

Supporting Statement A for Paperwork Reduction Act Submission for  
Developmental Studies to Improve the National Health Care Surveys

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Extension

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## Attachments

- A. Authorizing Legislation
- B1. Federal Register Notice, 60-day Notice
- B2. Federal Register Notice, Public Comments

## 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 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, outpatient, 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). 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.

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 National Health Care Surveys. 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 National Health Care Surveys; 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 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.

To date, three generic studies (GenICs) have been approved. They focused on Long-Term Care Providers:

### **1. National Study of Long-Term Care Providers Feasibility Project to Collect Person-Level Data from Residential Care Communities and Adult Day Services Centers**

For this project, our objectives were to assess the feasibility of sampling and collecting person-level data over the telephone in residential care communities (RCCs) and adult day services centers (ADSCs), to assess the time required to complete the process over the telephone, and to identify the need for any protocol changes for 2018 national implementation. Participants for this feasibility project were recruited from respondents to the 2014 National Study of Long-Term Care Providers (NSLTCP). We included 90 RCCs and 90 ADSCs in the sample to complete interviews with 20 RCCs and 21 ADSCs. The average time to complete the sampling and resident/participant and debriefing interviews was 34 minutes for RCCs and 33 minutes for ADSCs. Overall, respondents did not have difficulties answering the interview questions and respondents shared ways to improve the experience or process.

### **2. Subject Matter Expert Interviews for the National Study of Long-Term Care Providers Gaps Project (in the field)**

The objective of this project is 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.

### **3. 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**

The objective of this project is to conduct the interviews with state government representatives that oversee residential care facility licensure categories that are not already included in NSLTCP. Specifically, we plan 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 (IDD) and meet the NSLTCP definition of residential care facility 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.

#### **Background**

The Division of Health Care Statistics (DHCS) is one of four data collection divisions within the National Center for Health Statistics (NCHS). The mission of DHCS is to collect, monitor, analyze, and disseminate data on the use, access, quality, safety, disparity, and cost of health care in the United States and on the healthcare organizations and professionals who deliver that care. DHCS conducts the National Health Care Surveys, a family of nationally representative surveys of encounters and health care providers in inpatient, outpatient, ambulatory, and long-term care settings. Some surveys are ongoing; others are periodic. The currently-active surveys include the following:

- National Hospital Discharge Survey (NHDS; 1965-2010); National Hospital Care Survey (NHCS; 2011-present); OMB No. 0920-0212, Exp. Date 01/31/2019
- National Ambulatory Medical Care Survey (NAMCS; 1973-1981, 1985, 1989-present); OMB No. 0920-0234, Exp. Date 03/31/2019
- National Hospital Ambulatory Medical Care Survey (NHAMCS; 1992-present); OMB No. 0920-0278, Exp. Date 02/28/2019
- Data Collection for the Residential Care Community and Adult Day Services Center Components of the National Study of Long-term Care Providers; OMB No. 0920-0943, Exp. Date 05/31/19

These surveys share certain design features; each representative national survey samples health care providers and collects data from encounters sampled with each provider. More information is available at DHCS website: [www.cdc.gov/nchs/dhcs/dhcs\\_surveys.htm](http://www.cdc.gov/nchs/dhcs/dhcs_surveys.htm).

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.

## Needs and circumstances motivating the current request

In recent years, DHCS has experienced tremendous changes in the type and content of data collected, as well as in the manner in which data are collected, in their National Health Care Surveys. Through these survey experiences, DHCS realizes the need to engage in continuous research evaluation and improvement on quality and efficiency in existing and proposed survey operations and data collection. Furthermore, NHCS needs to be poised in their data collection to anticipate, as well as to be responsive to, the ongoing changes happening in health services delivery systems – e.g., the expansion of electronic health record use in all health care settings and the growing number of mid-level, non-physician clinicians delivering health services. Research studies will examine not only ways to improve existing survey design and operations, but also to assess feasibility and address challenges that may arise with future expansions of the National Health Care Surveys. The following highlights several key illustrative, but not exhaustive, examples of needs and circumstances motivating the current request for survey research:

### I. Improve and refine existing survey design and procedures

1. The NHDS was replaced in 2011 with the National Hospital Care Survey, which integrates NHDS and NHAMCS into one hospital survey.
  - o Recruitment efforts for hospitals to partake in the National Hospital Care Survey have proven difficult; to date, about 110 hospitals out of a sample of 581 have agreed to participate. To ensure that National Hospital Care Survey will be successful, studies to collect new data under this generic clearance request are needed to:
    - Better understand recruitment problems by identifying barriers to recruitment for field representatives and reasons for non-participation among respondents in order to develop strategies to increase enrollment rate.
  - o A major change in the National Hospital Care Survey data collection method is the use of administrative Uniform-Bill (UB-04) claims forms to collect data on all inpatient and ambulatory care provided in participating hospitals that have adopted electronic health records. Submitting these claims to NCHS has been challenging for hospitals. For example, some hospitals that process their own claims do not know how to output and submit the data from their systems to NCHS. Administrative data may not include key elements that the National Health Care Surveys traditionally have collected but need (e.g., race and social security number). Further, administrative data retrieval may be complex and costly for hospitals utilizing clearinghouses to process, “clean-up” and submit their UB-04 claims. Studies to collect new data under this generic clearance request are needed to:
    - Better understand the feasibility of retrieving administrative data and in turn strategize ways to expedite the retrieval process;
    - Determine if accurate billing records are accessible by the key personnel who can then transmit the data to NCHS;
    - Determine information that must be obtained from participating hospitals for survey purposes and strategize ways to accommodate data elements that are missing in the claims data; and
    - Assess technical difficulties (e.g., data compatibility, sample size, duplication of records) that DHCS may encounter while accepting hospital electronic medical record files through a secure data network.

2. With the expansion of electronic health record (EHR), DHCS initiated two new mail supplements to NAMCS: the EHR Supplement and the now completed Physician Workflow Supplement.
  - o The EHR Supplement began in 2008 with an annual supplemental sample of 2,000 physicians, increasing to 10,302 physicians in 2010 and continuing annually. The Physician Workflow Supplement, an annual follow-up data collection initiative to better understand the effect of EHR adoption on physician practices, has for its base sample the respondents to the 2011 EHR Supplement. Because of the increased volume of participating physicians and the ongoing changes to items on the EHR Supplement to monitor “meaningful use” adoption of health information technology, DHCS is faced with the need to explore and develop new ways to continuously improve recruitment strategies, cognitively test newly proposed survey items and response categories, and alleviate respondent burden. Pilot studies to collect new data under this clearance request are needed to:
    - Explore the use of monetary and non-monetary token incentives to improve response rates for hard-to-reach physician populations;
    - Compare different modalities of survey administration (e.g., internet, post-mail, and telephone) to increase respondent’s convenience to complete the survey;
    - Cognitively test survey instructions, items and response categories that are newly developed or are undergoing continuous updating to assess their level of comprehensibility, completeness, reliability, and burden on respondents;
    - Triangulate different sources of data (e.g., administrative data, interviews with different staff within the same office) to validate survey responses especially those that are self-reported; and
    - Experiment with different aspects of the survey (e.g., mode, length, format, flow, and response categories) to determine the most significant factors in reducing non-response or recall bias, and alleviating respondent burden.

## II. Explore and evaluate alternative approaches to data collection

1. The advent of significant nationwide EHR adoption allows for new ways for DHCS to collect, aggregate, and store clinical health data more effectively and efficiently. In 2012, DHCS conducted a small pilot study in 9 study sites with the Palo Alto Medical Research Institute (PAMFRI) to evaluate alternative approaches to collecting NAMCS data from office-based physician practices.
  - o Moving toward greater collection of health care data by electronic means, DHCS intends for all of its National Health Care Surveys to be poised to accept electronic files from medical records as they become available in sampled sites. Because this will be a significant overhaul to current DHCS survey operations and data collection, large pilot studies to collect new data under this generic clearance request are needed to:
    - Further investigate the feasibility of data retrieval/management and impact on the completeness, quality, and reliability of data using data extraction from an EHR using computer code and/or data export utilities, and data transmission using continuity of care documents.
    - Compare the impact of electronic data extraction and transmission to traditional data abstraction by Census field representatives.
    - Assess the feasibility and impact of collecting/managing electronic data in a variety of settings including mid-size/large provider and hospital networks, managed care health plans, and other inpatient, outpatient, and long-term care

settings that are either in-scope or out-of-scope from the National Health Care Surveys.

2. Motivated by the rapid growth of mid-level, non-physician clinicians in health services delivery, ongoing changes in major sectors of the U.S. healthcare delivery systems, and expected future interagency agreements with other federal agencies to expand healthcare data collection beyond the current scope of the National Health Care Surveys, DHCS will need to collect new data under this generic clearance request to:
  - Develop new sample frames for providers that are currently out-of-scope from the National Health Care Surveys, including:
    - o Specialty clinicians – e.g., dentists, psychologists, podiatrists, chiropractors, optometrists, among others;
    - o Mid-level providers – e.g., physician assistants, advanced practice nurses, nurse practitioners, certified nurse midwives, among others; and
    - o Allied-health professionals – e.g., certified nursing aides, medical assistants, radiology technicians, laboratory technicians, pharmacists, dietitians/nutritionists, among others.
  - Develop new sample frames of currently out-of-scope health care settings, including:
    - o Mid-size/large provider and hospital networks, managed care health plans, prison-hospitals, long-term care hospitals, home care agencies, facilities exclusively serving individuals with intellectual/developmental disability, among others.

Appropriate for a generic clearance request

The OMB document “Questions and Answers When Designing Surveys for Information Collections,” describes generic surveys: “A generic clearance is considered only when the agency is able to demonstrate that there is a need for multiple, similar collections, but that the specifics of each collection cannot be determined until shortly before the data are to be collected... Individual collections should not raise any substantive or policy issues or go beyond the methods specified in the generic ICR.” See the following website for further information: [www.whitehouse.gov/sites/default/files/omb/inforeg/pmc\\_survey\\_guidance\\_2006.pdf](http://www.whitehouse.gov/sites/default/files/omb/inforeg/pmc_survey_guidance_2006.pdf).

This generic clearance request is in accordance with this description because the pilot studies covered in this clearance are intended to be broad with research aims designed to: (1) explore ways to refine and improve upon existing survey designs and procedures; and (2) explore and evaluate proposed survey designs and alternative approaches to data collection. Therefore, specifics cannot be determined for any particular tests until shortly before the data are to be collected. Additionally, DHCS believes that each data collection under this clearance request would be non-controversial in nature and each would not raise any substantive policy issues. Proposed data collection fitting into CDC's broader research agenda

The DHCS National Health Care Surveys have and will continue to provide policy-relevant national and sub-national data that directly address the mission, research agenda, and 21<sup>st</sup> Century vision for the CDC and NCHS. The NCHS mission is “to provide statistical information



as the Nation's principal health statistics agency that will guide actions and policies to improve the health of the American people"<sup>1</sup> NCHS is authorized to collect data under Section 306 of the Public Health Service Act (42 U.S.C. 242k). See Attachment A.

## 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 National Health Care Surveys.

The National Health Care Surveys 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 National Health Care Surveys. 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,

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<sup>1</sup> Centers for Disease Control and Prevention (CDC) website, written by CDC's Office of Enterprise Communication. Available at <http://www.cdc.gov/about/mission.htm>. Accessed May 2014.

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 Long Term Care Survey, 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 (NHCS) and the National Hospital Ambulatory Medical Care Survey (NHAMCS) may be investigating the addition of facility and patient information especially as it relates to insurance and electronic medical records. 4) Within DHCS, a study may be undertaken within the Bureau of Justice Statistics, Department of Justice, to investigate the possibility of obtaining data on the provision of victim services at the hospital level.

### 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 the current 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

#### Federal Register Notice:

In compliance with 5 CFR 1320.8(d), a 60-day Federal Register notice was published in the Federal Register on December 1, 2016, Volume 81, Number 231 pages 86715-86717. There were two public comments received as a result of this notice. Copies of both the notice (Attachment B1) and the comments (Attachment B2) are attached to this supporting statement.

Consultation with persons outside the agency: 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. Assurance of confidentiality provided to 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 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.

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 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.”*

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, Section 513 of PL 107-347), 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 of 2002

(CIPSEA, Title 5 of Public Law 107-347). 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. In addition, NCHS complies with the Federal Cybersecurity Enhancement Act of 2015. This law requires the federal government to protect federal computer networks by using computer security programs to identify cybersecurity risks like hacking, internet attacks, and other security weaknesses. If information sent through government networks triggers a cyber threat indicator, the information may be intercepted and reviewed for cyber threats by computer network experts working for, or on behalf, of the government.

This is a request for a generic clearance and some of the GenICs may include the collection of information in identifiable for (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 that 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.

#### 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

#### 11. Justification for sensitive questions

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 Respondents	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)	6,667	1	1	6,667
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					7,085

B. Annualized Cost to Respondents

The latest publicly available data (2015) 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. The OES collects data from over 1.2 million business establishments through six semiannual panels over a three year period. It is a Federal-State cooperative program between the Bureau of Labor Statistics and State Workforce Agencies (SWAS), and uses the OMB-required occupational classification system (the Standard Occupational System (SOC)). Per the OES the mean hourly wage rate is \$23.23/hour across all occupations. At an average wage rate of \$23.23 /hour and an average burden of a little over one hour, the cost per respondent is \$24.08. The total annualized burden hours are 7,085 for an estimated cost of \$164,585 (Table 2, below). This estimated cost does not represent any 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
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7,085	\$23.23	\$164,585
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13. Estimates of other total annual cost burden to respondents or recordkeepers

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

No changes.

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.