Supporting Statement A for Request for Clearance:

NATIONAL ELECTRONIC HEALTH RECORDS SURVEY

OMB No. 0920-1015
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Supporting Statement

NCHS National Electronic Health Records Survey

- Goal of the study: To collect information on office-based physicians' adoption and use of electronic health record (EHR) systems, practice information, patient engagement, controlled substances prescribing practices, use of health information exchange, and documentation and burden associated with medical record systems.
- Intended use of the resulting data: To help provide more information about the use and adoption of EHRs by office-based physicians both nationally and by state. Data from the National Electronic Health Records Survey (NEHRS) have been used by researchers in reports and programs such as *Health, United States* and *Healthy People 2020*, in addition to various other reports and research across federal, public, and international communities.
- Methods to be used to collect data: Data will be collected directly from a sample of office-based physician respondents through either a self-administered web questionnaire, self-administered paper questionnaire or computer-assisted telephone interview.
- Subpopulation to be studied: Non-federally employed office-based physicians.
- How data will be analyzed: Data will be weighted to provide national and state estimates.

The National Center for Health Statistics (NCHS) requests approval for a revision of 3 years for data collection through the National Electronic Health Records Survey (NEHRS) (OMB No. 0920-1015, Exp. Date 07/31/2020). We are requesting approval to collect data on 2020, 2021 and 2022 NEHRS cohorts using the updated instrument. In addition to the requested approval, we also request the ability to submit non-substantive change packages, as needed, for form modifications occurring throughout the 2020-2022 study period.

A. Justification

1. Circumstances Making the Collection of Information Necessary

NEHRS is a national survey of office-based physicians conducted by the National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC). NEHRS is sponsored by the Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services (DHHS). The survey is conducted under the authority of Section 306 of the Public Health Service Act (41 USC 242k) (**Attachment A**). The 60-day Federal Register Notice was published on August 8, 2019 (**Attachment B1**); there was one public comment (**Attachment B2**).

Although there are other surveys that collect information from office-based physicians in the United States, NEHRS is unique in that it provides detailed national and state-based representative information about electronic health record (EHR) adoption and use among these physicians. Additional justifications for conducting NEHRS include the need for more complete data to study: (1) health information sharing and coordination of care in physician offices, (2) the introduction of new medical technologies, and (3) the adoption and use of EHRs. The approved 2019 NEHRS (**Attachments C1** and **C2**) is similar to the proposed 2020 NEHRS (**Attachment C3**). These data collections will focus on evolving health information exchange (HIE) and interoperability; particularly with respect to electronically sending, receiving, integrating, and searching for patient health information through these systems.

2. Purpose and Use of Information Collection

The purpose of this study is to collect information on office-based physicians' adoption and use of EHR systems, practice information, patient engagement, controlled substances prescribing practices, use of HIE, and the documentation and burden associated with medical record systems (which include both paper-based and EHR systems). DHHS currently uses NEHRS data to evaluate progress towards meeting the *Healthy People 2020*'s Health Communication and Health Information Technology objective 10 (i.e., increase the proportion of medical practices that use electronic health records). The *Healthy People 2020* objectives are designed to serve as a road map for improving the health of all people in the United States by the year 2020, and NEHRS data support efforts to quantify national improvement. In addition, ONC uses NEHRS data for benchmarking EHR adoption and use across the United States, and for evaluating progress toward Health Information Technology for Economic and Clinical Health (HITECH) Act program goals. NEHRS data also support efforts to access the burden outlined in Section 4001(a) of the 21st Century Cures Act (Public Law 114-255, 42 USC 201). This Act directs DHHS to

develop a report outlining how the department could reduce regulatory and administrative burden related to the use of EHRs.

NEHRS provides a range of baseline data on the characteristics of U.S. office-based physicians practicing ambulatory medical care, including a specific focus on EHR adoption and use. Having data that identify a physician's office's ability to perform specific computerized tasks helps track the adoption and use of new health information technologies across various physician and practice characteristics (e.g., specialty, office type, and ownership) over time. These annual data, together with trend data, may be 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 use, organization, and delivery of ambulatory care.

NEHRS information is also useful to health planning agencies, managers of health care delivery systems, and others concerned with planning, monitoring, and managing health care resources for HIE, care coordination, safety implications, and the use of health information technology. It is valuable to those who develop and evaluate new and modified health care systems and arrangements. It also provides valuable information about the speed and effectiveness with which certain advances in medical practice are adopted by the office-based physician.

Users of NEHRS include numerous federal 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 an in-depth analysis of the entire NEHRS data set covering multiple years.

For 2020, ONC maintains the currently approved content from 2019 to collect necessary trend and practice data in order to evaluate the HIE content and Promoting Interoperability (formerly Meaningful Use) incentive program goals. The data collected in the 2020 NEHRS will be used to show the use of any EHR and the use of certified EHR systems by state and physician specialty.

To ensure these necessary trends and practice data are collected, only a few modifications in the approved questions from 2018 and 2019 NEHRS are proposed for the 2020 NEHRS questionnaire. These changes can be found in **Attachment D** and are highlighted. The rationale for these changes is to improve clarity, reduce the burden and update the cybersecurity language. NCHS anticipates modifications in the survey instrument for 2021 and 2022. During 2020, in collaboration with ONC, NCHS will review all survey questions. NCHS will submit a non-substantive change or revision package as needed. If cognitive testing is deemed necessary, NCHS will ensure testing is performed on relevant survey questions.

3. Use of Improved information Technology and Burden Reduction

Two of the three modes of data collection used for NEHRS take advantage of technology and reduce the burden to respondents: a self-administered web instrument and a computer-assisted telephone interview (CATI). The web instrument is offered first via email for physicians for

whom we have an email address, followed by a U.S. Postal service letter to all sampled physicians. The web instrument and CATI incorporate skip patterns and logic checks. The skip patterns use responses to initial survey questions by a respondent to determine if other survey questions are not applicable, allowing a respondent to automatically skip over them. This instrument design feature allows for a reduction in response burden, where applicable. Similarly, logic checks reduce the burden and improve data quality by limiting invalid responses. One example of such a logic check is that only the 50 U.S. states and the District of Columbia are available responses for the state of the physician's office location.

In recent years that NEHRS has been conducted, there has been an increasing number of physicians who have responded through the self-administered web instrument compared to earlier years. This shows the preference for receiving email invitations and responding to the survey through the web instrument. As such, beginning with the 2019 NEHRS there has been added emphasis on locating physician email addresses. Tracing of these email addresses is projected to increase the number of physician respondents who are administered the survey through the web, and reduce the number of needed follow-up contacts among these physicians.

4. Efforts to Identify Duplication and Use of Similar Information

NCHS staff have had extensive contacts regarding the NEHRS survey items with organizations and individuals in both the private and public sectors who are familiar with EHR adoption and use. Advice from consultants, attendance at relevant meetings, and literature reviews have been used to identify other sources that collect data on EHR adoption and use similar to those collected by the NEHRS; however, outside of the NEHRS and the traditional National Ambulatory Medical Care Survey (NAMCS) (OMB No. 0920-0234, Exp. Date 05/31/2022) physician-level data, there have been no other sources that would be able to provide annual national and state-level estimates. In addition, beginning in 2019 NAMCS is only collecting general information on EHR adoption, and therefore NEHRS will be the sole source for detailed national and state-level data on EHR adoption and use.

5. Impact on Small Businesses or Other Small Entities

A number of NEHRS respondents are physicians in private solo practices or small group practices. In order to reduce the 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 used for any NEHRS, NAMCS or NAMCS supplement data collection in the prior two years, and data topics will be kept to the minimum necessary for the study.

6. Consequences of Collecting the Information Less Frequently

The consequence of collecting the information less frequently than annually would be that we would not be able to capture the rapidly changing use of health information technology. An annual data collection allows the ability to observe changes from year to year that inform decision making, describes current adoption rates, monitor trends, and inform planning necessary for policies.

NEHRS also assists in measuring the progress of EHR adoption, Section 4001(a) of the 21st Century Cures Act, *Healthy People 2020*, and the overarching goals of the HITECH Act. The survey questions on NEHRS will help guide the policymaking process surrounding Promoting Interoperability (formerly Meaningful Use). The information obtained from these questions (i.e., questions related to EHR functionality, HIE, documentation, and burden associated with medical record systems) will provide great value to ONC and NCHS. If NEHRS is not collected annually, the result will be difficultly in measuring trends and the progress of EHR adoption and the overarching goals of the HITECH Act, *Healthy People 2020* and 21st Century Cures Act.

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
   A. Federal Register Notice

   A 60-day Federal Register Notice was published in the Federal Register on August 8, 2019, volume 84, page number 38986 (**Attachment B1**). One public comment was received (**Attachment B2**); which, in conjunction with a Department of Health and Human Services definition change, resulted in the replacement of the phrase "mid-level provider" with "advanced practice provider" within the questionnaire.

   B. Efforts to Consult Outside the Agency

   Both ONC and NCHS have worked closely on the development of the EHR questions currently used in the survey, and those planned for the 2020 NEHRS and beyond. 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 E**.

9. Explanation of Any Payment of Gift to Respondents

   NEHRS will not offer a monetary incentive to respondents for participation. Non-monetary tokens have been shown to boost physician response rates.[1] The decision to use a non-monetary token would be based on available funds and the need for NCHS to boost physician response rates to maintain nationally representative data. Examples of potential non-monetary items might include a pen, note pad or similar item valued around $2.00 per sampled physician, and would cost about $20,600 annually.

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

    This submission has been reviewed by the Information Collection Review Office (ICRO), who determined that the Privacy Act does apply. The applicable System of Records Notice is 09-20-0167 Health Resources Utilization Statistics. The NCHS Privacy Act Coordinator and the NCHS

[1] Beatty, P. Jamoom, E.W. "The Effect of Non-Monetary Incentives in a Longitudinal Physician Survey." AAPOR, Boston, MA, May 17, 2013.

Confidentiality Officer have also reviewed this package and have determined that the Privacy Act is applicable.

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."

Physicians have numerous opportunities to review the details of the NEHRS to decide to participate or decline participation. All letters explain in clear, concise, and straightforward language the basics of the survey, that participation is completely voluntary, that the physician will not be penalized for nonparticipation, and that NCHS takes full responsibility for all survey-related actions. Phone numbers for the study coordinator and NCHS' Ethics Review Board (ERB) are also included if the physicians or their proxy have any questions or comments about the study. The physician or proxy can also refuse by mail or phone. By mail, the letter indicates how to respond if the physician chooses not to participate. During the phone interview for nonresponse, the physician or proxy may refuse to participate.

NEHRS will include a routine set of measures to safeguard confidentiality. This includes the following measures. First, all staff, including contractors, who have access to confidential information are given instruction by NCHS staff on the requirement to protect the confidentiality, and are required to sign a pledge to maintain confidentiality. Second, only authorized personnel are allowed access to confidential records, and only when their work requires it. Third, when confidential information is not in use, it is stored in secure conditions.

In keeping with NCHS policy, if any NEHRS data are made available via public-use data files, all individually identified information, such as physician name, address, and any other specific information, will be removed. Confidential data are never released to the public. All NCHS public data releases are reviewed by the NCHS Disclosure Review Board to avoid data breaches, such as the release of detailed geographic information that may allow anyone to identify practices or physicians in NEHRS.

NEHRS provides national estimates on provider and practice characteristics. The majority of the data collected is not personally identifiable; however, some are classified as information in identifiable form (IIF). Below is a list of all IIF data items collected in NEHRS. These data items are necessary to properly identify and locate sampled physicians. OMB has approved all of these items previously for the NEHRS Information Collection (OMB No. 0920-1015, Exp. Date 07/31/2020)). None of these data items are released to the public.

- Physician name
- Physician or office mailing address
- Physician or office telephone number
- Physician or office email address
- Physician National Provider Identifier (NPI)

NPI (National Provider Identifier) number is a unique identifier for healthcare providers. This data element will allow for linkage of physician specialty information to other administrative sources of information. Information linking provider identifiers to their characteristics (e.g., specialty, provider age) is also available from CMS for research purposes (https://nppes.cms.hhs.gov/#/).

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

The NEHRS data collection plan has been approved by NCHS's ERB (Protocol #2016-07, **Attachment F**) based on 45 CFR 46. In addition, the ERB has granted a waiver of the documentation of informed consent by physicians.

There are no sensitive questions included within the NEHRS data collection instrument.

12. Estimates of Annualized Burden Hours and Costs

A. Burden Hours

2020, 2021 and 2022 NEHRS are expected to sample 10,302 physicians each year. In previous requests for approval for NEHRS, previous years' response rates were used in an attempt to project an estimate of the annualized burden hours based on experience in administering NEHRS as a self-administered paper instrument, self-administered web instrument, and CATI. However, in this request, we have calculated the annualized burden hours based on the assumption that all sampled physicians will respond. While we recognize

that, in reality, not all respondents will complete the survey; this method of estimation of the burden for NEHRS is comparable to the approach used by many other surveys conducted by NCHS.

Table 1 below represents estimates for each year of data collection over the approval period (2020-2022). NEHRS will be administered to 10,302 physicians each year of the approval period.

Table 1. Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (Hours)	Total Burden (Hours)
Office-based physicians or office staff	NEHRS	10,302	1	30/60	5,151
Total		10,302			5,151

B. Burden Cost

The average annual cost for office-based physicians and office staff to participate over the three data collections is estimated to be $309,523.59. The hourly wage estimates for completing the forms mentioned in Table 1 are based on information from the Bureau of Labor Statistics website (http://www.bls.gov). The tables used for this calculation are the "May 2018 National Occupational Employment and Wage Estimates" for (1) health care practitioners and technical occupations, physicians and surgeons, and (2) office administrative and support administrative support occupations. The total burden hours were evenly divided between the physicians and administrative staff based on information from the 2017 NEHRS data collection. As a result, the hourly wage rate of $60.09 in Table 2 is an average of the mean hourly wages for physicians and surgeons (i.e., $101.43) and administrative and support staff (i.e., $18.75).

Table 2. Estimated Annualized Respondent Costs

Type of Respondent	Form Name	Total Burden (Hours)	Hourly Wage Rate	Total Respondent Costs
Office-based physicians or office staff	NEHRS	5,151	$60.09	$309,523.59

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

There will be no annual capital or maintenance costs to the respondent resulting from the collection of information for NEHRS.

14. Annualized Cost to the Government

The estimate of the average annual cost to the government for the 2020-2022 NEHRS is given below.

Table 3. Annualized Cost to the Government

Cost	Item
$690,237.00	Contract costs for contract staff salaries, data collection, data entry and data processing for NEHRS
$149,744.50	Federal employee salaries
$839,981.50	Average total cost for 12 months

15. Explanation for Program Changes or Adjustments

Currently, the approved annualized burden is 6,295 hours and the proposed annualized burden is 5,151 hours. The adjusted decrease of 1,144 burden hours is due to the completion and removal of former supplemental surveys. This revision also requests removal of the cybersecurity language in the instruments and letters and streamlining the information in the letters.

16. Plans for Tabulation and Publication and Project Time Line

Plans for the tabulation and publication and project timeline are provided in Table 4.

Table 4. Project Time Schedule

Activity	Time Schedule
Data collection begins with email or mail letter invitation to web instrument	Within two months after OMB approval
Data collection ends with CATI	Within eight months after OMB approval
Analyses	Within 12 months of OMB approval
Publish Web tables, QuickStat or Data Brief	Within 18 months of OMB approval

NEHRS data must be weighted to produce national and state estimates about office-based physicians and their practices. The weighting process takes place at NCHS after data processing and initial data cleaning. This estimation is accomplished by inflating the responses from each surveyed physician or his/her staff in NEHRS to the national and, in most yearly cycles, state level. For each unit in the sample, a weight is assigned that permits the estimation of physician population totals.

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

The display of the OMB expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.