve quality, and eliminate health care disparities. In 2010, OMH published the Enhanced Standards for CLAS in Health and Health Care to revise the National CLAS Standards in order to reflect advancements made since 2000, expanding their scope and improving their clarity to ensure better understanding and implementation. The aim of both the National Standards for CLAS in Health and Health Care and the Enhanced Standards for CLAS in Health and Health Care is to advance health equity and eliminate health care disparities through the provision of culturally and linguistically appropriate services. The future 2016 NAMCS CLAS supplement will provide important information that will aid in understanding the types of cultural and linguistic training received by office-based physicians; physician awareness of patients’ cultural and linguistic needs; as well as organizational policies related to services and provision of these services in patient care.

The 2016 NAMCS CLAS supplement questions we are evaluating are attached (see Attachment 1). Two questions from the CLAS supplement (10a and 39) have been approved by both the NCHS ERB and OMB to appear on the 2015 NAMCS, but they have yet to be tested through cognitive interviewing. As the other CLAS supplement questions are new and untested, DHCS and OMH decided that a thorough evaluation of the questionnaire was necessary. This cognitive interviewing project will evaluate the *current* form, and any suggested modifications to emerge from the analysis of the cognitive interviews that may be added to the 2016 NAMCS CLAS supplement. This evaluation project has been scheduled to meet DHCS’ production deadlines for a potential 2016 national roll-out. The evaluation will focus on office-based physicians. The testing procedure conforms to the cognitive interviewing techniques that have been described in QDRL’s generic OMB clearance package (No. 0920-0222, exp. 06/30/2015).

As many as twenty 60-minute cognitive interviews may be conducted with office-based physicians. Throughout the project, the QDRL will brief DHCS staff on the progress and findings of the interviews, and small changes to the questionnaire may be incorporated based on these discussions.

Office-based physicians in the sample area will be recruited from a list developed by the QDRL based on Centers for Medicare and Medicaid Services’ Physician Compare web tool[[1]](#footnote-1). An advance letter signed by Charles J. Rothwell, Director of NCHS (see Attachment 2), will be sent to organizations from this frame which explains the purpose of both the NAMCS CLAS and the proposed cognitive interviewing project, and alerts them to the fact that the QDRL will be reaching out to them to schedule an interview. The QDRL will then contact these physicians a week after the letter was sent and attempt to recruit them into the project. The 5 minute telephone screener used for verifying eligibility of the sampled doctor is shown in Attachment 3. Note that wording of the template has been approved and is contained within our umbrella package. Only project specific information has been added to the document. Though our goal is to conduct 60-minute full-length interviews (including the completion of a Respondent Data Collection Sheet), if during recruitment individuals repeatedly express willingness for a shorter interview, we may conduct shorter interviews in lieu of no interview at all. It is anticipated that as many as 48 physicians may need to be screened in order to recruit 20 respondents.

Cognitive interviews will be conducted by QDRL staff members with English speaking respondents in a private room in the doctor’s office or a mutually agreeable location. Interviews will be audio recorded. These recordings will allow researchers to insure the quality of their interview notes.

After respondents have been briefed on the purpose of the study and the procedures that QDRL routinely takes to protect human subjects, respondents will be asked to read and sign an Informed Consent (Attachment 4). Only project specific information has been added to the document. Respondents will also be asked to fill in their demographic characteristics on the Respondent Data Collection Sheet (Attachment 5), which has been modified for this particular establishment-based project. This document is contained in our umbrella package. The burden for completion of this form is captured in the interview.

The interviewer will then ask the respondent to confirm that he/she understands the information in the Informed Consent, and then state that we would like to record the interview. The recorder will be turned on once it is clear that the procedures are understood and agreed upon. The interviewer will then orient the respondent to the cognitive interview with the following introduction:

*[QDRL staff name] may have told you that we will be working on some questions that will eventually be added to national surveys. Before that happens, we like to test them out on potential respondents. The questions we are testing today focus on physicians’ training, awareness, and provision of culturally and linguistically appropriate services.* *We are interested in your answers, but also in how you go about making them. I may also ask you questions about the questions—whether they make sense, what you think about when you hear certain words, and so on.*

*I want you to fill out the survey while I observe. Occasionally, I will stop you to explain some of your answers or how you thought about a question. Please try to tell me what you are thinking as you figure out how to answer. Also, please tell me if:*

*there are words you don’t understand,*

*the question doesn’t make sense to you,*

*you could interpret it more than one way,*

*it seems out of order,*

*or if the answer you are looking for is not provided.*

*The more you can tell us, the more useful it will be to us as we try to develop better questions. Okay? Do you have any questions before we start? If yes, answer questions. If not, let’s get started.*

Although the primary collection modes for the CLAS supplement are web and self-report mail-back, the cognitive interviews will be primarily conducted using retrospective probing. The respondents will be presented with the questionnaire and will be observed by the cognitive interviewer during the administration in order to note any clear usability issues with the instrument. Following the completion of the instrument, the cognitive interviewer will retrospectively probe the respondent following the normal form outlined in our generic clearance.

After the interview, respondents will be given the thank-you letter signed by Charles J. Rothwell, Director, National Center for Health Statistics, Centers for Disease Control and Prevention (Attachment 6), which has been modified for this particular establishment-based project. This document is contained in our umbrella package. Respondents will also receive a copy of the informed consent form, and $100. This amount has been increased over and above the normal cognitive interview incentive level for a number of reasons. First, the recruitment of physicians is necessary for the success of the cognitive study. Second, given funding and time constraints cognitive interviews will be limited to the Washington DC/Baltimore metropolitan area. Lastly, we will be asking the respondents to participate in the cognitive interview during their working hours, placing an extra burden on these respondents. Our proposed incentive level will be invaluable to obtaining a high response rate and reducing the number of cancelations from this busy, specialized population.

After the interview, respondents will be asked to read the Special Consent for Expanded Use of Audio Recordings (Attachment 7). There will be no coercion and the respondents will be told that they can call and reverse the decision at any time if they change their minds. If respondents do sign the special consent form they will be given a copy of that as well.

Extreme care will be taken with all recordings and paperwork from the interviews conducted off-site. Recordings and identifying paperwork will be stored in a secured travel case until returned to NCHS, at which point they will be transferred to the usual secured locked storage cabinets.

In total, for this project, the maximum respondent burden will be 24 hours. A burden table for this project is shown below:

| **Form Name** | **Number of****Participants** | **Number of****Responses/****Participant** | **Average hours****per response** | **Response****Burden****(in hours)** |
| --- | --- | --- | --- | --- |
| Screener | 48 | 1 | 5/60 | 4 |
| Questionnaire  | 20 | 1 | 60/60 | 20 |

Attachments (5)

cc:

V. Buie

T. Richardson

DHHS RCO

1. <http://www.medicare.gov/physiciancompare/> [↑](#footnote-ref-1)