

Supporting Statement A

Revision Request for Clearance

NATIONAL HEALTH INTERVIEW SURVEY

OMB No. 0920-0214, Expiration Date 12/31/2020

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Supporting Statement

NCHS National Health Interview Survey

- Goal: To collect data to measure and monitor the amount, distribution, and effects of illness and disability in the population and the utilization of health care
- Intended use: For use by the Department of Health and Human Services (DHHS) to monitor trends in illness and disability and to track progress toward achieving many of the health objectives for the nation, and for the public health research community to conduct epidemiologic and policy analysis of such timely issues as characterizing those with various health problems, measuring levels of health insurance coverage, determining barriers to accessing and using health care, and evaluating the impact of health programs.
- Data collection methods: In-person household interviews via Computer Assisted Personal Interview.
- Subpopulation to be studied: Civilian noninstitutionalized population residing in the United States.
- Data analysis methods: Descriptive, bivariate, and multivariate statistics, including frequencies; chi-square and t-tests; and linear, logistic, and multilevel regression.

The National Health Interview Survey (NHIS) is a critical ongoing source of information on the health of the civilian, noninstitutionalized population of the United States. On December 29, 2019, OMB approved the NHIS through the 2020 data collection (OMB# 0920-0214, expires 12/31/2020), including the estimated sample size and estimated annual burden.

In this revision request, OMB approval is being sought to:

- Conduct the National Health Interview Survey in 2021, 2022, and 2023.
- Carry out cognitive testing and methodological projects, using web and/or mail survey tools, that will inform the development of new rotating and sponsored content
- Conduct follow-up studies by web, phone, or mail to ask follow-up questions on topics that are 1) already included in the NHIS and 2) on a few new topics
- Recruit NHIS participants to participate in a follow-up health exam

A three-year clearance is requested. Attachments 4-9 capture the content, the assessment of duplication with other surveys and the proposed uses of data for the 2021 NHIS and proposed follow-back studies. Attachment 12 conveys a list of potential content for 2022 and 2023. Nonsubstantive change requests will be submitted to request approval to make subsequent minor modifications to the questionnaire(s) and to conduct methodological testing.

A. Justification

1. Circumstance Making the Collection of Information Necessary

Background

The NHIS is conducted by the National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC), to comply with the NCHS mandate under 42 USC 242k (Attachment 1) to collect, on an annual basis, statistically valid data on the amount, distribution, and effects of illness and disability in the population and on the utilization of health care services for such conditions. NHIS data are used widely throughout the Department of Health and Human Services (DHHS) to monitor trends in illness and disability and to track progress toward achieving many of the health objectives for the nation. The data are also used by the public health research community for epidemiologic and policy analysis of such issues as characterizing those with various health problems, measuring levels of health insurance coverage, determining barriers to accessing and using health care, and evaluating the impact of changes in federal health programs. (Attachment 3a).

In accordance with the 1995 initiative to increase the integration of surveys within DHHS, respondents to the NHIS serve as the sampling frame for the Medical Expenditure Panel Survey (MEPS; OMB# 0935-0118, expires 12/31/2020). MEPS uses completed interviews from the NHIS to identify and select the desired sample, contact that sample to collect additional data, and combine their survey data with the original NHIS data. These procedures reduce survey costs, reduce overall burden on the public, and increase the amount of data available for critical health-related analysis.

The NHIS has been conducted every year since 1957. The current design of the NHIS questionnaire implemented in 2019, features a rotational schedule consisting of annual core, rotating core and sponsored content modules. Attachment 3b provides a visual depiction of the content and module structure. The NHIS sample adult and sample child questionnaires include annual core content that is scheduled to be fielded every year, rotating content that is fielded periodically, emerging content to address new topics of growing interest to NCHS, CDC, and DHHS, and sponsored content that is fielded when external funding is available.

The 2021 NHIS

The 2021 NHIS will include the same annual core content as the 2019 and 2020 NHIS, along with new rotating and sponsored content (that will replace the 2020 rotating and sponsored modules) and repeated rotating and sponsored content (that has appeared on the 2019 and/or 2020 NHIS). (Attachments 3c-3e).

Content to be removed

Rotating sample adult core content that was on the NHIS in 2020 and will rotate off the 2021 NHIS includes dental services and other provider services, physical activity, walking for transportation and leisure, sleep, fatigue, smoking history and cessation and alcohol use. Sponsored content that will be removed include content on asthma, diabetes prevention, diabetes family history, opioid use, pain management and cancer control items on lung cancer screening, environment for walking and sun care protection.

Items on dental services, mental health services, other provider services, height and weight, physical activity, neighborhood characteristics, sleep, and screen time will rotate off the sample child core. Sponsored content on asthma will be also be removed.

Content to be added

In July of 2020, the NHIS fielded 31 items in response to the COVID-19 pandemic for which an emergency OMB approval was obtained (Attachments 4a-4c). Topics include positive COVID-19 cases (on both sample adult and sample child), underlying health conditions, immunosuppression, access to care (on both sample adult and sample child), access to cancer care, access to skilled and informal caregiving, social support, impact of chronic pain, and social distancing at current or most recent job. All 31 items will be continued into 2021.

The 2021 rotating sample adult core will include questions that were previously fielded in the 2019 NHIS including items on chronic pain, preventive screening tests, and aspirin use. New rotating core include items on allergies and psychological distress, both of which were fielded in the pre-redesigned NHIS. New sponsored content includes items on epilepsy, myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS), insulin affordability, diabetes distress, A1C testing, colorectal cancer, prostate cancer, cervical cancer and breast cancer screening, occupational health, life satisfaction, hepatitis A and B vaccination coverage, COVID-19 vaccination coverage, and loss of the sense of taste and smell. New sponsored cancer control content that focuses on cancer screenings uses questions similar to those used in the 2019 NHIS.

The 2021 rotating sample child core will include items on stressful life events previously fielded in 2019 and on allergies previously fielded in the NHIS. New content included for analyses of the adolescent follow-back study (see below) includes items on social and emotional support, bullying, health care utilization and life satisfaction.

For the 2021 questionnaire, a summary of the proposed new content, and documentation of the efforts to reduce duplication and proposed uses of the data are included in Attachments 5a and 5b. The full set of annual and rotating core and sponsored content items are presented in Attachments 9a-c.

Follow-up studies

Two future follow-up studies are being planned for the NHIS. The first is a pilot study that follows up with adolescents age 12-17 in the 2021 and 2022 NHIS by web, phone, or mail to ask them questions about topics that were already included in the NHIS and some new content specifically for the follow-back.

The second follow-up study involves re-contacting sample adults in the NHIS to participate in a health exam. A pilot study will be conducted in cooperation with staff from the National Health and Nutrition Examination Survey in 2021 to determine the feasibility of including a follow-up health exam in the 2022 and 2023 NHIS.

Adolescent Follow-back

The adolescent follow-back survey is a pilot test of whether online surveys can be successfully used to collect additional data from NHIS households. It is part of the CDC Public Health Data Modernization Initiative. A key metric for evaluating the success of the pilot test will be the completion rates realized. A second goal of the adolescent follow-back survey is to assess the reliability of parent reports about adolescent children.

Using the usual procedures of the NHIS, one “sample child” aged 17 years or less is randomly selected from each household (if any children live in the household) to be the subject of a detailed interview. However,

sample children themselves are not interviewed. Instead, a knowledgeable adult responsible for the child's health and health care (typically a parent or guardian) answers questions about the sample child's health. Because of this design, NCHS and survey sponsors are limited to asking questions on topics that parents can reliably report.

This limits the ability of the current NHIS to explore some issues thought to be related to health, such as physical activity, sedentary activity, use of social media and electronic devices, eating habits, school activities, extracurricular activities, friendships, bullying, and risk behaviors such as smoking and alcohol. Few existing surveys collect data directly from adolescents, and even fewer can link those data to extensive parent-reported data such as those collected by the NHIS. A follow-back survey will be conducted online or by mail with adolescents following their parents' completion of the NHIS interview.

Data to be collected from adolescents include 86 items on general health and well-being, height and weight, health care utilization, content of care in past year (or at last wellness visit), health care access, use of complementary and alternative health, physical activity, sleep, screen time, cognition, concussions, behavior, depression and anxiety, sexual orientation and gender identity, mental health care use and unmet need, social support, stressful life events, bullying, everyday discrimination, and demographics. Eight items on the survey environment and experience with the survey will also be asked.

Many of these items will also be asked of parents in either 2021 or 2022 and answers will be compared to assess the reliability of parent report. Attachment 7a identifies new items and details which items will be fielded in conjunction with either the 2021 or 2022 sample child interview. Attachment 7b describes the content more fully and provides justification, efforts to reduce duplication, and proposed use of the data. The adolescent questionnaire can be found in attachment 9e.

Follow-up health exam

The second follow-up study involves re-contacting NHIS sample adults to participate in a health exam. A pilot study will be conducted in cooperation with staff from another NCHS survey — the National Health and Nutrition Examination Survey — in 2021 to determine the feasibility of including this follow-up health exam in the 2022 and 2023 NHIS. This pilot study is also part of the CDC Public Health Data Modernization Initiative. The pilot study would potentially inform an upcoming redesign of NHANES. The NHANES sample design is highly clustered, and declining response rates are affecting the sample yield. Stable annual estimates are not possible from the current NHANES design, especially for population subgroups. On the other hand, the NHIS sample design has less clustering and yields a large sample size. If the pilot study is successful and a sufficient percentage of NHIS adult respondents provide biological specimens (including venous blood and urine) and physical measurements (including height, weight, and blood pressure) following the survey interview, the NHIS may be able to supplement NHANES data collection with annual national prevalence estimates for overweight, obesity, hypertension, diabetes, kidney disease, Hepatitis C virus infection, and other key measures.

Criteria for prioritizing core content

Since the NHIS is the nation's premier health survey, questions relating to public health remain a priority. Specifically, the redesign focuses on risk and protective factors related to the leading causes of illness and death, health insurance, and access to health care. The NHIS also prioritizes content that is relevant to

agency goals, needed for long-term monitoring, able to be measured well in household interviews, and able to create estimates reliably with one or two years of data (see attachment 3a for further justification.)

Adding Questions to the National Health Interview Survey (NHIS): Guidance for Sponsors

The information in this section is provided in response to the terms of clearance for the approval of a nonsubstantive change request (ICR# 201912-0920-009) on December 17, 2019. The terms of clearance stated the following:

“... to develop guidelines for sponsored content, including the impact on the total length of the NHIS and the criteria to be used to determine if the sponsored content is appropriate for the NHIS. Non-substantive change mechanism may be used to modify existing questions and add depth/additional detail to existing questions. Requests to add questions, including cycling modules in or out, must be consistent with the principles of the recent redesign.”

The main objective of the NHIS is to monitor the health of the United States population through the collection and analysis of data on a broad range of health-related topics. The National Health Survey Act of 1956 provided for a continuing survey and special studies to secure accurate and current statistical information on the amount, distribution, and effects of illness and disability in the United States and the services rendered for or because of such conditions. A major strength of this survey lies in the ability to describe these health characteristics by demographic and socioeconomic characteristics. NHIS data are used widely throughout the Department of Health and Human Services (DHHS) to monitor trends in illness and disability and to track progress toward achieving national health objectives. The data are also used by the public health research community for epidemiologic and policy analysis of such timely issues as characterizing those with various health problems, determining barriers to accessing and using appropriate health care, and evaluating federal health programs.

The NHIS includes annual core content that is in the survey every year and rotating core content that is included with a fixed periodicity. Content that is sponsored by agencies external to NCHS, can be on annually, periodically, or one-time. Additionally, content can remain the same from year to year or it can vary.

Given the analytic goals of the NHIS, the National Center for Health Statistics' (NCHS) status as a federal statistical agency, the need to maintain high data quality and follow OMB standards, and the requirements to minimize public burden, a number of factors are considered prior to making decisions about what content can be sponsored on the NHIS. The following guidance is given to potential sponsors.

Considerations for adding sponsored questions on the NHIS

- NHIS content generally covers measures of health status, causes of morbidity and mortality, populations at risk, other known risk and protective factors, intermediate outcomes, and related medical or social service use. As a result, NHIS content focuses on health conditions, functioning and disability, health insurance, health care access, health care service use, and health-related behaviors, as well as covariates of health outcomes and demographics that permit assessment of health disparities.
- Questions may be included to evaluate the impact of health and health care policies, federal health programs, or nationwide health promotion initiatives. The NHIS does not generally include

questions on opinions, attitudes, stated preferences or other hypotheticals. The NHIS also does not generally include questions intended only to evaluate the need for or impact of targeted programs or focused health communication efforts.

- Sponsored content may be used to collect data on new topics or to go into more depth about subjects already on the NHIS, including rotating core content. Sponsors may also provide funding to field existing rotating content on years that they are not scheduled to be included.
- NCHS survey content, including sponsored content, must not advocate for or appear to favor any specific health policy or political viewpoint.
- Estimates of interest should have expected prevalence greater than 2 percent and be fielded with a universe of sufficient size to permit reliable estimates with a single year of data. Occasionally, questions with less than 2-percent prevalence can be included if they are needed to support the complete measurement of a larger topic area or are planned for inclusion across multiple contiguous years.
- For low prevalence estimates, questions can be included in the survey over several contiguous years in order to increase sample size if multi-year pooled data will improve the stability of estimates, the prevalence estimates are expected to be stable across those years, and high-quality nationally representative data on the topic are not available elsewhere. For such situations, a sponsor is expected to make a commitment for multiple years.
- When baseline estimates of health outcomes or covariates associated with a new policy or part of an emerging trend are needed, a low baseline prevalence may be acceptable when the expectation is that the estimate will increase over time (e.g., the receipt of a new vaccine) and the question(s) will be included for several years to track trends.
- The same sponsored content can be included periodically (e.g., every 5 years) to monitor generally increasing or decreasing (or stable) trends, i.e., where the estimates do not show both increases and decreases in the period between data collections. When monitoring trends, questions and contexts should be kept consistent to avoid the impact of methodological changes on estimates.
- NHIS is a household survey where interviewers ask adult respondents questions in person and enter responses into a computer. Sampled adults answer for themselves whenever possible and a knowledgeable adult gives answers for the sampled child. Questions should be simple and written in such a way that respondents with varying levels of cognition can understand the question, recall the relevant information, and provide a straightforward response. Certain topics lend themselves well to the household survey, while others do not. Certain constructs have the potential to be too complicated for the NHIS or too difficult for respondents to recall or report accurately. Certain subject matter may be too sensitive for interviewers to ask or respondents to answer. To the extent it is known, sponsors are expected to provide evidence that the proposed questions are of high quality and appropriate for the population being surveyed.
- The NHIS questionnaire, including sponsored content, must remain constant for the duration of a given calendar year. Exceptions may be made if the questions pertain to a seasonal topic.

Process for adding sponsored questions on the NHIS

- NCHS determines what content will be included in the NHIS. Prioritization criteria include alignment with the HHS mission and the goals of the NHIS, data quality and appropriateness of the NHIS to measure the proposed content, ability to release data in the public-use files, and available space.
- The average length of the NHIS interview is intended to be under 60 minutes. To achieve this goal, the average length of the sample adult interview can be no more than 48 minutes. (The remaining time is reserved for the household roster and, in households with children, the sample child questionnaire). Approximately 10-12 minutes is reserved for sponsored and emerging content. If there is more acceptable sponsored content than available space, priority will be given to content that best reflects HHS health improvement priorities, fits well with the data year's rotating core modules, and is funded by a sponsor annually. Content for any individual sponsor may not exceed 25 questions.
- Sponsors are advised to start a conversation with NCHS well in advance of when the questions are intended to be included in the NHIS. Due to limited space, rotating and sponsored content on the NCHS are planned in advance. Cognitive testing of the questions is often part of the development process and must be built into the schedule. However, NHIS is designed to be flexible, and should there be a need, it may be feasible to include sponsored content on the NHIS within a shorter timeframe.
- NCHS releases information through reports, as well as public-use and restricted-use datafiles. As a federal statistical agency, NCHS is responsible for ensuring the privacy of survey respondents and the confidentiality of their responses. NCHS determines what is included in the public-use and restricted-use files. Any data that are included solely in the restricted-use data will be available through the NCHS restricted-use data center. Any sponsored content that does not have disclosure risk will be included in the public-use files.
- All items on the NHIS, including sponsored content, undergo question quality evaluation using methods such as expert consultations, focus groups, cognitive testing, or field tests.
- NCHS ultimately is responsible for the questions and content included on the NHIS. NCHS is responsible for working with the NCHS Ethics Review Board (ERB) and the Office of Management and Budget (OMB) to obtain their approval. Changes may be needed to any sponsored content depending on ERB or OMB feedback. NCHS will work with the sponsor to resolve any issues.

2. Purpose and Use of Information Collection

The purposes of the NHIS are (1) to provide national data on an annual basis on the prevalence of chronic conditions and impairments, the extent of disability, the utilization of health care services, and other health-related topics; (2) to provide more detailed information on selected topics periodically and on a one time basis; and (3) to provide a sampling frame for the Medical Expenditure Panel Survey and other follow-back surveys. It is also a main provider of data for the Congressionally mandated *Health, United States* report and

provides data for many indicators used in monitoring progress toward current Healthy People goals and for detailing health disparities.

A major strength of the NHIS is its ability to display health characteristics by selected demographic and socio-economic characteristics of the U.S. civilian, noninstitutionalized population. NHIS data are typically used for program planning and evaluation, public health education and health promotion and epidemiological research. Input to the design of questions is solicited from experts in a variety of organizations within the federal government, and from outside researchers and public health professionals.

In addition to the principal questionnaires, like in past years, a small sample of respondents will be reinterviewed as a quality control measure; the reinterview questionnaire is provided in Attachment 9d. Methodological tests and follow-back surveys needed to expand the depth and breadth of information related to topics in the main NHIS and on new topics are briefly described in Attachment 6.

3. Use of Improved Information Technology and Burden Reduction

Like in past years, the survey will be conducted by Computer Assisted Personal Interview (CAPI), using Blaise software, which reduces the time required for collecting, transferring, processing, and releasing data. CAPI usually reduces the average duration of interviews compared to a paper questionnaire with identical content.

In order to reduce burden on Spanish-speaking respondents, the NHIS questionnaire has been translated into Spanish (and programmed into the CAPI software in this version), thus allowing the survey to be conducted seamlessly by Spanish-speaking interviewers.

The questionnaire launched in January 2019 was streamlined compared to past years' questionnaires. In addition, critical family-level content has moved from what had historically been collected in the family questionnaire to the sample adult and sample child questionnaires. This substantially reduces the amount of information collected about all household members. Together, these revisions result in reduced public burden while minimizing the loss of information to be collected. Additionally, the redesigned NHIS questionnaire introduced a new content structure, according to which certain sections of the core content will rotate on and off the survey with a fixed periodicity. This allows the NHIS to monitor a greater number of health topics while reducing respondent burden within any given year.

4. Efforts to Identify Duplication and Use of Similar Information

NHIS is the primary source of information for DHHS regarding the U.S. noninstitutionalized civilian population's health status, health care access, health care coverage, and progress toward achieving national health objectives. Measures included on the NHIS are often used by other federal data collection systems for calibration. NHIS questions are intended to be consistent with those on other federal surveys, but the NHIS does not duplicate detailed content collected in other topically specialized federal surveys. At the same time, some overlap between NHIS core content and that covered by other surveys is needed. This is the only way to ensure that the NHIS collects an adequate number of covariates to allow for varied and meaningful analysis of the NHIS data.

During the process of redesigning the questionnaire for 2019, wording of questions on other federal surveys were examined. In most cases where NHIS content areas were found to overlap with those covered by other

federal surveys, the terminology used in those surveys has been adopted into the new NHIS questionnaire to increase consistency in definitions. The specific surveys examined were

- National Health and Nutrition Examination Survey (NHANES)
- Medical Expenditure Panel Survey (MEPS)
- National Survey of Drug Use and Health (NSDUH)
- Behavioral Risk Factor Surveillance System (BRFSS)
- National Survey of Children's Health (NSCH)
- American Community Survey (ACS)
- Survey of Income and Program Participation (SIPP)
- American Housing Survey (AHS)

In addition, NCHS has participated in interagency workgroups established to harmonize content across major DHHS surveys, including questions on mental health, sexual orientation, health insurance, and tobacco use. Results from past and ongoing harmonization efforts have been carried through into the redesigned questionnaire.

NCHS intends to continue its efforts to collaborate with other agencies that collect similar content or rely on our data for policy decisions. For example, cognitive testing results (which show how respondents interpret questions) may suggest minor revisions to specific questions to ensure they are appropriate to meet NHIS measurement objectives. These results will not only be made available on the NCHS Q-Bank website, but also will be shared with agencies that we have collaborated with in the redesign process. This may lead to discussions about the performance of the questions and about the fitness of the questions for specific measurement objectives, recognizing that NHIS objectives may differ from other agency's objectives. While we cannot assure the use of our specific questions by other agencies, we will make every effort to keep them informed of our rationale for making decisions about questions. Agencies who want to add follow-up questions to the NHIS to explore objectives in more detail than needed to meet NHIS measurement goals will be welcome to do so throughout the life of the new design. Attachments 4b, 5b and 7b document efforts to identify and reduce duplication.

5. Impact on Small Businesses or Other Small Entities

Information collection for the NHIS does not involve small businesses or other small entities.

6. Consequences of Collecting the Information Less Frequently

The continuous nature of the NHIS is necessary for several reasons. First, many of the data items collected in the NHIS are used for annual tracking of health events and circumstances, including the National Objectives for Health Promotion and Disease Prevention and the health status of minority populations. Second, the continuous design makes it possible to aggregate data over longer periods of time to include enough cases to study rare events and small populations, such as population subgroups or persons with certain conditions. Third, the Medical Expenditures Panel Survey (Household Component and Medical Providers Component, OMB No. 0935-0118, expires 12/31/2020) now depends on the NHIS for their sample, and failure of the NHIS to collect data annually may cause this survey to be postponed or canceled. Fourth, a continuous survey is more cost-effective because it makes possible a stable interviewing staff, which increases the quality of the data and avoids start-up and shut-down costs. Fifth, NHIS quarterly data releases allow rapid assessment of important health topics. Finally, the continuous design allows for a predetermined schedule of rotating core content, collecting data less than annually would lead to health outcomes not being able to be examined in

combination and/or with all the covariates of interest available. Reducing the frequency of data collection would undermine all these desirable features of the NHIS.

There are no legal obstacles to reducing the burden.

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

This request fully complies with the regulations 5CFR 1320.5.

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

A. Public Comment

A 60-day Federal Register Notice was published in the Federal Register on April 16, 2020, Vol. 85, No. 4, pp. 21234-21235. (See Attachment 2a). Five comments were received (see Attachment 2b) and a summary of the program's response is contained in Attachment 2c.

B. Other Consultations Outside the Agency

In 2008, the Board of Scientific Counselors (BSC) of NCHS commissioned a panel to review the NHIS. The panel issued a report, in which it states that, "The NHIS is the gold standard for U.S. survey data. The size, scope and the quality of the NHIS data set it apart from the vast majority of other U.S. health surveys." The full report may be found at: <http://www.cdc.gov/nchs/data/bsc/NHISFinalReportwithexecsumm112108.pdf>

A new sample design was implemented with the 2016 NHIS. Sample areas were reselected to account for changes in the distribution of the U.S. population since 2006, when the previous sample design was first implemented. Commercial address lists were used as the main source of addresses, rather than field listing; and the oversampling procedures for black, Hispanic, and Asian persons that were a feature of the previous sample design were not implemented in 2016. For the 2016 NHIS sample redesign, sampling experts at NCHS collaborated with their counterparts at the U.S. Census Bureau to develop a timeline and procedures for implementing the new sample. Workgroups at NCHS and the Census Bureau conducted methodological and procedural research on approaches to creating a new sample, with specific focus on the new source of sample addresses (e.g., accuracy, geocoding quality, coverage of college dormitories, etc.) and the anticipated flexibility to alter overall sample size and/or shift sample allocations between States from year to year.

Prior to the launch of a redesigned NHIS questionnaire in 2019, a large-scale, multi-wave consultation effort was undertaken. It is described in detail in Attachment 3f.

9. Explanation of Any Payments or Gifts to Respondents

No incentives are used to recruit participants for the annual NHIS. An incentive of \$5 in cash will be provided to adolescents who complete the 16 minute adolescent follow-back survey as a token of appreciation, which reflects a similar rate seen in other adolescent surveys (e.g. the National Survey on Drug Use and Health offers \$30 for an hour-long interview). An additional non-conditional \$5 cash token of appreciation will be provided to adolescents who have not completed the survey after the first few weeks of the study period. A \$75 incentive is planned for NHIS sample adults who participate in a follow-up health exam. This amount is

consistent with other studies that collect biomeasures such as the National Health and Nutrition Examination Survey (NHANES).

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

The NCHS Privacy Act Coordinator has determined that the Privacy Act is applicable because information in identifiable form is being collected. The Privacy Act System of Records relevant to this data collection is entitled Health and Demographic Surveys Conducted in Probability Samples of the U.S. Population (09-20-0164). The Office of the Chief Information Security Officer (OCISO) has a current copy of the Privacy Impact Assessment.

Confidentiality assurances to respondents are shown in Attachment 1. The collection, transfer, processing, storage, and release of NHIS data are conducted in compliance with section 308(d) of the Public Health Service Act (42 USC 242m), the Confidential Information Protection and Statistical Efficiency Act of 2018 (CIPSEA; Title III , PL-115-435), and the Privacy Act of 1974, 5 U.S.C. § 552a. NCHS will use the data for statistical purposes only, and will grant data access to NCHS staff, contractors, and agents for this purpose only when required and with necessary controls.

All NCHS employees and agents who access NHIS data are subject to the confidentiality procedures set forth in CIPSEA, which states:

“Whoever, being an officer, employee, or agent of an agency acquiring information for exclusively statistical purposes, having taken and subscribed the oath of office, or having sworn to observe the limitations imposed by section 512, comes into possession of such information by reason of his or her being an officer, employee, or agent and, knowing that the disclosure of the specific information is prohibited under the provisions of this title, willfully discloses the information in any manner to a person or agency not entitled to receive it, shall be guilty of a Class E felony and imprisoned for not more than 5 years, or fined not more than \$250,000, or both.”

Information in Identifiable Form

Information in identifiable form (IIF) is collected for linkage with other federal sources of data and to enable the MEPS and NHIS follow-back surveys to develop a sampling frame from NHIS data. All of these items have been routinely approved and collected in the past. The identifiable information includes:

- Name
- Date of birth
- State/Territory where born (if born in US)
- Last four digits of the Social Security Number and/or Medicare number
- Mailing address
- Phone numbers
- Medical information

The NHIS continues to collect, on a confidential basis, data needed to recontact respondents for additional information and for participation in the MEPS, NHIS follow-back surveys and other special projects, as well as to match respondents to administrative records such as the National Death Index. This ability to track

respondents and match to other records greatly expands the usefulness of the data at very low cost and with no added respondent burden.

The collection of information in identifiable form requires strong measures to ensure that private information is not disclosed in a breach of confidentiality. Only those NCHS employees, those specially designated agents (including staff at the U.S. Census Bureau), and those NHIS research partners who must use the personal information for a specific purpose can use such data.

All NCHS employees as well as all contract staff, receive appropriate training and sign a “Nondisclosure Statement.” Staff from collaborating agencies are also required to sign this statement, and members of outside agencies are required to enter into a more formal agreement with NCHS. Everyone else who uses NHIS data can do so only after all identifiable information is removed.

To aid interviewers in guarding the confidentiality and security of data, all data collected for the NHIS will be collected on Census Bureau-furnished laptop computers that are secured with encryption software. This software encrypts data contained on the computer and has two levels of password protection. In the event of computer theft or other loss of the computer, the software prevents unauthorized access to any data on the computer, thereby adding an extra layer of security and confidentiality to the data. The transmission of confidential data from the Census Bureau to NCHS will be protected through procedures such as encryption and carefully restricted access, as is the storage of confidential data on both agencies’ servers. In addition, a routine set of measures will be taken to safeguard confidentiality, including the following: all Census Bureau and NCHS staff who have access to confidential information are given instruction by NCHS staff on the requirement to protect confidentiality, and are required to sign a pledge to maintain confidentiality; only such authorized personnel are allowed access to confidential records, and only when their work requires it; and when confidential information is not in use, it is stored in secure conditions.

It is NCHS policy to make NHIS data available via public use data files to the scientific community. Publicly released data sets are available indefinitely on the NCHS website. A concerted effort is made to avoid any disclosures that may allow a researcher to go back and find individuals in the general population. To this end, prior to their release, the NHIS data files are reviewed by the NCHS Disclosure Review Board to evaluate hundreds of tabulations of data estimates along with the survey methods in order to determine where disclosure risks might arise and how to minimize them. Several techniques are used to minimize these risks, including collapsing categories, top and bottom coding, adding noise to variables, removing detailed geographic information that may allow someone to identify individuals in the general population, along with other statistically sound means. This results in all personal identifiers being removed from the public release files; this includes participant name, address, survey location number, and so forth. Researchers wishing to conduct analysis on variables not available in the public use data files may submit a research proposal to use the NCHS Research Data Center. Procedures for submitting the proposal and other important information can be found here <http://www.cdc.gov/rdc/>.

The process of informing respondents of the procedures used to keep information confidential begins with the advance letter and information brochure mailed in advance (Attachments 10a and 10b) and will carry through to interviewer training and all communications with potential respondents. The advance letter includes all appropriate 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. These mailings may be supplemented with other mailed material (postcards and letters) that are leveraged based on Census Regional Offices’ need to establish contact with prospective

respondents (Attachment 10c). After the interview, all respondents are mailed an official “Thank You letter” to express appreciation for their participation (Attachment 10d).

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

Under the 2018 requirements of the Common Rule (45 CFR 46.102(l)(2)), the NHIS was determined to be a public health surveillance activity so Institutional Review Board approval is not required. In accordance with the *NCHS’ Practices and Procedures for the Protection of Human Subjects in Primary Data Collection Excluded from or Exempt under the Common Rule*, the NHIS informed consent procedures were reviewed and approved by the NCHS Ethics Review Board on 10/4/2019 (Attachment 11).

Some of the NHIS research topics include potentially sensitive questions. With the exception of the set of questions pertaining to stressful life events for children that were first on the 2019 NHIS, all these questions have been on the NHIS for a number of years. In the informed consent procedure, participants are advised of the voluntary nature of their participation in the survey or any of its components. Sample adults, sample child respondents, and household respondents are informed that they can choose not to answer any questions they do not wish to answer and that they may stop the interview at any time.

The potential sensitivity of questions was an evaluation criterion in determining content of the survey. The multi-purpose nature of the NHIS makes it necessary to exclude topics so sensitive that they may interfere with participation.

Questions asked about the following topics are considered by some to be of a sensitive nature:

- Social Security and Health Insurance Claim Number (last four digits)
- Citizenship Status
- Sexual Orientation and Gender Identity
- Stressful life events for children

Social Security Number and Health Insurance Claim Number: The last four digits of the social security number is asked on the NHIS questionnaire to allow linkage with administrative and vital records such as the National Death Index (NDI; OMB# 0920-0215, expires 12/31/2020). The NDI is a computerized central file of death record information. It is compiled from data obtained by NCHS from the State vital statistics offices. The data contain a standard set of identifying information on decedents from 1979 to the present. Records are matched using Social Security Number and other variables such as name, date of birth, sex, state of residence, and marital status. Of these, social security number is the most important identifier for successful matching. The last four digits has been shown to be nearly as effective for matching as the full number.

Medicare beneficiaries are given a health insurance claim number. The NHIS asks for the last four digits of that number so that the NHIS data can be linked to Medicare claims information for purposes of statistical research.

Citizenship Status: Health care coverage availability and offerings can differ by citizenship status. To best estimate the coverage status among those eligible, it is useful to obtain information about the citizenship status of NHIS sample persons.

Sexual Orientation: Beginning in 2013, questions on sexual orientation were added to the NHIS. Extensive testing occurred prior to this addition to examine the impact of the questions on interview break-off,

nonresponse or refusals, and other possible negative reactions. Multiple rounds of cognitive testing and three rounds of field testing were conducted. Treating the questions as sensitive by offering ACASI administration did not alter the results. Since introducing the questions on the NHIS in January 2013, there have been no complaints from respondents or negative outcomes. These questions have been recommended for use by the interagency workgroup established to harmonize content across major DHHS surveys.

Gender Identity: An item on gender identity is planned for the Adolescent Follow-back survey only.

Stressful life events for children: Questions pertaining to stressful life events are included in the child questionnaire. These questions were first asked in the 2019 NHIS and may be considered sensitive. However, these questions have been regularly asked in the National Survey of Children’s Health (OMB# 0607-0990, expires 05/31/2022), without complaints from participants. The questions ask about events over the entire course of a child’s life. Introductory text is read to respondents before beginning these questions, which informs respondents that some people may feel uncomfortable answering these types of questions and that they may skip any questions they do not want to answer.

12. Estimates of Annualized Burden Hours and Costs

A. Time Estimates

This submission requests OMB approval for three years of data collection, to occur within the context of ongoing data collection activities (OMB# 0920-0214, expires 12/31/2020). The average burden for each survey component for one complete survey cycle is shown in the table below.

The estimated overall average annual burden for 2021, including the roster, adult questionnaire, child questionnaire, methodological projects, adolescent follow-back survey, health exam and the reinterview component, is 42,845 hours. The average annual burden for 2022 and 2023 is estimated to be comparable to this estimated burden for 2021. Any future modification that might impact the instruments and/or burden estimates will be submitted as a nonsubstantive change request for OMB review, as applicable.

Lines 1-3 of the burden table represent the different sections of the NHIS questionnaire. Line 4 covers the methodological projects such as web and/or mail-based methodological, cognitive testing activities, and pilot studies (Attachment 6). Line 5 covers the adolescent follow-back survey. Line 6 covers a follow-up health exam. Small quality control resurveys of participating households are represented on line 7.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per respondent	Average Burden per Response (in hours)	Total Burden Hours
Adult Household Member	Household Roster	36,000	1	4/60	2,400

Sample Adult	Adult Questionnaire	30,000	1	48/60	24,000
Adult Family Member	Child Questionnaire	10,000	1	19/60	3,167
Adult Family Member	Methodological Projects	15,000	1	20/60	5,000
Sample Child	Adolescent follow-back survey	1,200	1	16/60	320
Sample Adult	Health Exam	10,000	1	45/60	7,500
Adult Family Member	Reinterview Survey	5,500	1	5/60	458
Total					42,845

Not all questions apply to each person, and the questionnaire instrument automatically skips over questions that do not apply, based on earlier information given by the respondent. Thus, no respondent is ever asked all of the questions in the questionnaire.

The estimate of response burden above is based on an average length of interview per household. Variations occur in individual household interview times primarily because of differing numbers of persons in the household and variations in the number of health conditions reported in the household.

The burden on any single member of a sample family also varies according to who is designated respondent for each component. In some sample families the same adult could be the respondent for all of the major components: roster, adult, and child. In other families there could be a different respondent for each component. In the first case, the total average burden on the single respondent would be about one hour; in all other cases the burden on a single respondent would be less.

Compared to 2020, the amount of time for the 2021 sample adult questionnaire will increase by about 9 minutes for a total survey administration time of 51 minutes due to the addition of COVID-19 related content, rotating core, and sponsored content. It is expected that the COVID-19 items will be dropped from the NHIS after 2021 reducing the length of the sample adult questionnaire to 47 minutes. There is no expected increase in the length of the sample child questionnaire in 2021 compared to 2020 (see attachments 9a-9c for NHIS roster, sample adult and sample child content). Similarly, the amount of burden hours remains the same for methodological projects (see attachment 6) and the reinterview survey (see attachment 9d). The adolescent web follow-back has 94 items, so is expected to take 16 minutes to

administer beginning around July of 2021 and continuing through December of 2022 (see attachment 9e). The follow-up health exam is expected to take about 45 minutes and would potentially begin in January of 2022 pending a successful pilot study in 2021. The goal is to complete approximately 15,000 health exams with NHIS sample adults in 2022 and 2023 if the pilot study is successful.

B. Cost to Respondents

At an average wage rate of \$21.00 per hour, the estimated annualized cost for the 42,845 burden hours is \$899,745. This estimated cost does not represent an out of pocket expense but represents a monetary value attributed to the time spent doing the interview.

Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Adult Household Member	Household Roster	2,400	\$21.00	\$50,400
Sample Adult	Adult Questionnaire	24,000	\$21.00	\$504,000
Adult Family Member	Child Questionnaire	3,167	\$21.00	\$66,500
Adult Family Member	Methodological Projects	5,000	\$21.00	\$105,000
Sample Child	Adolescent follow-back survey	320	\$21.00	\$6,720
Sample Adult	Health Exam	7,500	\$21.00	\$157,500
Adult Family Member	Reinterview Survey	458	\$21.00	\$9,625
Total				\$899,745

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

There are no annual capital or maintenance costs to the respondent resulting from this collection of information.

14. Annualized Cost to the Federal Government

As shown in the table below, the total cost of the 2021 NHIS is estimated to be about \$42 million, the same as for the 2020 survey. This includes costs to NCHS directly and to its fieldwork contractor, the Bureau of the Census. For NCHS, the estimated cost for the 2021 data collection is about \$9 million. This cost includes work on survey design, evaluation, analysis, comparability studies, coding, processing, questionnaire design laboratory testing, field pretests, weighting, and estimation, printing of survey materials, and staff observation costs (travel and per diem). It is estimated that Census Bureau costs for survey planning, design,

and data collection for the 2021 NHIS will be about \$33 million, which is transferred to the Census Bureau through an Interagency Agreement.

Total 2021 Survey Costs	42 million
U.S. Bureau of the Census (Interagency Agreement)	33 million
Sampling	4.5 million
Survey Management	1.5 million
Field Operations	23.5 million
Data Editing	1.5 million
Programming and IT	2.0 million
National Center for Health Statistics	9 million

Approximately \$9 million of these costs are provided to NCHS through Interagency Agreements with survey sponsors.

15. Explanation for Program Changes or Adjustments

For the 2021 NHIS, the average total burden is estimated to be about 42,845 hours, representing an increase of 8,474 hours compared to the 2020 NHIS (34,371 burden hours). This overall net increase is a result from the expected increases in sample sizes and the addition of a follow-up survey with sample children and a follow-up health exam with sample adults (See Section 12a above and Attachment 6 on Methodological Projects).

16. Plans for Tabulation and Publication and Project Time Schedule

The following are key activities and projected completion dates for the 2021 NHIS:

<u>Activity</u>	<u>Projected Completion Date</u>
2021 data collection	Following OMB approval, for 12 months
Early release of selected estimates (Quarter 1)	Eight months after OMB approval
2021 data file available	18 months after OMB approval
Publication of Summary Statistics	Two years after OMB approval

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.