

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

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Supporting Statement

National Center for Health Statistics National Ambulatory Medical Care Survey (NAMCS)

- Goal of the study: To assess the health of the population through patient use of physician offices and health centers (HCs, formerly known as community health centers), which include federally-qualified health centers (FQHC), FQHC look-alikes and Urban Indian Health Centers, and to monitor the characteristics of physician practices.
- Intended use of the resulting data: These data are used to monitor public health, used by DHHS for program planning and to inform national policies, and used by health care researchers, medical schools, policy analysts, congressional staff, the news media, and many others to improve our knowledge of medical practice patterns and patients.
- Methods to be used to collect data: A stratified, randomized list of sampled providers is generated from a universe of physicians. Basic practice characteristics are collected, and these sampled providers are then assigned a pre-determined 7-day reporting period to collect cross-sectional patient medical record data. For HCs, a randomized list of health centers is generated from a universe of HCs. Data from all patient medical records are collected for the full calendar year from the stratified sample of HCs.
- The subpopulation to be studied: The subpopulation includes two separate populations. Sampled physicians in private practice and patient visits seen by these physicians. Additionally, sampled HCs and patient visits to these HCs for the calendar year will be collected.
- How data will be analyzed: NAMCS data are weighted and analyzed using appropriate statistical approaches. Public-use files will be made available where possible. Findings will be released in NCHS reports, journal articles, and research papers, as well as released to researchers for analysis.

The National Center for Health Statistics (NCHS) requests approval for a revision of an approved data collection, the ongoing NAMCS (OMB No. 09200234: Exp. Date 05/31/2022). On 05/23/2019, NAMCS was approved to collect data for the three years – 2019, 2020, and 2021. A non-substantive change was approved on 07/01/2020, which included the addition of coronavirus disease (COVID-19) questions to the Physician Induction Interview and the Health Center (HC) Facility Interview questionnaires. The current approval being requested will be to collect data in the 2021, 2022, and 2023 NAMCS cohorts using updated instruments and methods. In addition, we also request the approval to submit non-substantive change packages, as needed, for modifications occurring throughout the 2021-2023 study period. Changes from 2020 that are included in this request are:

- Continuing previously approved 2019-2021 survey activities for the next 3 years (2021, 2022, and 2023);
- Modifying existing questions for clarification and to keep current with medical practice and terminology;
- Update and more accurately reflect the burden associated with NAMCS;
- Change the data collection process for HCs from manual abstraction to transmission through electronic health records (EHRs);
- Allow for a new HC facility interview
- Discontinue interviews and reinterview study of HC providers for 2021-2023;
- Provision of a set-up fee to sampled HCs;
- Conduct methodological work to improve upon future survey; and,
- Inclusion of the potential for experiments involving physician incentives, as well as including the option to request additional revisions that may allow for improved data collection.

Continuing data collection activities:

- Collection of patient visits to office-based NAMCS physicians;
- Continue COVID-19 questions in 2021 and for subsequent data years when information is pertinent;
- Continue a reinterview study for 2021-2023 NAMCS physicians, who do not participate in EHR visit data submission; and,
- Continue to include the potential for a supplemental sample of office-based physicians from which visit data are collected through submission of EHRs, with approved 2019 sample size, for subsequent survey years when deemed necessary.

A. Justification

1. Circumstances Making the Collection of Information Necessary

NAMCS is a national survey of office-based physicians and HCs conducted by the NCHS, Centers for Disease Control and Prevention (CDC). The survey is conducted under authority of Section 306 of the Public Health Service Act (42 USC 242k) (**Attachment A**).

An overarching purpose of NAMCS is to meet the needs and demands for statistical information about the provision of ambulatory medical care services in the United States; this fulfills one of NCHS missions, to monitor the nation's health. Additional justifications for conducting NAMCS include the need for more complete data to study: (1) the performance of the U.S. health care system, (2) care for the rapidly aging population, (3) changes in services such as health insurance coverage change, (4) the introduction of new medical technologies, (5) the use of HCs in the health care community, and (6) the use of EHRs. Ongoing societal changes have led to considerable diversification in the organization, financing, and technological delivery of ambulatory medical care. This diversification is evidenced by the proliferation of insurance and benefit alternatives for individuals, the development of new forms of physician group practices and practice arrangements (such as office-based practices owned by hospitals), and growth in the number of alternative sites of care.

New/modified activities planned for the 2021-2023 survey period:

COVID-19 Response

On July 1, 2020 OMB granted approval to a non-substantive change to NAMCS in response to the COVID-19 pandemic. This non-substantive change allowed for the inclusion of 5 questions (with a few of these containing sub-questions) that have been used to assess whether physician offices/HCs: (1) encountered shortages in personal protective equipment (PPE); (2) encountered shortages in COVID-19 tests; (3) turned away or referred elsewhere presumptive positive COVID-19 patients; (4) had any health care providers at their practice or center who tested positive for COVID-19; and (5) used telemedicine or telehealth to facilitate patient care. All 5 items will be continued into 2021 and for subsequent data years where the information is pertinent.

NAMCS Sample Size

From 2021 onward the term Health Center will replace the term Community Health Center, per guidance from the Health Resources and Services Administration (HRSA). The currently approved and final fielded sample size for 2020 is 104 total HC delivery sites and 312 HC providers.

In 2021, the sample size will be reduced to 50 HCs, and in 2022 allocated funds will cover a total sample of 110 HCs. In 2023 the sample size will increase to 115 HCs. Health Centers recruited into the survey will continue to provide EHR data for a minimum of five years or until they no longer wish to participate. There will be no sample of HC providers.

The annualized 2021-2023 NAMCS sample size is projected to be 5,000 office-based physicians and 92 HCs. These data expand the capacity of the NCHS/CDC and partners for monitoring the effects of expanded health coverage on use of appropriate preventive services.

Office-based Physicians Induction Interview

The Physician Induction Interview collects a variety of information, including physician and practice information. **Attachment C1** shows the currently fielded 2020 Physician Induction Interview. **Attachment C2** provides the full list of 2021 questions in the order that it would appear in the instrument for office-based physicians and highlights in red the changes from 2020 to 2021. These changes include updates to the currently approved list of top currently used EHR systems provided by The Office of the National Coordinator for Health Information Technology (ONC), sponsors of the National Electronic Health Records Survey (NEHRS).

We propose the addition of methodological work to improve physician response, investigate the current sampling frames, and explore recommendations made at the NCHS Board of Scientific Counselors (BSC) NAMCS Workgroup Meeting (**Attachment D**). Some of this work includes the addition of a post-completion monetary incentive experiment of \$100, for the 2021 survey year, with a possible extension. The Census Bureau field representatives (FRs) will inform NAMCS eligible physicians about the incentive when they make an appointment for the Physician Induction Interview (**Attachment C2**) and remind the physician of that incentive at the beginning of the scheduled interview. At the completion of the Induction Interview, the FR will confirm the physician's office mailing address to which the incentive can be sent and thank the physician for their time. **Attachment C3** shows the draft language to be used at the beginning and end of the Induction Interview. Full justification for need for the incentive can be found in "Section 9: Explanation of Any Gifts or Incentives to Respondents."

Office-based Physicians Induction Interview

For the remaining 2020 data collection and the 2021 data collection year we are only conducting the induction component of the NAMCS Office-based Physicians (Abstraction) survey. Abstraction was stopped because the response rate for extraction was extremely low during the first quarter of the 2020 data collection. The response rate was low for several reasons including: inability to access physician offices due to safety concerns for both physicians and FRs and the additional burden placed on physicians by the COVID-19 pandemic. We also added questions to the Physician Induction Interview to provide insight into the impact of COVID-19 on the operations of physician offices in the United States.

Health Center Provider Induction Interview

The HC Provider Induction Interview collects a variety of information, including information about HC providers. **Attachment E** shows the currently fielded 2020 Interview. Starting with the 2021 survey we will no longer be collecting specific information on HC providers and propose removing the HC Provider Induction Interview.

Health Center Induction Interview

The HC Facility Induction Interview collects a variety of facility-level information. **Attachment F1** shows the currently fielded 2020 HC Facility Induction Interview. In 2021 we propose removing the current HC Facility Induction Interview and utilizing a new HC Facility Interview. **Attachment F2** provides the full list of questions on the new 2021 HC Facility Interview.

Health Center Visit Data

For decades NAMCS has provided national data on ambulatory care. However, as the delivery of health care continues to change, the survey also must evolve, through using modernized data infrastructure and additional modes of data collection, such as the integration of EHRs. NCHS currently relies solely on manual record abstraction to collect HC clinical visit data. HRSA reports that 99% of FQHCs¹, a significant segment of the current NAMCS HC universe, use EHRs. Therefore, in 2021 NAMCS data collection procedures for visits to HCs will be through submission of EHR data from a sample of HCs directly to NCHS using the existing NCHS Healthcare Electronic Health Records (HEHR) platform. The reporting period will change from 1 week of visit data for selected providers to a full 12 months of EHR data from the entire HC. For 2021, the sample size will be reduced to 50 HCs, with plans to increase to 110 in 2022, and then 115 HCs in 2023. NCHS is partnering with the HRSA on the 2021 HC data collection. A \$10,000 set-up fee will be given to every fully participating HC. The electronic patient record form (PRF) (**Attachment G1**) will no longer be utilized because the data will no longer be collected using manual abstraction, but instead data will be collected through submission of EHRs according to the National Health Care Surveys' Health Level Seven International (HL7) Implementation Guide (IG) for Clinical Document Architecture (CDA®) Release 1, Release 1.2, or Release 1.3 - US Realm, and transmitted to the HEHR platform. This IG was created by NCHS to provide a format for EHR data transmission to NCHS by survey participants. A list of the data elements collected can be found in **Attachment H**. The IG and its templates can be found in **Attachments I** and **J**.

2. Purpose and Use of the Information Collection

The purpose of this study is to collect information about physician practices, information about characteristics and clinical data on ambulatory patients (e.g., diagnoses, services/tests, medications, and visit disposition), and the resources used for their care. The resulting published statistics and data sets help health care providers and professionals plan for more effective health services, improve medical and health education, and assist the public health community in understanding the patterns of diseases and health conditions. In addition, policy makers use NAMCS data to identify: (1) quality of care issues, (2) medical resource utilization, and (3) changes in health care over time.

If NAMCS data were not collected, there would be no national estimates on health care issues faced by office-based physicians or HCs. Items on the NAMCS Physician Induction Interview (**Attachment C1** and **C2**) result in data that allow researchers to examine a variety of health

¹ <https://bphc.hrsa.gov/uds/datacenter.aspx?q=tehr&year=2018&state=>

topics, including: experiences with providing care during the COVID-19 pandemic, EHR system use and associated system characteristics, and characterization of the health care workforce including staffing composition of office-based practice, autonomy of advanced practice providers, and coordination of care.

NAMCS provides a range of baseline data on the characteristics of office-based physicians and HC facilities providing ambulatory medical care. Data collected include the demographic characteristics of patients, medical diagnoses, medications, and visit disposition that are used to make annual estimates as well as estimate trends that are used to monitor the effects of change in the health care system, provide new insights into ambulatory medical care, and stimulate further research on the utilization, organization, and delivery of ambulatory care.

NAMCS information is also useful to managers of health care delivery systems, and others concerned with planning, monitoring, and managing health care resources at both physician offices and HCs. It is valuable to those who develop and evaluate new and modified health care systems and arrangements, and the continuing nature of the survey permits observation and measurement over time of different medical examinations and procedures for managing and treating patient problems. It also provides valuable information on the patterns of selected conditions and the adoption and usage of new medical practices among office-based physicians and HCs.

Users of NAMCS include numerous governmental agencies, state and local governments, medical schools, schools of public health, colleges and universities, private businesses, non-profit foundations, corporations, and professional associations, as well as individual practitioners, researchers, administrators, and health policymakers. Uses vary from the inclusion of a few selected statistics in a large research effort, to in-depth analyses of the entire NAMCS data set covering multiple years.

For 2021 and moving forward, NAMCS is planning to allow for the submission of EHR data by selected sampled office-based physicians (as has previously been done in the years 2016-2017) and by all sampled HCs. Those eligible physicians who are registered with our National Health Care Surveys Registry (NHCS)² can earn credit as part the Centers for Medicare and Medicaid Services' (CMS) EHR Incentive Programs: PI and the Merit-based Incentive Payment System (MIPS) as a fulfillment of the public health reporting measures of PI/MIPS.

3. Use of Improved Information Technology and Burden Reduction

The use of electronic collection in NAMCS has reduced the burden for respondents when answering both the NAMCS Physician Induction Interview and HC Facility Induction Interview questions. Using a computer-assisted interviewing instrument or other means of electronic data collection (e.g., web portal) for these interviews allows the U.S. Census Bureau FRs or contractors automatically skip unnecessary survey questions, reduce incorrect or inconsistent entries and the need for paper flashcards and, thus, ultimately reducing time spent on these NAMCS Interviews.

² https://www.cdc.gov/nchs/dhcs/nhcs_registry_landing.htm.

For office-based physicians who have been sampled for visit data abstraction by U.S. Census Bureau FRs, the use of a computerized data entry system (**Attachment G1** and **G2**) simplifies data collection activities by reducing data entry errors and omissions, as well as providing on-screen look-up tables for selected variables. Compared to using the paper-and pencil method, this computerized system reduces both FR and respondent burden and improves data quality.

For physicians who are selected or choose to submit their visit data electronically, as well as all sampled HC facilities starting in 2021, submission of NAMCS visit data will occur electronically through the NCHS HEHR System using the National Health Care Surveys' IG created in collaboration with ONC and multiple NCHS subunits including the Office of Classifications and Public Health Data Standards. Through use of the HEHR System, manual data collection procedures are reduced relative to manual abstraction, simplifying data collection/transmission, and reducing the burden among these selected physicians and the HC facilities.

To encourage selected physicians and all sampled HC facilities to submit data electronically using their EHR system, the NCHS National Health Care Surveys Registry (which encompasses NAMCS) is included as part of the CMS EHR Incentive Programs PI/ MIPS. Eligible physicians/clinicians can register intent and possibly submit EHR patient data as a fulfillment of the public health reporting measures of PI/MIPS. Those who do this attest to meeting one of the public health reporting measures of PI/MIPS and are able to receive PI/MIPS credit through CMS, which is a substantial incentive and recruitment tool for participation in NAMCS.

To successfully complete survey participation via EHR submission, sampled physicians and (starting in 2021) HCs must demonstrate the ability to electronically submit EHR data via the IG. For 2021-2023, HCs will be offered a one-time \$10,000 set-up fee to help offset the cost of implementing the NHCS IG. Data elements about the physician and physician's practice location(s) are requested of sampled office-based physicians, and limited facility information is requested of HCs. In addition, all sampled physicians submitting EHR data and HCs will be invited to a testing and validation stage, and ultimately to submit EHR data via the IG. All of these sampled physicians and the HCs will be asked to provide all patient visits for a designated reporting period (one week physicians; a full year for HCs). Reporting period for the physician component of NAMCS may change in the future, dependent upon methodological work. Data received from participants will be evaluated, and if acceptable, will be added to the NAMCS data set.

4. Efforts to Identify Duplication and Use of Similar Information

NCHS staff have had extensive contacts regarding survey items with organizations and individuals in both the private and public sectors who are familiar with physician and HC utilization data. Advice from consultants, attendance at relevant meetings, and literature reviews have been used to identify other sources that collect nationally representative data similar to those collected by NAMCS, and three have been identified and are discussed below.

The National Health Interview Survey, or NHIS (OMB No. 0920-0214, Exp. Date 12/31/2023) is a population-based survey in which information is obtained through household interviews. In

addition to the recall problems that may be associated with household respondents, NHIS respondents cannot provide the detailed medical information about diagnoses, diagnostic/therapeutic procedures, or medications. They can only be expected to provide counts of physician visits and general medical information.

The Medical Expenditures Panel Survey, or MEPS (Agency for Healthcare Research and Quality, OMB No. 0935-0118, Exp. Date 11/30/2022), is a survey of households and their members' health care providers (including physicians in office-based practices), health insurance companies, and employers. As with NHIS, household respondents cannot supply detailed medical information. Medical information collected from physician respondents does not include detailed data on medications, and other therapeutic services. Both NHIS and MEPS also experience an unknown degree of reporting bias because it is likely that respondents may be reluctant to report medical contacts for sensitive problems (e.g., psychiatric disorders).

The Bureau of Primary Health Care at HRSA has their Uniform Data System (UDS), which is a mandatory reporting system of federally-qualified health centers who are funded under Section 330 of the Public Health Service Act. Those not funded by Section 330, as well as Indian Health Centers, are not required to submit these data to the UDS. NAMCS collects data on all three of these types of HCs. While the UDS collects general characteristics and information on the funded health centers, it does not include visit data to the extent of which are collected by NAMCS.

These data sources include useful information but are not adequate for collecting and providing the detailed patient visit data from office-based physicians and HC facilities that are collected by NAMCS. The depth of data collected in NAMCS about ambulatory patients, as well as physicians, allows for rich analysis regarding the provision of ambulatory medical care and is an ideal source of data for understanding the care provided in these settings.

5. Impact on Small Businesses or Other Small Entities

A portion of NAMCS respondents are physicians in private solo practices or a small group. In order to reduce respondent burden for these and all respondents, the survey procedures select only a sample of physicians to be contacted. The sample each year will not overlap with samples from which data were collected for any NEHRs, NAMCS, NAMCS supplement, or other physician surveys conducted by NCHS in the prior two years. Also, data topics will be kept to the minimum necessary for the study. Furthermore, the data collected on each patient visit is limited to data already obtained by the physician and is recorded in the patient's medical record and is further limited to a minimum number of items which adequately describe the utilization of ambulatory medical care. For physicians sampled for abstraction, visit data are only collected from a designated one-week period. U.S. Census Bureau FRs also complete that abstraction themselves in order to further minimize burden.

A reduction in NAMCS respondent burden has been noted for office-based physicians who have been sampled to submit EHR data relative to having data collected through abstraction. We estimate that more than 80% of sampled physicians who work in large medical group practices or are employed by large health care integrated delivery networks will not be personally involved in submitting NAMCS Physician Facility Interview (PFI) or EHR visit data. The remaining office-based physicians who are sampled to submit data electronically are estimated to be practicing in small medical practices and will submit data themselves; however, the NAMCS PFI will only collect information necessary to produce national estimates using their EHR data which limits time spent completing this form. We expect that many of these physicians in small practices will have their staff work on NAMCS tasks. Also, for office-based physicians sampled for collection of data using EHRs, and all sampled HCs, no abstraction will be used. Instead, use of the NCHS IG will allow for NAMCS data elements to come from already available information captured by their respective EHR systems. Furthermore, once a HC is sampled for participation in NAMCS and the initial set-up is completed, burden will be further reduced in future years as the Center would continue to participate in NAMCS and there may be no need for a new HC Facility Interview. The HCs will continue in the survey until a new sample is drawn which we anticipate will be in a minimum of 5 years.

6. Consequences of Collecting the Information Less Frequently

The rapidly changing environment of ambulatory care delivery makes it important to have annual data for decision making, describing the public's use of physician and HC services, monitoring the effects of change, and planning possible changes in payment policies. This information has become even more crucial with the need to track the effects of the health care industry's changing arrangements for delivering care by having continuous data collection before, during, and after major health care and public health changes, such as the opioid epidemic and the COVID-19 pandemic. Less frequent collection would also limit the study of rare visit characteristics, for which NAMCS data can be used to study by combining data across years to increase reliability.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

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

Federal Register Notice

This project fully complies with all guidelines of 5 CFR 1320.8(d). A 60-day Federal Register Notice was published in the Federal Register on January 28, 2021, volume 86, No. 17, page number 7398 (**Attachment B**). No public comments were received.

Efforts to Consult Outside the Agency

NCHS has worked closely with consultants both within and outside CDC on the development and procedures for NAMCS, and planning for future years of data collection. Most recently NCHS has consulted the BSC in an effort improve NAMCS data collection efforts. This resulted in a report produced by a special BSC Workgroup convened to formulize recommendations for improvement (**Attachment D**). NCHS will continue to work closely with these outside individuals and agencies as the need for consultation arises. Currently, there are no outstanding unresolved issues. A list containing the names of the consultants is provided in **Attachment K**.

9. Explanation of Any Payment or Gift to Respondents

NCHS is requesting approval to conduct an experiment with a post-completion monetary incentive of \$100. With the ongoing COVID-19 pandemic, NAMCS has received approval to ask participating physicians survey questions related to experiences providing health care during the COVID-19 pandemic beginning with the last two quarters of its 2020 data collection. However, in order to provide reliable estimates on these experiences, the response rates must be adequate to produce reliable estimates. With the early 2020 response rates at 27.8%, and challenges in fielding NAMCS created by COVID-19, we would like to propose an experiment to use monetary incentives to increase this response rate and ensure reliable estimates can be made.

Incentives have been used as a way of increasing survey response rates for many years. Current literature shows that adding incentives help to increase response rates for many types of surveys with monetary incentive faring better than non-monetary incentive.^{3,4} An Australian physician randomized controlled trial on unconditional (monetary incentive before survey completion) and conditional incentives (monetary incentive after survey completion) showed that both types of incentives fair better in increasing response rates than with no incentive.⁵

Although research seems to favor unconditional, or prepaid incentives before survey completion, for NCHS to remain fiscally responsible we propose a post- completion monetary incentive experiment. This will allow the survey to benefit from the boost monetary incentives can give without using government funds irresponsibly. This incentive will be given on completion of the induction portion of the survey. Conditional incentives will allow for the benefits of monetary incentive while still being fiscally conservative. The incentive will be introduced at the beginning of the Induction Interview (**Attachment C2**) conducted by a FR and then again at the conclusion of the Induction Interview after confirming the right mailing address (**Attachment C3**).

We are partnering with HRSA on the HC component. Approval is requested to employ a one-

³ 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.

⁴ 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.

⁵ Young JM, O'Halloran A, McAulay C, Pirota 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.

time \$10,000 set-up fee provided to every HC which participates starting with the 2021 survey year. This fee will assist HC's with the administrative costs of setting up their EHR data in the format of the IG to HEHR.

Any future plans to offer additional payment or gifts would be submitted to OMB for review and potential approval.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

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

An assurance of confidentiality is provided to all respondents, according to section 308 (d) of the Public Health Service Act (42 USC 242m) which states:

“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)

NAMCS and related supplements provide numerous and varied national estimates on provider, visit, and practice characteristics. Although a majority of the data collected are not considered

personally identifiable, some fit the definition of information in identifiable form (IIF). A list of all IIF data items is highlighted below, and all were approved by OMB in the previous packages to be collected on survey forms. None of these data are released to the public or become part of public-use files.

With the traditional physician offices of NAMCS utilizing automation, the need to record potentially identifiable information on paper is eliminated. Medical record numbers are entered into the computerized instruments but will only be used for survey operations purposes. The medical record number will aid field representatives in abstracting data from the various record systems in the facility. It will also aid the identification of separate visits among EHR records. Once the case is complete and the data are ready to be transmitted to NCHS, the medical record number will be wiped from the dataset and will not be retained beyond that time.

Beginning in 2021, NAMCS is requesting to increase the PII, also referred to as information in identifiable form, it collects. An example of the value of PII is that it allows the potential for linkage to the National Death Index (NDI), the U.S. Department of Housing and Urban Development (HUD) and other sources for the HC EHR data collection and office-based physicians who submit EHR data. The list of requested PII includes the following data elements for patients, physicians, and HCs.

Information in Identifiable Form Categories:

- Physician/HC provider name
- Physician/HC provider mailing address
- Physician/HC provider telephone number
- Physician/HC provider National Provider Identifier (NPI)
- Physician/HC provider Federal Tax ID/Employer Identification Number (EIN)
- HC executive director name
- HC mailing address
- HC contact person
- Physician office/HC staff name
- Patient medical record number
- Patient date of birth
- Patient name
- Patient Address
- Patient ZIP Code
- Patient Date of visit
- Patient Social security number (where available)
- Patient control number
- Medicare health insurance benefit/claim number

NAMCS will include a routine set of measures to safeguard confidentiality, including the following: all staff, including contractors at the U.S. Census Bureau and other contractors, who have access to confidential information are given instruction by NCHS staff on the requirement to protect confidentiality, and are required to sign a pledge to maintain confidentiality; and only such authorized personnel are allowed access to confidential records, and only when their work requires it. When confidential information is not in use, it is stored in secure conditions. The FR

enters patient medical record data directly into his or her assigned laptop alone and nowhere else. Once the data collection is completed, the FR electronically transmits the data onto a secure server and the data are wiped from the FR's laptop. As mentioned earlier, transmission of NAMCS EHR data will be directly sent to NCHS via Secured File Transmission Protocol (SFTP) through the Secure Access Management Services (SAMS) and/or DIRECT secure messaging. SAMS is accessed through a website and will provide secure transmission for the NAMCS data submissions.

Participating physicians who submit EHR data and (starting in 2021) HCs will be asked to submit all data through the HEHR system at NCHS. The HEHR system was developed to provide the Division of Health Care Statistics the technical support it needs to implement the public health registry component of the NHCS and to support the receipt of data from eligible providers and hospitals in accordance with the PI Program rules. This includes, but is not limited to, planning, designing, developing, and maintaining the infrastructure necessary to operate the surveys registry portal to allow for registration of providers and hospitals that intend to participate in the survey and submit data. Upload interfaces via CDC's SAMS and/or DIRECT secure messaging are also included.

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. DIRECT is a national encryption standard for securely exchanging clinical healthcare messages/data via the internet. DIRECT provides strong security and privacy protection using a unified standard that all systems can leverage.

On receipt of the data within the HEHR system, all data considered PII, both direct and indirect, and non-PII will be loaded/saved to specially designated and configured file servers and database servers that are in accordance with the Confidential Information Protection Statistical Efficiency Act (CIPSEA). HEHR system servers are secured physical components that are only accessible by NCHS-designated staff. The HEHR system will communicate with Consolidated Statistical Platform (CSP) (another CIPSEA compliant system) primarily for analytic purposes.

In keeping with NCHS policy, NAMCS data are made available via public-use data files on the NAMCS website once individually identified information is removed. Confidential data are never released to the public. All personal identifiers such as physician/provider name, patient name, patient address, patient date of birth, and any other specific information are removed from the public release files. All data releases are reviewed by the NCHS Disclosure Review Board to avoid data breaches, such as release of detailed geographic information that may allow anyone to identify practices or individuals in the general population.

The ambulatory health care data website dedicated to NAMCS (https://www.cdc.gov/nchs/ahcd/namcs_participant.htm) describes the survey, answers questions

respondents may have on why they should participate, and describes how the Privacy Rule permits data collection for NAMCS.

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

The NAMCS data collection plan has been approved by NCHS's Ethics Review Board (ERB) (Protocol #2016-03) based on 45 CFR 46. In addition, the Board has granted (1) a waiver of the requirement to obtain informed consent from the patient, (2) a waiver of the documentation of informed consent by physicians, and (3) in accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Regulation (45 CFR 164.512), a waiver of patient authorization for release of patient medical record data by health care providers.

The ERB letter granting approval for Protocol #2021-03 for the NAMCS for the maximum allowable period of one year is presented in **Attachment L**.

In the introductory letter (**Attachments M1, M2, and M3**) from the NCHS Director, it states that participation in NAMCS is voluntary and there is no effect on the respondent for not participating. Please note, there are 4 letters in **Attachment M1**. The first two are intended for our office-based physicians with the second letter being an experimental office-based physician letter that was used during quarters 3 and 4 of 2020 and may be used in the future. The last two are intended for HC executives/medical directors and HC providers. All four letters provide an overview of the study, are the primary tools to obtain informed consent to participate in the study, and state the legal authority for NAMCS data collection is Section 306 of the Public Health Service Act (42 U.S.C. 242k).

In 2021, NAMCS is requesting to increase the PII it collects. One example of the value of PII is that it allows linkage to the NDI and other data sources such as CMS data and HUD data. The list of requested items considered to be sensitive includes the following data elements for patients, physicians, and HCs:

Patient:

- Name
- Birth date
- Address
- ZIP Code
- Visit dates
- Social security number (where available)
- Medical record number (where available)
- Patient control number
- Medicare health insurance benefit/claim number

Physician/Provider/ Facility:

- NPI number
- Physician Federal Tax ID/EIN
- Physician name
- Physician mailing address

- Physician telephone number
- HC executive director name
- HC mailing address
- HC contact person
- Physician office/HC staff name

It is necessary for NAMCS to collect some protected and approved health information, such as date of visit, birth date, and ZIP code. These data are used internally to create certain composite variables, such as patient age, which contains 6 mutually exclusive groups. Also, in cases when the Census Bureau abstracts the data from the medical record, the patient's name or address may be viewed in the process of collecting the survey data. Strict procedures are utilized to prevent disclosure of identified PII data. At no time are the patients contacted to obtain information.

After the abstracted data have been collected and processed, a file of the sample visits will be sent to NCHS. The only identifiable elements on the file are date of visit, ZIP code, and birth date. For the public use files, date of visit is converted to month and day of week, birth date is converted to patient's age, and ZIP code is deleted. Patient's ZIP code is used within NCHS to match the visit data to characteristics of the patient's residential area, such as median household income or percent of the population who are high school graduates.

Starting with 2021, HC visit data will not be abstracted and instead EHR visit data will be submitted directly to NCHS via the IG. Along with that change, office-based physicians who submit EHR data and HCs will now include patient first and last name, social security number (SSN), and patient address in their submitted visit records. This is in addition to birth date, zip code, and sex which are currently collected in the NAMCS. These PII data elements will be collected and retained to aid in the goal of linking to the NDI, HUD, and other data sources. Although linkages could be made to the NDI without the SSN, researchers planning to use the NDI are encouraged to collect or compile as many of the NDI data linkage items as possible. For more information on the NDI, see the web link, NCHS -National Death Index Home Page at <http://www.cdc.gov/nchs/ndi.htm>.

Since 2012, we have been collecting medical record number for internal survey operations purposes. This process will continue throughout the 2022-2023 survey years, temporarily pausing for the remaining 2020 and 2021 survey years. The medical record number will be collected in the PRF instrument (**Attachment G2**) to aid the field representative in abstracting data from the various record systems in the facility. Some facilities maintain patient visit information in more than one electronic or paper system, and the medical record number would help the field representative to ensure that they are abstracting data for the correct patient. All information, including medical record number, recorded on laptop-based survey instruments are encrypted and securely transmitted to databases at the Census bureau. In these cases, no actual data remain on the FRs PRF instrument. After the final case is transmitted forward from Census and the medical record number is no longer necessary, the medical record numbers will be deleted from the dataset. NCHS will never receive any medical record number as part of a data delivery from Census abstraction.

In EHR data collected from office-based physicians and HCs starting in 2021, medical record numbers will be retained. The retention of the medical record number for EHR submissions will allow the collection of a single patient's data from several sources within a physicians' office or the HC. This will provide access to more comprehensive and detailed clinical information, as well as additional outcomes and quality measures.

Federal Tax Identification number and NPI number will also be collected. A federal tax identification number, also known as an EIN, is used to identify a business entity (e.g. medical practice) in the administration of tax laws and helps in the identification of sampled physician offices and HCs. NPI is used to uniquely identify a health care provider in standard transactions, such as health care claims. HIPAA requires that covered entities use NPIs in standard transactions. NPI of physicians participating in NAMCS is collected as part of the interview, offering the ability to link the individual patient's care with the specialty of the providers from whom care was received. Information linking provider identifiers to their characteristics (e.g., specialty, provider age) is available from CMS for research purposes (<https://nppes.cms.hhs.gov/NPPES/>). We will not disclose in any manner the identity of specific providers but only analyze the data in aggregate according to physician characteristics.

12. Estimates of Annualized Burden Hours and Cost

Burden Hours

The NAMCS is expected to sample about 6,000 physicians each year, as well as 50 HCs in 2021, 110 HCs in 2022, and 115 in 2023. Once selected HCs are retained in the sample. An additional 60 HCs will be added in 2022 to total up to 110 HCs, and an additional 5 will be added in 2023 to total up to 115 HCs. In previous requests for approval for NAMCS, the response rates of the latest publicly available data were used to estimate the annualized burden hours. However, in this request we have calculated the annualized burden hours as though all sampled units will respond and provide full participation during abstraction of visit data or transmission of EHR data. While we recognize that not all sampled units will complete the survey or fully participate, this method of estimating the burden for NAMCS is comparable to the approach used by many other surveys conducted by NCHS.

This submission requests OMB approval for the completion of the 2020 data collection and for the following three years, 2021-2023, of NAMCS data collection. In 2020, data collection is estimated to be 50% complete at the time of this approval. The estimated annualized burden is 6,819 hours and is summarized in the table below. As done in past submissions, NAMCS activities are presented separately for office-based physicians and HCs. As described earlier, the office-based physicians will have a subgroup of physicians who submit a modified Induction Interview questionnaire and patient visit data through their EHR system.

2020

For the 2020 data collection, each sampled physician receives an introductory letter (**Attachment M1**), along with endorsement letter(s) from a professional organization that supports the survey (**Attachment N**). Office-based physicians are contacted by U.S. Census field representatives who determine their eligibility and ask the physicians to complete a Physician

Induction Interview questionnaire (**Attachment C1**). Completion of the Physician Induction Interview questionnaire takes approximately 30 minutes. For 2020, approximately 3,000 physicians were sampled and are asked to complete the Induction Interview questionnaire. Assuming half the total 2020 sample will be interviewed in calendar year 2021, the total expected response burden for the 2020 NAMCS Physician Induction Interview questionnaire is estimated at 250 hours annualized over the 3 years.

For the 2020 data collection, each sampled HC delivery site receives an introductory letter (**Attachment M1**), along with an endorsement letter from a professional organization that supports the survey (**Attachment N**). The letter provides an overview of the study and is the primary tool used to obtain informed consent to participate in the study. HC delivery sites are contacted by a U.S. Census field representative who determines their eligibility and asks them to complete the HC Facility Induction Interview questionnaire (**Attachment F1**). Then, up to three of the HC site's providers are sampled. Completion of the HC Facility Induction Interview questionnaire takes approximately 30 minutes. Currently, approximately 104 HC delivery sites are sampled a year and asked to complete the HC Facility Induction Interview questionnaire. Assuming that half the total 2020 HC sample will be contacted in 2021, the total expected response burden for the 2020 NAMCS HC Facility Induction Interview questionnaire is estimated at 9 hours annualized over the 3 years. Field representatives contact sample HC providers to complete a HC Provider Induction Interview questionnaire (**Attachment E**). Completion of the HC Provider Induction Interview questionnaire takes approximately 30 minutes. Currently, approximately 312 HC providers are sampled annually and asked to complete the HC Provider Induction Interview questionnaire. Again, assuming at most half the total 2020 HC sample will be surveyed in 2021, the total expected response burden for the 2020 NAMCS HC Provider Induction Interview questionnaire is estimated at 26 hours annualized over the 3 years.

Next, a set number of 30 visits are targeted for abstraction from each sampled provider using the PRF (**Attachment G1**). Because this abstraction is performed by Census Bureau staff, and not HC staff, burden for the completion of these PRFs does not exist. However, there is an anticipated 1 minute of response burden to be incurred by staff when trying to orient the field representatives to their medical record system, or in certain cases where the HC does not grant full access to the field representatives, to pull records from their system and relay that information (**Attachment O1**). In 2020 30 visits are targeted for abstraction from each sampled HC provider using the PRF by U.S. Census Bureau staff. Assuming half the 2020 HC sample will be surveyed in 2021, the annualized burden to complete this process is estimated at 26 hours for the 2020 data collection.

A reinterview study (**Attachment P1**) is finally used to assess consistency of responses provided during the Induction Interview questionnaire. This quality control measure will be administered by U.S. Census Bureau staff to each FR at least once, and after their case disposition is determined. In the 2020 survey year the U.S. Census Bureau approximates 100 reinterviews to be conducted for the second half of the survey year. It is estimated that the annualized burden to the respondents will total 8 hours for the 2020 data collection.

2021-2023

For the 2021-2023 data collection, each sampled physician will still receive an introductory letter (**Attachment M2 and M3**), along with endorsement letter(s) (**Attachment N**) and complete a Physician Induction Interview questionnaire with a field representative (**Attachment C2**). The Induction Interview questionnaire takes approximately 30 minutes. Also, the addition of COVID questions via non-substantive change (approved 7/1/2020; OMB No. 0920-0234, Exp. Date: 05/31/2022) will not affect the burden of the Induction Interview. No one respondent will answer all sub-questions included, and the interviewer will have gained efficiency in the response options for the other non-COVID-19 questions, the additional questions will be absorbed by the current estimated burden calculations. Each year, approximately 3,000 physicians will be interviewed. The 2021-2023 NAMCS Physician Induction Interview questionnaire is expected to be 1,500 hours annually.

In the 2022-2023 data collection, for office-based physicians a set number of 30 visits will be targeted for abstraction from each sampled physician using the PRF (**Attachment G2**). There is an anticipated 1 minute of response burden to be incurred by physician staff when trying to orient the field representatives to their medical record system, or in certain cases where the physician does not grant full access to the field representatives, to pull records from their system and for abstraction by the field representative (**Attachment O2**). The burden to complete this process is estimated at 1,000 hours for the 2021-2023 data collection, annualized over three years.

For the 2022-2023 EHR sampled physician data collection, we presume that none of the sampled EHR physicians will be personally involved in submitting either their NAMCS PFI (**Attachment Q**) or EHR visit data; all burden associated with EHR participation will be with their staff. The three-year annualized average burden associated with completing the NAMCS PFI for an annualized average of 2,000 physicians is 30 minutes. The only other burden associated with submitting visit data will be preparing and transmitting EHR files (40 minutes total annualized over three years for staff associated with each sampled EHR physician) (**Attachment R**). For each year, approximately 2,000 physicians will be sampled on average, asked to complete the PFI, and submit EHR visit data. The total response burden for the 2021-2023 NAMCS PFI is expected to be 1,500 hours annualized over three years. The total expected response burden for the 2022-2023 NAMCS EHR submission is expected to be 2,000 hours annualized over three years.

For the 2021-2023 HC data collection will still receive an introductory letter (**Attachment M2 and M3**) in a welcome packet and additional outreach letters if there is no response to the initial letter. HCs will be asked to complete an initial Facility Interview Questionnaire (**Attachment F2**) and to prepare and transmit EHR Visit data (**Attachment R**). In 2021, 50 HCs will be sampled, with the plan to increase to a total of 110 in 2022, then 115 HCs in 2023. The total expected response burden for the 2021-2023 NAMCS HC Facility Interview Questionnaire is estimated at 69 hours annualized over three years. The total expected response burden for the 2021-2023 NAMCS HCs to prepare and transmit EHR visit data is estimated at 368 hours annualized over three years.

It is approximated there will be 250 reinterviews a year in 2021, and the procedure will continue with similar quantities for subsequent survey years. Reinterviews will no longer be conducted for HC survey respondents. The annualized burden to complete this process is estimated at 63 hours for the 2021-2023 data collection (**Attachment P2**).

Table 1-Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)
Office-based Physicians or Staff (Abstraction)	Physician Induction Interview (2020)	500	1	30/60	250
HC Executive/Medical Directors	HC Facility Induction Interview (2020)	17	1	30/60	9
HC Providers	Provider Induction Interview (2020)	52	1	30/60	26
HC Provider Staff	Pulling, re-filing medical record forms (FR abstracts) (2020)	52	30	1/60	26
Office-based Physicians (Abstraction) and HC Providers	Reinterview Study (2020)	33	1	15/60	8
Office-based Physicians or Staff (Abstraction)	Physician Induction Interview (2021-2023)	3,000	1	30/60	1500
	Pulling, re-filing medical record forms (FR abstracts) (2021-2023)	2,000	30	1/60	1,000
Office-based Physician Staff (EHR Submission)	PFI (2021-2023)	2,000	1	45/60	1,500
	Pulling, re-filing medical record forms (EHR Onboarding) (2021-2023)	2,000	1	60/60	2,000
HC Staff	HC Facility Interview (2021-2023)	92	1	45/60	69
	Prepare and transmit EHR for Visit Data (quarterly) (2021-2023)	92	4	60/60	368
Office-based Physicians (Abstraction)	Reinterview Study (2021-2023)	250	1	15/60	63
Total					6,819

Burden Cost

The cost to providers for each data collection cycle is estimated to be \$258,594.75. This is an increase of \$77,773.75 from the current estimate of \$180,821 that was submitted in the last non-substantive OMB change package. Please note that this increase is partially due to a change in the methodology for burden calculation for this current package, no longer utilizing response rates to calculate burden. The hourly wage estimates for completing various NAMCS forms and activities used in the table below are based on information obtained from the Bureau of Labor Statistics (BLS) web site (<http://www.bls.gov>). Specifically, we used the “May 2019 National Occupational Employment and Wage Estimates” for the categories including: (1) management occupations, (2) healthcare practitioners and technical occupations, and (3) office and administrative support occupations.

Data were gathered on mean hourly wages in 2019 for (1) physicians, (2) advanced practice providers (i.e., physician assistants, nurse practitioners, and nurse midwives) providing care at HCs, and (3) other professionals involved in managing either a private office-based practice or a HC (e.g., nurses, receptionists, etc.). The total cost estimate for NAMCS is detailed by the type of respondent who will complete the associated components of the survey. Specifically, the respondent costs include estimates for completing the Physician Induction Interview items (regardless of whether or how physicians submit visit records), HC facility induction items, and pulling and re-filing medical records/submitting EHR files.

Overall, the average hourly wages presented in Table 2 were averaged across different specialties and positions to capture who may complete each applicable form. The numbers indicated below represent an estimated annualized respondent cost for survey years 2021-2023.

Table 2-Annualized Respondent Cost

Type of Respondents	Form Name	Total Burden Hours	Average Hourly Wage Rate	Total Respondent Costs
Office-based Physicians (Abstraction)	Physician Induction Interview (2020)	63	\$100.00	\$6,300.00
Office-based Physician’s Staff (Abstraction)	Physician Induction Interview (2020)	188	\$33.35	\$6,269.80
HC Executive/Medical Directors	HC Facility Induction Interview (2020)	9	\$91.14	\$820.26
HC Providers	Provider Induction Interview (2020)	26	\$88.54	\$2,302.04
HC Provider Staff	Pulling, re-filing medical record forms (FR abstracts)	26	\$33.35	\$867.10
Office-based Physician (Abstraction) and HC Staff	Reinterview Study (2020)	8	\$33.35	\$266.80

Office-based Physicians (Abstraction)	Physician Induction Interview (2021-2023)	375	\$100.00	\$37,500.00
Office-based Physician's Staff (Abstraction)	Physician Induction Interview (2021-2023)	1,125	\$33.35	\$37,518.75
Office-based Physician's Staff (Abstraction)	Pulling, re-filing medical record forms (FR abstracts) (2021-2023)	1,000	\$33.35	\$33,350.00
Office-based Physician's Staff (EHR Submission)	PFI (2021-2023)	1,500	\$33.35	\$50,025.00
Office-based Physician's Staff (EHR Submission)	Pulling, re-filing medical record forms (EHR Onboarding) (2021-2023)	2,000	\$33.35	\$66,700.00
HC Staff	HC Facility Interview (2021-2023)	69	\$33.35	\$2301.15
HC Staff	Prepare and transmit EHR for Visit Data (quarterly) (2021-2023)	368	\$33.35	\$12,272.80
Office-based Physician Staff (Abstraction)	Reinterview Study (2021-2023)	63	\$33.35	\$2,101.05
Total				\$258,594.75

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

For this project there will be no annual capital or maintenance costs to the respondent resulting from the collection of information.

14. Annualized Cost to the Federal Government

The estimate of average annual (one-data cycle) cost to the government for the 2021-2023 survey is \$11,747,341.

Expense Description	Total Cost
Interagency Agreement for data collection with the U.S. Census Bureau	\$5,000,000
Printing	\$10,901
Contract costs for coding and keying data	\$500,000
Contract costs for collecting and processing physician EHR data	\$3,000,000
Contract costs for collecting and processing HC EHR data	\$2,434,000
Sponsoring agency expenses: Staff salaries, benefits, other miscellaneous costs	\$802,440
Total cost for 12 months	\$11,747,341

15. Explanation for Program Changes or Adjustments

The revision of HC visit data submission along with changing the method of burden calculation will increase the requested burden by 1,780 hours from the 5,039 total hours reported in the most previously approved package. Burden calculation for this current package no longer utilizes response rates to calculate burden. The total NAMCS burden will now request 6,819 hours.

16. Plans for Tabulation and Publication and Project Time Schedule

The duration of activities for core NAMCS (traditional office-based physicians and HCs) will span 12 months. The desired timetable for key activities for the 2021 survey is as follows:

Steps	Timeline	Activity
1	Within one month of OMB approval	Begin data collection for 2021 survey
2	One year after OMB approval	Formally end reporting period
3	Three months after reporting period ends	Close out fieldwork
4	One year and five months after OMB approval	Begin cleaning and weighting
5	One year and six months after OMB approval	Begin data analysis
6	Two years after OMB approval	Public-use data available on Internet Publish reports and on-line data summary tables

Plans for types of data analyses will include, for example, data being presented in the following tables: patient visits by age, sex, and race/ethnicity; expected source(s) of payment; principal reason for visit; primary diagnosis; diagnostic service; disposition; and provider type seen. The NCHS publishes the data on the Internet and in various *NCHS Data Briefs* and other reports, such as the most recent NAMCS *Data Brief* titled “Characteristics of Office-based Physician Visits, 2016.”⁶

The standard tables from the traditional summaries, referred to as *Summary Tables*, will continue to be produced in PDF format on the web. The NAMCS 2016 *Summary Tables* are available at: https://www.cdc.gov/nchs/data/ahcd/namcs_summary/2016_namcs_web_tables.pdf. Other tables are also available, some combining data across surveys or across years at: https://www.cdc.gov/nchs/ahcd/web_tables.htm.

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

The expiration date will be displayed.

⁶ <https://www.cdc.gov/nchs/data/databriefs/db331-h.pdf>

18. Exceptions to Certification for Paperwork Reduction Act Submissions

The data collection fully complies with the guidelines in 5 CFR 1320.9, and no exception is requested to the certification for Paperwork Reduction Act for this submission.