Supporting Statement A for Paperwork Reduction Act Submission for

Developmental Studies to Improve the National Health Care Surveys

OMB No. 0920-1030
(Expires 04/30/2020)

Extension

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May 12, 2020

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Attachments

**Developmental Studies to Improve the National Health Care Surveys**

**Request for Extension of a Generic Clearance for Data Collection**

- Goal of the study: to conduct developmental studies on survey design and data collection activities that are part of the National Health Care Surveys (NHCS). The NHCS surveys include the National Hospital Care Survey, National Ambulatory Medical Care Survey, National Hospital Ambulatory Medical Care Survey, and National Post-Acute and Long-Term Study, formerly known as the National Study of Long-Term Care Providers.

- Intended use of the resulting data: the data will enhance research to evaluate and improve upon survey design and operations, as well as examine the feasibility and address challenges that may arise with future expansions of the National Health Care Surveys.

- Methods to be used to collect: A number of methods may be involved and a GenIC will be submitted to describe each developmental study. Various topics could include, among others, improved participation; movement to electronic health records; development of new and expanded sampling frames.

- The subpopulation to be studied: The overall subpopulations are inpatient, ambulatory, and long-term care facilities, their characteristics and the patients and residents of these locations.

- How data will be analyzed: The information collected through this generic Information Collection Request will not be used to make generalizable statements about the population of interest or to inform public policy; however, methodological findings may be reported.

## Section A: Justification

1. Circumstances Making the Collection of Information Necessary

This submission requests approval for the extension of a generic clearance for three-years to conduct developmental studies on survey design and data collection activities that are part of the National Health Care Surveys. The surveys are conducted by the Division of Health Care

Statistics (DHCS) within the National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC). NCHS is authorized to collect data under Section 306 of the Public Health Service Act (42 U.S.C. 242k) (Attachment A). DHCS will submit to the Office of Management and Budget (OMB) a subsequent Information Collection Request (GenIC) for each data collection effort proposed in this clearance request. The previously approved annual burden estimated was 7,085 burden hours. We are requesting 3,000 total burden hours in this request. We are anticipating that there may be exploratory studies for COVID-19, as well as electronic health records and other projects in addition to the two planned projects described in this package in Section A1 (projects 6 and 7).

This clearance covers new survey research that will evaluate and improve upon survey design and operations, as well as examine the feasibility and address challenges that may arise with future expansions of the NHCS. Specifically, this generic request covers research studies with the following aims:

(1) Explore ways to refine and improve upon existing survey design and procedures aimed at increasing participation and response rates, developing and refining survey items, assessing and addressing the feasibility of health care data retrieval, triangulating and validating survey responses, reducing data collection burden for respondents, and lowering measurement errors and mode effects; and

(2) Explore and evaluate proposed survey designs and alternative approaches to data collection, in inpatient, outpatient, and long-term care settings that are currently either in-scope or out-of-scope from the NHCS; these studies are especially important with the advent of nationwide electronic health record adoption.

The goal of these studies is to evaluate and enhance DHCS existing and proposed data collection protocols to increase research capacity and improve health care data quality and efficiency for the purpose of monitoring public health and well-being at the national, state and local levels, thereby informing the health policy decision-making process. The information collected through this generic Information Collection Request will not be used to make generalizable statements about the population of interest or to inform public policy; however, methodological findings may be reported.

Since the last approval (April 7, 2017), three new generic studies (GenICs) have been approved. However, two additional approved GenICs were still in the field when the prior extension was sought. These two projects will be described first, followed by the three new approvals. Two projects are described but all are still in the planning stage and have not been submitted yet. Other exploratory studies (such as for COVID-19 data) are under consideration.

### 1. Subject Matter Expert Interviews for the National Study of Long-Term Care Providers Gaps Project (Completed)

The objective of this project was to conduct interviews with 18 subject matter experts including researchers, state officials (e.g., Medicaid agencies and state regulatory offices), and staff at disability advocacy organizations and provider associations to identify: 1) gaps in the coverage of paid, regulated long-term care services providers and services users in NCHS' biennial National Study of Long-Term Care Providers (NSLTCP) and 2) ways for NCHS to consider working towards addressing these gaps in future waves of NSLTCP. Three provider types were

identified by key informants as most important to include in the NSLTCP: residential care communities with four or more beds exclusively serving individuals with intellectual and developmental disabilities, Adult Day Service Providers primarily serving individuals with intellectual and developmental disabilities, and Nonmedical Home Care Agencies.

**2. State Agency Interviews about Residential Care Facilities Licensed to Exclusively Serve Residents with Intellectual and Developmental Disabilities for the National Study of Long-Term Care Providers (Completed)**

The objective of this project was to conduct the interviews with state government representatives that oversee residential care facility licensure categories that are not already included in NSLTCP. Specifically, we planned to conduct interviews with up to 65 state regulatory agency staff (state government representatives) in the 50 states and the District of Columbia to: (1) confirm that we have identified the appropriate licensure categories of residential care facilities that serve adults with intellectual and developmental disabilities and meet the NSLTCP definition of residential care community and (2) for each relevant licensure category, obtain information about the availability of a listing of licensed facilities, what data are included on the listing, how current the listing is, and how to obtain the listing in the future when developing the frame for the 2018 NSLTCP survey of residential care facilities. As a result of this study, the recommendation was to not collect data for residential care communities that only serve adults with intellectual and developmental disabilities in future waves of the NSLTCP. The study found that those places would not meet the current size and 24/7 care eligibility requirements; not all states license them; and they would require a different data instrument.

**3. Frame Development for the Residential Care Component of the National Study of Long-Term Care Providers (Completed)**

The objective for this project was twofold: (1) to develop an up-to-date, state-based sampling frame of residential care facilities ("conventional" residential care communities) for the 2018 survey, like has been done for the previous three waves of the National Study of Long-Term Care Providers (NSLTCP) and (2) for the first time, include and flag in the frame residential care communities licensed to exclusively serve the intellectually disabled/developmentally disabled adult populations ("Intellectual and developmental disability-exclusive" residential care communities), to inform NSLTCP waves beyond 2018**.** The 2018 sample frame included 43,770 "conventional" residential care communities and 15,629 Intellectual and developmental disability -exclusive" residential care communities.

**4. Frame Development for the Residential Care Component of the National Post-Acute and Long-Term Care Study (Currently in the field until June 2020)**

The objective for this project is to develop an up-to-date, state-based sampling frame of residential care facilities for the 2020 survey, like has been done for the previous four waves of the National Post-Acute and Long-Term Care Study (NPALS) (formerly known as the National Study of Long-Term Care Providers or NSLTCP).

The specific data collection activities will be to contact state agencies to:

- Confirm current state-specific licensing categories of residential care.
- Obtain state lists of communities for these licensing categories of residential care.

**5. Hospital-Based Victim Services Frame Development Project**

The objective for this project is to build a frame of victim services and programs within hospitals throughout the US. The National Hospital Care Survey hospital frame will be used to identify eligible hospitals. This frame will contain contact and program information about all the existing programs, services, and partnerships dedicated for victims of crime and abuse in each hospital. Information will also be gathered on both future plans for the creation of new victim services and identifying electronic systems that document victim services.

**6. Physician Knowledge of Guidelines for Opioid Prescription (in planning stage)**

A pilot study is being planned to collect data on physician knowledge, awareness, and adherence to guidelines for opioid prescription for pain management. A mail survey would be sent to approximately 1,000 physicians, drawn from a universe of physicians available to NCHS. Guidelines are obtained from a number of sources, such as State guidelines, American Academy of Pain Medicine Guidelines; American College of Physicians Guidelines for low back pain; and the findings of the NIH Interagency Pain Research Coordinating Committee.

**7. Validation of Algorithm for Identifying Opioid-involved Hospital Visits (in planning stage)**

A special project is planned to validate the NCHS-developed enhanced natural language processing (NLP) algorithm for identifying opioid-involved hospitals visits. Presently hospital encounters with opioid involvement are documented using the code-based ICD-10-CM classification. There is some thought, however, that this method produces an undercount of opioid use. The new method to be studied involves the use of machine learning and natural language processing to evaluate the unstructured and free text sections of the EHR encounter that would otherwise not be captured with the sole use of code-based methods. The validation study will validate the results of the enhanced opioid-involved identification algorithm by utilizing the actual hospital records. The outcome would be used to investigate if an enhanced algorithm can be produced that would assist researchers in identifying hospital encounters involving opioid use. Such efforts would provide greater visualization into hospital care patterns, risk factors and healthcare initiatives associated with fatal and non-fatal opioid overdoses. The study would involve approximately 10 hospitals.

Background of DHCS Surveys

The background of the DHCS surveys, as well as the detailed original discussion for the currently-approved generic data collection, is found in Attachment C.

2. Purpose and Use of the Information Collection

Research covered in this generic clearance would greatly benefit DHCS in its efforts to improve the quality and efficiency of all of its survey operations and design relevant to the NHCS.

The NHCS collect critical, accurate data that are used to produce reliable national estimates – and in recent years, state-level estimates – of clinical services and of the providers who delivered those services in inpatient, outpatient, ambulatory, and long-term care settings. The data from these surveys are used by providers, policy makers and researchers to address important topics of interest, including the quality and disparities of care among populations, epidemiology of medical conditions, diffusion of technologies, effects of policies and practice guidelines, and changes in health care over time. Research studies need to be conducted to improve existing and proposed survey design and procedures of the National Health Care

Surveys, as well as to evaluate alternative data collection approaches particularly due to the expansion of electronic health record use, and to develop new sample frames of currently out-of-scope providers and settings of care.

To improve existing survey design and procedures, examples of studies may include evaluation of different incentive approaches to improve recruitment and enrollment efforts to increase participation rates of all health care surveys; testing of new survey items to obtain additional data on providers/patients/residents while minimizing misinterpretation and human error in data collection; testing data collection in panel surveys; triangulating and validating survey responses from multiple data sources; assessment of the feasibility of data retrieval; and development of protocols that will locate, identify, and collect accurate survey data in the least labor-intensive and burdensome manner at the sampled practice site.

To explore and evaluate proposed survey designs and alternative approaches to collecting data, especially with the nationwide adoption of electronic health records, studies may expand the evaluation of data extraction of electronic health records and submission via continuity of care documentation to small/mid-size/large medical providers and hospital networks, managed care health plans, prison-hospitals, and other inpatient, outpatient, and long-term care settings that are currently either in-scope or out-of-scope of the NHCS. Research on feasibility, data quality and respondent burden also may be carried out in new surveys of health care providers and establishments that are currently out-of-scope of the National Health Care Surveys.

Furthermore, anticipated studies may include the following: 1) Within the National Ambulatory Medical Care Survey (NAMCS), new clinical groups may be expanded to include dentists, psychologists, podiatrists, chiropractors, optometrists), mid-level providers (e.g., physician assistants, advanced practice nurses, nurse practitioners, certified nurse midwives) and allied-health professionals (e.g., certified nursing aides, medical assistants, radiology technicians, laboratory technicians, pharmacists, dieticians/nutritionists), among others. Current sampling frames such as those from the American Medical Association may be studied as well as frames that are not currently in use by NAMCS, such as state and organizational listings of other licensed providers. 2) Within the National Post-Acute and Long-Term Care Study, studies on new frames and data items from home care agencies, long-term care hospitals, and facilities exclusively serving individuals with intellectual/developmental disability may be undertaken. Similarly, data may be obtained from lists compiled by states and other organizations. Data about the facilities as well as residents will be investigated. 3) In the inpatient and outpatient care settings, the National Hospital Care Survey and the National Hospital Ambulatory Medical Care Survey may be investigating the addition of facility and patient information especially as it relates to insurance and electronic medical records.

3. Use of Improved Information Technology and Burden Reduction

The specific data collection procedure will be addressed in each GenIC, including use of improved information technology and burden reduction. There are no legal obstacles to reduce the burden.

4. Efforts to Identify Duplication and Use of Similar Information

These research projects will all be internal projects related to current or proposed DHCS surveys. Therefore, there is no similar data to be identified.

5. Impact on Small Businesses or Other Small Entities

Any impact on small businesses will be addressed in each GenIC.

6. Consequences of Collecting the Information Less Frequently

These research activities are one-time data collections._

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

None of the special circumstances listed apply to this data collection.

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

A. Federal Register Notice:

In compliance with 5 CFR 1320.8(d), a 60-day Federal Register notice was published in the Federal Register on January 23, 2020, Volume 85, Number 15, pages 3918-3920. A copy of the notice is attached to this supporting statement. (Attachment B1)

Three anonymous non-substantive comments were received from this Notice. (Attachment B2)

B. Outside Consultation

Consultations will be described in each individual GenIC.

9. Explanation of Any Payment or Gift to Respondents

Currently no payment or gift is anticipated (with the exception of those studies that address monetary incentives). However, this topic will be addressed in each survey-specific GenIC.

10. Protection of the Privacy and Confidentiality of Information Provided by Res*pondents*

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 the GenICs may include the collection of information in identifiable form. The applicable System of Records Notice is 09-20-0167 Health Resources Utilization Statistics. Specific Privacy Act applicability will be addressed in each GenIC.

Confidentiality will be provided to respondents as assured by Section 308(d) of the Public Health Service Act (42 USC 242m) as follows:

*"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 304, 306, or 307 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 in the case of information obtained in the course of health statistical or epidemiological activities under section 304 or 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 the Confidential Information Protection and Statistical Efficiency Act (Title III of the Foundations for Evidence-Based Policymaking Act of 2018 (Pub. L. No. 115-435, 132 Stat. 5529)) which states:

*"(f) Fines and Penalties. -- 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 this section, 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 subchapter, 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."*

Standards for Federal government surveys highlight the importance of the interviewers' responsibilities under the Privacy Act of 1974 (5 U.S.C. 552a), the Privacy Act Regulations (34 CFR Part 5b), Section 308(d) of the Public Health Service Act (42 U.S.C. 242m), the Confidential Information Protection and Statistical Efficiency Act (CIPSEA -Title III of the Foundations for Evidence-Based Policymaking Act of 2018 (Pub. L. No. 115-435, 132 Stat. 5529)), HIPAA and other regulations.

**Assurance of Confidentiality** (shown on all survey forms)– We take your privacy very seriously. All information that relates to or describes identifiable characteristics of individuals, a practice, or an establishment will be used only for statistical purposes. NCHS staff, contractors, and agents will not disclose or release responses in identifiable form without the consent of the individual or establishment in accordance with section 308(d) of the Public Health Service Act (42USC 242m) and the Confidential Information Protection and Statistical Efficiency Act (Title III of the Foundations for Evidence-Based Policymaking Act of 2018 (Pub. L. No. 115-435, 132 Stat. 5529)). In accordance with CIPSEA, every NCHS employee, contractor, and agent has taken an oath and is subject to a jail term of up to five years, a fine of up to $250,000, or both if he or she willfully discloses ANY identifiable information about you.

This is a request for a generic clearance and some of the GenICs may include the collection of information in identifiable form (IFF). When that is the case, the IFF will be described in each individual GenIC.

1. An overview of the data collection system will be provided in each GenIC.
2. A description of the information to be collected will be provided in each GenIC.
3. A description of how collected information will be shared and for what purpose. NCHS and other sponsoring agencies, through interagency agreements, will use the information collected on the development and testing of questionnaires and data collection protocols for the main purpose of evaluating and further improving the quality of data in national surveys. Although information collected through this Generic IC request will not be used to make generalizable statistics about the population of interest, findings resulted under this clearance may be included in research methodological reports prepared by NCHS staff or contractors. The results also may be prepared for presentations at professional meetings or publications in professional journals.
4. The impact the proposed collection will have on the respondent's privacy: Ensuring information quality is an integral part of the information collection process and the pre-dissemination review of the information disseminated by NCHS. Improving

information quality is incorporated into the clearance process as required by the Paperwork Reduction Act.

All study data are collected under an Assurance of Confidentiality. When indicated, studies will collect, on a confidential basis, data needed to re-contact respondents for additional information and for participation in potential follow-back surveys, and possibly to match respondents to administrative records. The ability to track respondents and match to other records greatly expands the usefulness of these data at very low cost.

5. Whether individuals are informed that providing information is voluntary or mandatory. All NCHS data collections are voluntary and respondents are informed via letter or other method. Specifics will be provided in each GenIC.
6. Opportunities to consent, if any, to sharing and submission of information: This is addressed through the IRB and will be described for the GenIC.
7. How the information will be secured: Only those NCHS employees, contract staff, and full research partners who must use the personal information for a specific purpose can access and use such data resulted from the studies. Everyone else who uses the data can do so only after all identifiable information is removed.

   For more than 50 years, NCHS has protected confidential information collected in its surveys. The collection of identifiable information requires strong measures to ensure that private information is not disclosed accidentally or deliberately in a breach of confidentiality. All NCHS employees, as well as all contract staff, receive appropriate confidentiality training and sign a "Nondisclosure Statement." Staff members of collaborating agencies are also required to sign this statement, and outside agencies are required to enter into a more formal agreement with NCHS. All contractor and NCHS project staff follow strict procedures to collect, monitor, and analyze these data. This procedure prevents information from being removed from the area for purposes other than official NCHS survey data collection. The transmission and storage of confidential data are protected through procedures such as encryption and carefully restricted access. Only those NCHS employees and our full research partners who must use the personal information for a specific purpose may have access to and use such data.

   Prior to release of any data collected under this clearance, the NCHS Disclosure Review Board (DRB) reviews the information to ensure that disclosure risk is at a minimum. Tabulated data are reviewed to ensure that no disclosure risk exists.

Data will be treated in a confidential manner. The process of informing respondents of the procedures used to keep information confidential begins with material mailed in advance and carries through to interviewer training and all communications with potential respondents. All elements of informed consent, including the purpose of the data collection, the voluntary nature of the survey, with whom the information will be shared, and the effect upon the respondent for not participating are provided in the introductory statements read/provided to respondents prior to the interview, survey, focus group, or other mode of data collection.

NCHS and subcontractor staff routinely employ technical, physical, and administrative measures to secure information and safeguard privacy and confidentiality. These include:

- when confidential materials are moved between locations, records are maintained to insure there is no loss in transit,
- hard copies of confidential information are stored in secure areas when not in use,
- access to the data processing and storage areas is controlled, with only authorized personnel allowed in secure locations,
- individual data banks and files are protected by passwords and other techniques, which prohibit access by non-approved project staff,

- building security forces are on duty 24 hours, seven days per week at all sites,
- public use data releases are reviewed and approved by the NCHS Disclosure Review Board (DRB),
- access to nonpublic data is restricted to those who must have such access.

Interviewers, supervisors, and staff receive thorough training on legal and ethical obligations. All employees and contract staff sign an Affidavit of Nondisclosure as a condition of employment. This data collection is under the Privacy Act of 1974 (5 U.S.C. 552a), the Privacy Act Regulations (34 CFR Part 5b), Section 308(d) of the Public Health Service Act (42 U.S.C. 242m), the Confidential Information Protection and Statistical Efficiency Act (CIPSEA, Section 513 of PL 107-347), HIPAA, and other regulations.

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

IRB Approval
In addition to OMB approval, we obtain the following clearances prior to implementing *each* proposed module:

- NCHS Research Ethics Review Board (ERB),
- the NCHS Associate Director for Science and Human Subjects Officer, and

the NCHS Confidentiality Officer

Any sensitive questions would be discussed in each project specific GenIC.

12. Estimates of Annualized Burden Hours and Costs

There is no cost to respondents other than their time to participate. Average burdens are designed to cover 15-30 minute interviews as well as 90 minute focus groups, longer on-site visits, and situations where organizations may be preparing electronic data files. The overall burden estimates are presented in Table 1 below. The burden for each individual project will be shown in each GenIC.

Table 1. Estimates of Annualized Burden Hours

| Type of Respondents | Form name | Number of Respon-dents | Number of responses per respondent | Average burden per response (in hours) | Total burden hours |
|---|---|---|---|---|---|
| Health Care Providers and Business entities | Interviews, surveys, focus groups, experiments (in person, phone, internet, postal/electronic mail) | 2,582 | 1 | 1 | 2,582 |

| | | | | | |
|---|---|---|---|---|---|
| Health Care Providers, State/local government agencies, and business entities | Interviews, surveys, focus groups, experiments (in person, phone, internet, postal/electronic mail) | 167 | 1 | 2.5 | 418 |
| Total | | | | | 3,000 |

B. Annualized Cost to Respondents

The latest publicly available data (July 2019) are from the Occupational Employment Statistics Survey (OES), a mail survey that measures occupational employment for wage and salary workers in non-farm establishments in the US. Per the OES the mean hourly wage rate is $27.99/hour across all occupations. At an average wage rate of $27.99/hour and an average burden of a little over one hour, the cost per respondent is $30.80. The total annualized burden hours are 3,000 for an estimated cost of $92,400 (Table 2, below). This estimated cost does not represent out-of-pocket expense, but represents a monetary value attributed to the time spent.

Table 2. Annualized cost to respondents.

| Total Burden hours | Average estimated cost per respondent | Total average estimated cost per year |
|---|---|---|
| 3,000 | $30.80 | $92,400 |

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

No capital, start-up, or maintenance costs are involved.

14. Annualized Cost to the Federal Government

While actual annualized costs will vary dependent on the scope of future survey submissions, it is anticipated that the costs related to staff salaries for planning and implementing the future surveys might average $100,000.

15. Explanation for Program Changes or Adjustments

The previously approved annual burden estimated was 7,085 burden hours. We are requesting 3,000 total burden hours. This program change of -4,085 hours is due to the number of respondents per GenIC from previous submissions. We are anticipating that there may be exploratory studies for COVID-19, as well as electronic health records and other projects in addition to the two planned projects described in this package in Section A1 (projects 6 and 7). The requested burden provides us with the most flexibility for future projects.

16. Plans for Tabulation and Publication and Project Time schedule

No national or regional estimates are being produced, so there is no schedule for data release. Results of the scientific research may be released in scientific papers or presentations.

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

N/A. Not requesting exemption.

18. Exceptions of Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.