Supporting Statement B for Revision Request for Clearance: NATIONAL AMBULATORY MEDICAL CARE SURVEY

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- Att A Applicable Laws and Regulations
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B. Collections of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

The National Ambulatory Medical Care Survey (NAMCS) target universes are non-federally employed physicians (excluding those in the specialties of anesthesiology, radiology and pathology) practicing in the United States and classified as "office-based patient care," as well as Health Centers (HCs) which have electronic health record (EHR) systems. The projected sample sizes for the physician component is 3,000 traditional office-based physicians in 2021-2023, as well as 3,000 EHR submitting physicians in 2022-2023. The projected sample sizes for the 2021-2023 HC component are 50 HCs in 2021, 110 HCs in 2022, and 115 centers in 2023. <u>HCs recruited into the survey will continue to provide EHR data for a minimum of five years or until they no longer wish to participate.</u> Details on the universe and sampling methods of these components are provided below.

Office-based Physicians

The first NAMCS universe consists of non-federally employed physicians (excluding those in the specialties of anesthesiology, radiology, and pathology) practicing in the United States who were classified by the American Medical Association (AMA) or the American Osteopathic Association (AOA) as being in "office-based, patient care" and those classified by AMA as being "hospital employed" (as a proxy for hospital-owned practices). For the planned investigation into frame errors, anesthesiologists and "unclassified" physicians will be added to the sampling frame for the 2021 sample, where the "unclassified" group includes physicians from eligible specialty groups whose primary type of practice and present employment are unclassified.

To generate estimates representative of this universe NAMCS will annually draw a fresh sample of at least 3,000 office-based physicians. The sample of 3,000 for 2021 will include 2,600 traditional office-based physicians, 100 anesthesiologists, and 300 "unclassified physicians." No visit records will be collected from the 2021 sample. For each of the 2022 and 2023 surveys, NAMCS will draw a sample of 3,000 office-based physicians from which visit data will be collected using manual abstraction methods, and another sample of 3,000 office-based physicians from which visit data will be collected through submission of EHRs, totaling 6,000 office-based physicians. These samples will be drawn in such a manner that national estimates can be made, as well as estimates by the four U.S. Census regions.

Prior to selecting the 2022 and 2023 samples, physicians in the sampling frame who have registered for the National Health Care Surveys Registry will be identified. All individuals who are part of the National Health Care Surveys Registry (PI registry) have (by registering) agreed to submit EHR data when asked, and in return can receive credit from the Centers for Medicare and Medicaid Services' (CMS) EHR Incentive Programs: PI and the Merit-based Incentive Payment System (MIPS) as a fulfilment of the public health reporting measures of PI/MIPS.

Each sample will be stratified with strata defined by the four U.S. Census regions and the 15 MD physician specialty/DO groups. A stratum for anesthesiologists and a stratum for "unclassified" physicians will be added to the sample for 2021. The samples for 2022 and 2033 will also be stratified by PI registration status. From each of these sampling strata, systematic random sampling will be used to select physicians from a list in which the physicians are sorted (in order of priority) by: Census division, MSA status (i.e., in MSA vs. not-in MSA, where MSA is Metropolitan Statistical Areas defined by the OMB), and practice type (i.e., primary care, surgical, medical).

The total physician sample for each year is divided into 52 representative groups, which are randomly assigned to the 52 weeks of the year. During the assigned week for each sampled physician in the 2022-2023 samples, a number of visits are selected for data collection. For those physicians who have been sampled from the non-registrant group where visit data will be collected through manual abstraction, a systematic random sample of approximately 30 patient visits is selected from chronologic lists of the visits made to the physician during that week. For those physicians who have been sampled from the registrant group and will provide data through EHR submission, all visits made to the physician during that week are selected. This approach provides for continuous data collection throughout the year to account for seasonal variation in disease and patient visit patterns.

Health Centers

The second universe consists of HCs which have EHR systems. The HC universe includes three different types of HCs : (1) HCs that receive grant funds from the federal government through Section 330 of the Public Health Service Act; (2) look-alike HCs who meet all the requirements to receive 330 grant funding, but do not actually receive a grant; and (3) Urban Indian Health Centers (HCs). The list of federally funded HCs (330 grant) and look-alike HCs is provided by the Health Resources and Services Administration (HRSA) and the Urban Indian Health Centers list is provided by the Indian Health Service.

The 2021-2023 HC component of the NAMCS will use a stratified list sample of HCs with strata defined by Census region and MSA status (in MSA vs in non-MSA). From each sampling stratum, systematic random sampling will be used to select HCs from a list in which the HCs are arrayed by HC type (standard HC or Urban Indian Center) and Census division. The sampled HCs will continue in the survey until a new sample is drawn, which we anticipate will be in a minimum of 5 years. From each HC selected, NAMCS will collect electronic records for all visits. An initial sample of 50 HCs will be selected for 2021 with a potential of increasing the sample to 110 HCs in 2022 and 115 HCs in subsequent years. The sample will be used to produce visit estimates for the nation and the four Census regions.

				Annualized
	CY2021	CY2022	CY2023	Average
Physicians (Manual Abstraction)	3,000	3,000	3,000	3,000
Physicians (EHR Submission)	0	3,000	3,000	2,000
HCs	50	110	115	92

Table 1-Annual and Annualized NAMCS Sample Counts

2. Procedures for the Collection of Information

Office-based Physicians Who Submit Visit Data Through Manual Abstraction and the Remaining 2020 Data Collection for HCs

For physicians and, for the remainder of data collection in 2020 from HCs, an introductory letter is sent as the initial contact. See **Attachment M1** for copies of the introductory letters used in 2020, and **Attachment M2** for copies of the letters that will be used in 2021 and **Attachment M3** for those onward. The differences between the 2020 and 2021-2023 letters are updated language due to the Common Rule and most recent approved confidentiality language. When sent, these letters are accompanied by endorsement letter(s) (**Attachment N**) from specialty medical colleges and/or professional associations relevant to the sampled physician or HC and an informational/motivational insert (**Attachment S**).

The introductory letter is followed by a screener telephone call from a U.S. Census Bureau field representative (FR) to schedule an appointment for the Induction Interview (**Attachments C1** and **C2**), which includes instructions for the physician and staff on the sampling and collection of visit data using manual abstraction. Sampling only a fraction of the visits is intended to reduce the burden to busy physicians.

For the physicians who will be submitting visit data through manual abstraction, a computerassisted Physician Induction Interview is completed during a visit by the Census FR (**Attachments C1** and **C2**), which captures eligibility and (for eligible participants) collects information on selected practice characteristics. Beginning in 2021, some existing Induction Interview questions were modified for clarification and to keep up-to-date with current medical practice and terminology. In the 2020 survey, the HC Service Delivery Site and sampled HC health care providers will also complete Induction Interviews (**Attachments E** and **F1**).

After the Induction Interview is completed, the U.S. Census Bureau FR works with the physician or office staff member to generate a list of each patient visit in sequence of their occurrence during the preassigned reporting week. Visit sampling rates are assigned to physicians according to the number of visits they expect to see during their reporting week, such that approximately 30 of the visits made to the physician during his/her reporting week will be selected. The sampled visit data from the sampled week is then collected by the U.S. Census Bureau FR who performs abstraction using the computerized patient record form (PRF) (**Attachments G1** and **G2**).

The PRF is used to collect data on patient characteristics (e.g., age, sex), and visit characteristics such as date of visit, expected source of payment, reason for visit in patient's own words, diagnoses, laboratory or other medical procedures received or ordered, and medications provided or prescribed.

Office-based Physicians Who Submit Visit Data Using EHRs

Participating office-based physicians whose visit data are collected through submission of EHRs transmit their data via the National Health Care Surveys' Health Level Seven International (HL7) Implementation Guide for Clinical Document Architecture (CDA®) Release 1, Release

1.2, or Release 1.3 - US Realm (IG) created in collaboration with the Office of the National Coordinator on Health Information Technology (ONC) and multiple NCHS subunits including the Office of Classifications and Public Health Data Standards. This standard was created to address the diversity of EHR systems' data collection and storage. It also allows for automated extraction from the EHR or data repository. A series of training materials have been developed for each registered physician to use in guiding him/her in the submission process.

For sampled physicians who registered with the National Health Care Surveys Registry, the survey's selected contractor will initiate contact with the physician's organizational contact. The initial letter sent informs the organizational contact that provider(s) from their organization have been sampled for participation in NAMCS and reminds the organization of the physicians' willingness to submit electronic data for NAMCS when requested in order to meet the public health reporting objectives of PI/MIPs on Stage 3 (**Attachment M2** and **M3**). To receive credit and remain in good standing, the registered physician is required to respond to the initial letter within 30 calendar days from the date sent.

Sampled EHR physicians are asked to complete a Physician/Facility Information (PFI) questionnaire (**Attachment Q**). The questions on the PFI form represent a compressed version of the NAMCS Physician Induction Interview that is completed by office-based NAMCS physicians who have data collected through manual abstraction. Once the PFI is completed, it is reviewed to verify the physician's eligibility for NAMCS. Eligible physicians are invited to begin the process of testing and validation of their EHR systems and their ability to send EHR via the IG (**Attachments I** and J).

Once the results of testing and validation show that specific transmission and compatibility guidelines are met, the physician is then invited to the production phase of NAMCS EHR data collection. Electronic visit data will be submitted by the organizational contact or the physicians themselves (although we anticipate a very small number of physicians will be performing this task themselves) for each sampled provider based on an assigned 7-day reporting period. EHR visit data are expected to be delivered to the survey contractor within 30 days of the physician receiving his/her invitation to the production phase.

Select data items collected from EHRs are shown below. The full listing of all the variables can be found in **Attachment H.**

- Personal patient identifiers (EHR only: name, address, medical record number when available, Medicare/Medicaid number, and social security number when it is available)
- Date of birth
- Sex
- Date of visit
- Encounter number
- All other diagnoses including E codes and V codes
- Services provided or ordered during the visit:
 - O Diagnostic testing (e.g., lab, imaging, EKG, audiometry, biopsy)
 - Therapeutic procedures, including surgery, and non-medication treatments (e.g. physical therapy, speech therapy, home health care)

- National Provider Identifier (physicians and health care providers only)
- Race
- Ethnicity
- Marital Status
- Source(s) of payment
- Reason for visit
- Results of testing and procedures
- Medications and Immunizations
- Clinical notes (e.g., from physicians, nurses, physician assistants, and certified nurse midwives)

HC EHR Data Collection 2021-2023

Starting in 2021, HCs selected to participate in NAMCS will be sent an introductory letter **(Attachment M2** and **M3)** and information packet approximately 4 weeks prior to being contacted by phone. The letter will describe the purpose of the survey and authority for data collection, that participation is voluntary and that all collected identifying information is confidential. When sent, these letters are accompanied by endorsement letter(s) **(Attachment N)** from specialty medical colleges and/or professional associations relevant to the sampled HC and an informational/motivational insert **(Attachment S)**.

Also, the 2020 HC Induction Interview questionnaire will be modified, shortened, and renamed the "HC Facility Interview" to be used starting in 2021. The revised HC Facility Interview will be collected using electronic data collection methods (e.g., web portal) (**Attachment F2**). During the initial interview with the HC director, a research analyst completes the HC Induction Interview (**Attachment F2**). The major purpose of the Facility Interview is to gather information to assist in weighting of the collected visit data. Once the Facility Interview is completed, NCHS will work with the HC to set up data extraction. HCs will also be required to use the NCHS IG for data submission. A one-time set up fee of up to \$10,000 will be given to every participating HC.

Select data items are shown below with the full listing of all the variables can be found in **Attachment H.**

- Personal patient identifiers (EHR only: name, address, medical record number when available, Medicare/Medicaid number, and social security number when it is available)
- Date of birth
- Sex
- Encounter number
- All diagnoses
- Services provided or ordered during the visit:
 - O Diagnostic testing (e.g., lab, imaging, EKG, audiometry, biopsy)
 - Therapeutic procedures, including surgery, and non-medication treatments (e.g. physical therapy, speech therapy, home health care)
- National Provider Identifier (physicians and health care providers only)
- Race

- Ethnicity
- Marital Status
- Source(s) of payment
- Reason for visit
- Results of testing and procedures
- Medications and Immunizations
- Clinical notes (e.g., from physicians, nurses, physician assistants, and certified nurse midwives)

Monitoring Data Collection and Quality Control

Abstraction

Census Field representatives use a computerized patient record form (PRF) to abstract data for sampled visits from physicians' patient medical records. This computerization of the PRF allows for automated edits to be built into the instrument, so that keying errors are automatically detected as the FR is entering the data. Keying and data entry activities for medical coding are currently performed under contract with RTI, while drug coding is conducted in-house at NCHS. All medical and drug coding, as well as all data entry operations, are subject to quality control procedures; specifically, a 10% quality control sample of survey records are independently keyed and coded. Computer edits for code ranges and inconsistencies are also performed.

Quality control will be implemented through the proposed reinterview study. This study will be used to identify interview falsification. If falsification is identified, we will investigate with the U.S. Census Bureau possible reasons for the falsification. Reinterview results may be used to design supplemental training to improve abstraction quality or may lead to proposed modification of instructions or data collection forms.

Electronic Data Collection

NCHS will be responsible for overseeing the EHR data collection. NCHS will ask each HC or physicians who submit EHR to first submit a test file. The data will go through pre-processing report or testing and validation procedures to ensure that essential variables are present and are in a suitable format for NAMCS. NCHS will work with the HCs or physicians who submit EHR data to make any needed changes or additions to the files submitted.

Estimation Procedures

National and Census regional estimates will be produced based on two fundamental sources of data: (1) private non-federal office-based physicians, and (2) HCs designated as 330 grant-supported federally funded qualified health centers, federally qualified look-alikes, and Urban Indian Health Centers. The estimation procedure has four basic components: (1) inflation by reciprocals of the selection probabilities, (2) adjustments for nonresponse, (3) calibration ratio adjustment, and (4) weight smoothing.

Similar to prior survey years of NAMCS, the annual sample size has the statistical power needed to generate estimates for four Census regions. NAMCS data can also be used to make national estimates of office-based physicians and associated medical practices. These estimates are unbiased and based on a complex sampling design with multistage estimation. Physician weights are used to estimate national numbers and characteristics of office-based physicians (e.g., sex, age, and specialty) and their practices (e.g., numbers of physicians in the practice, single-specialty compared with multispecialty practices, and types and numbers of patient encounters in last full week of practice). The NAMCS physician sampling weight can also be modified to produce a national medical practice estimator (e.g., practice size, breadth of specialization, and selected diagnostic and therapeutic services available onsite). Data from the NAMCS samples are weighted by the inverse of selection probabilities with non-response adjustments done at least within Census region and, when feasible within physician specialty groups and/or MSA status. Calibration adjustment factors are used to adjust estimated physician total counts appropriate for each sample.

Each year, NCHS publishes weighted response rates by a variety of physician characteristics available from the sampling frame and the physicians themselves. Additional information concerning the 2021-2023 nonresponse is described below in "Section 3: Methods to Maximize Response Rates and Deal with Nonresponse."

Sampling Errors

The standard error is primarily a measure of the sampling variability that occurs by chance because only a sample rather than an entire universe is surveyed. Estimates of the sampling variability are calculated using Taylor series approximations in SUDAAN, which consider the complex sampling design of NAMCS. A description of the software and its approach has been published elsewhere.¹

3. Methods to Maximize Response Rates and Deal with Nonresponse

NAMCS uses multiple methods for maximizing physician response. The medical community, including the AMA and the AOA, is informed and consulted about the study, and NAMCS annually receives nineteen endorsement letters from various major medical societies and professional organizations used for enlisting sampled physicians (**Attachment N**). NAMCS survey procedures and forms are designed to minimize the time required of physicians to participate. All physicians selected in non-HC NAMCS samples are excluded from possible selection again for the following two years (regardless of whether they have signed-up for the Registry or not). In addition, the Census FRs are given detailed training in survey procedures with special modules on gaining physician cooperation.

NAMCS also uses a mailing insert to help persuade the physician, gatekeeper, or HC administrator to participate. It has answers to questions that physicians and advanced practice

¹ Research Triangle Institute. SUDAAN User's Manual, Release 9.0.1. Research Triangle Park, NC: Research Triangle Institute, 2005.

providers may have on why they should participate, describes how the Privacy Rule permits data collection for NAMCS, and provides a link to the NAMCS participant website.²

The survey uses procedures to verify the eligibility status of physicians to ensure they were not just refusal cases who were erroneously labeled as non-eligible, or out-of-scope. U.S. Census Bureau and NCHS staff review at least 50% of physicians coded as ineligible to confirm that these were not erroneously coded. If a physician was mistakenly classified and time permits, attempts will be made to return to processing the case and, if applicable, collecting visit data records. Through years of experience with NAMCS, techniques for converting refusals have been developed that are quite effective, flexible, and responsive to individual concerns. By primarily using supervisory personnel, there has been successful conversion of approximately 15% of initial refusals to successful participants.

To further maximize response rates, we continue to provide physicians, advanced practice providers, and heath care professionals the opportunity to earn continuing education credits by learning more about NAMCS through web-based educational modules presented on the CDC Public Health Training Network. The module, titled the "NAMCS: What Clinicians Need to Know" presents key NAMCS concepts, interspersed with quiz questions after each concept to reinforce learning. This educational module was last updated in 2017 and is currently being updated again for 2021 and onward.

Another incentive to help maximize response is that physicians and advanced practice providers can register with the National Health Care Surveys Registry. By voluntarily registering, these individuals have already agreed to participate in NAMCS when sampled by providing data through submission of EHRs when requested. We will continue to monitor data collection via EHRs among registrants for any nonresponse issues in an effort to not only identify them but determine future approaches that may increase response among those sampled physicians included in the Registry.

Prior observation of nonresponse cases in NAMCS found that a substantial portion of interviews break-off at the initial contact, or stage of the telephone screener (43%) and often the refusal is from the office staff rather than the physician or HC facility director. Each year in our annual statistical report, we describe weighted characteristics of NAMCS physician respondents and non-respondents on numerous variables including: age, gender, geographic region, metropolitan statistical area (MSA) status, type of doctor, specialty, specialty type, type of practice, and annual visit volume. In 2016 a nonresponse bias report about the 2012 NAMCS estimates was published as a *Vital Health Statistics* report,³ which found after adjustment for nonresponse by MSA status, Census division or targeted state, and physician specialty categories, no or minimal biases (<2.0% points) were observed by these characteristics between physician estimates based on the full eligible physician sample and physician estimates based on either of the two NAMCS respondent types (Induction Interview respondents and those who completed the Induction and submitted visit data).

² <u>https://www.cdc.gov/nchs/ahcd/namcs_participant.htm.</u>

³ <u>https://www.cdc.gov/nchs/data/series/sr_02/Sr02_171.pdf.</u>

4. Tests of Procedures or Methods to be Undertaken

In 2005, response rate for physicians who participated in the NAMCS was approximately 62%; however, this response rate has since declined. The preliminary Induction Interview response rate for the 2020 NAMCS Physician Component, as of October 2020, was approximately 27%. Given the current novel coronavirus (COVID-19) disease pandemic, and preliminary response rates for 2020, we expect the response rate in 2020 to decrease even further. Tracking for the initial fielding of the 2020 NAMCS shows that this response rate will continue to decrease, in part driven by the current novel COVID-19 pandemic.

Due to the decreasing physician response rates, we propose to conduct an experiment in which we provide an incentive to a subset of office-based physicians in the 2021 NAMCS sample. Although NAMCS has not previously used incentives for physicians, there has been literature which shows that incentives, regardless of whether they are provided before or after completion of survey, increase response rates. Specifically, monetary incentives – whether before or after survey completion – fare better than the use of no incentives. For example, Young et al. saw a 15% response rate with incentives provided before fielding of a survey, and a 11% response rate with incentives provided after a survey, both of which were found significantly higher than the 7% response rate for those with no incentive.⁴ Monetary incentives have also been found to produce higher response rates overall in physician surveys compared to non-monetary incentives.^{5,6} Because incentives provided to physicians both before and after completion of a survey have significantly increased response rates, to remain fiscally responsible we propose a post-completion monetary incentive of \$100 for participating physicians. This will allow the survey to profit from the benefits of using a monetary incentive while also limiting cost.

This experiment will test the effect of monetary incentive on the traditional NAMCS response rate. It will also help improve the response rate for the previously approved COVID-19 questions that are asked in the NAMCS Physician Induction Interview. If approved, the experiment will begin with the final quarter of data collection for the 2021 office-based physicians survey and possibly continue into the 2022 data collection year and onward. The proposed strategy for implementing the incentive would be as follows:

- The physician sample for the experimental period(s) will be divided into two subsamples that keep the distributions of physicians by region, specialty group, and MSA status similar between the two subsamples. Physicians in the experimental subsample will be offered the incentive while physicians in the control subsample will not.
- The approved NAMCS Screener portion of the interview will be conducted by a U.S. Census Bureau FR, which ensures the sampled physician is eligible to participate in the NAMCS.
- If the physician is eligible, an appointment to complete the NAMCS Physician Induction Interview will be scheduled. At this time, the Census Bureau FR will also inform the

⁴ Young JM, O'Halloran A, McAulay C, Pirotta M, Forsdike K, Stacey I, Currow D. Unconditional and conditional incentives differentially improved general practitioners' participation in an online survey: randomized controlled trial. Journal of Clinical Epidemiology 68:693-697; 2015.

⁵ David MC, Ware RS. Meta-analysis of randomized controlled trials supports the use of incentives for inducing response to electronic health surveys. Journal of Clinical Epidemiology. 67:1210-1221; 2014.

⁶ Pit SW, Vo T, Pyakurel S. The effectiveness of recruitment strategies on general practitioner's survey response rates – a systematic review. BMC Medical Research Methodology 14:76; 2014.

physician that they will receive \$100 in the form of cash or a gift card when they complete the NAMCS Induction Interview.

- At the beginning of the scheduled Induction Interview, the FR will remind the physician of the incentive, and then proceed to administer the approved NAMCS Physician Induction Interview.
- At the completion of the Induction Interview, the FR will confirm the physician's office mailing address (which is already verified in the approved interview) to which the incentive can be sent and thank the physician for their time.

In an effort to modernized data collection, NCHS has also submitted a proposal for a Patient Center Outcomes Research Trust Fund (PCORTF) project utilizing NAMCS data. The goals of this project are to: (1) leverage existing infrastructure and optimize advances in health information technology (health IT) in order to expand the collection and processing of EHRs for maternal health visits to HRSA supported HCs; (2) link these clinical visit data to mortality data available in the National Death Index and to social determinants of health measures available in administrative data from the U.S. Department of Housing and Urban Development (HUD); and (3) make available a nationally representative dataset on maternal health care, including its relation to COVID-19, at HCs in the United States.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The statistician responsible for the survey sample design is:

Iris Shimizu, Ph.D. Mathematical Statistician Statistical Research and Survey Design Staff Office of Research and Methodology National Center for Health Statistics (301) 458-4497 ishimizu@cdc.gov

The data collection agents are the U.S. Census Bureau and Booz Allen Hamilton, and the contacts for these two organizations are as follows:

Booz Allen Hamilton (BAH) Amit Sinha BAH Project Director National Center for Health Statistics (919) 704-1680 <u>pkq6@cdc.gov</u>

U.S. Census Bureau Lucinda Dalzell Survey Director, Demographic Programs Demographic Surveys Division U.S. Census Bureau (301) 763-1680 Lucinda.P.Dalzell@census.gov

The data will be analyzed under the direction of:

Sonja Williams, M.P.H. Acting Team Lead, Ambulatory Care Team Ambulatory and Hospital Care Statistics Branch Division of Health Care Statistics National Center for Health Statistics (301) 458-4774 iwn2@cdc.gov