

Supporting Statement A

Revision Request for Clearance

NATIONAL HEALTH INTERVIEW SURVEY

OMB No. 0920-0214, Expiration Date 08/31/2014

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Supporting Statement

NCHS National Health Interview Survey

This request is to modify selected sections of the National Health Interview Survey (NHIS)(OMB# 0920-0214, expires 08/31/2014), to extend the survey for three years, to conduct a supplemental project entitled the National Health Care Interview Survey (NHCIS), and to conduct a supplemental frame test. The NHIS is a critical ongoing source of information on the health of the civilian, noninstitutionalized population of the United States. The NHCIS is a followback survey of a nationally representative sample of 2012 NHIS respondents using telephone and internet modes. Its twofold purpose is to produce estimates from two points in time on issues related to health care reform and to determine whether a nationally representative internet panel can be identified for possible future surveys. The frame test employs an abbreviated NHIS interview administered by telephone and in-person to an augmentation sample of households identified using a commercially available frame to determine the feasibility of using this method to improve the NHIS state-level estimates.

On August 25, 2011, OMB approved the NHIS through the 2013 data collection, including the estimated sample size and estimated annual burden. On 10/11/2012, OMB approved a nonsubstantive change that allowed us to:

- Cycle out questions on complementary and alternative medicine, communication disorders, child balance, and food security fielded in 2012;
- Cycle in for 2013 questions on asthma, cancer screening, epilepsy, hepatitis B/C, immunosuppression, and HIV testing.
- Cycle in for 2013 and beyond a sexual identity module that includes questions on HIV testing, neighborhood characteristics, financial matters, sleep issues, and sexual identity.

In this application, we seek OMB approval to:

- Conduct the National Health Interview Survey for 2013-2015.
- Continue the increase in sample size funded under the Patient Protection and Affordable Care Act (Attachment 1).
- Conduct a web-based multimode follow-back survey of sample

adult respondents from the 2012 NHIS. The survey will focus on adult health, health care access and use, and health insurance coverage.

Modify selected sections of the 2013, 2014, and 2015 surveys through a nonsubstantive change clearance request. For example, the 2014, NHIS will include supplementary questions on occupational health, heart Disease and stroke, arthritis, vision, hearing, and balance, most of which have appeared on the NHIS in previous years. The 2015 NHIS will include supplementary questions on cancer control, last collected in 2010.

- Conduct a sample augmentation methodology study using an abbreviated NHIS questionnaire.

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 Healthy People objectives for the nation. 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 the impact of changes in federal health programs.

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). This survey (OMB# 0935-0018) is conducted by the Agency for Healthcare Research and Quality. MEPS uses completed interviews from the NHIS to identify and select the desired sample, contacts that sample to collect additional data, and combines 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 analysis.

The NHIS has been conducted every year since 1957. The current design of the NHIS was fully implemented in 1997, and consists of a standard Basic or Core Module, covering basic health topics and demographic characteristics, that are repeated every year. In addition to the Core Module, each year supplementary questions or modules may be included. For example, the 2013 NHIS will include supplementary questions on cancer screening, asthma, immune suppression, arthritis, epilepsy, and sexual identity. The 2015 NHIS will include supplementary questions on cancer control. Other topics are rotated in and out of the annual NHIS depending on funding availability and data requirements of federal programs such as Healthy People 2020.

The NHIS serves a critical role in providing information for monitoring and evaluating the performance of public health programs. The NHIS meets this need in several ways. First, the NHIS provides information on the overall health status of the U.S. population and its health needs, which serves as a background of "contextual" data against which program goals and performance measures are formulated and evaluated. Secondly, data from the NHIS serve as the national benchmark against which individual state monitoring efforts are compared.

New Projects to Enhance the Utility of the NHIS

Beginning in 2013, NCHS intends to conduct two new projects to expand the depth and breadth of information we collect related to the Affordable Care Act. The National Health Care Interview Survey (NHCIS) will be administered to NHIS respondents from 2012. This multimode follow-back survey will provide valuable information related to health on a nationally representative sample at two points in time. Its secondary purpose is to evaluate using the internet to conduct followback surveys as a less expensive and quicker alternative to telephone and in-person interviews. A probability sample of adult respondents that are not part of the sample frame for the MEPS will be drawn from the 2012 NHIS to respond to a questionnaire approximately a year after their original interview. Almost all of the questions are drawn from the 2012 NHIS and pertain to health care reform (Attachment 3g). Subject to data quality reviews, the followback interview survey data will be released as a public use microdata file as well as substantive reports. The file will include all completed telephone and online interviews weighted to represent the civilian noninstitutionalized population of the US.

This project also lends itself to useful methodological research. It would be valuable to the Department to have available an internet panel drawn from a nationally representative population with which quick surveys could be conducted. Currently we have available only commercial internet panels, most of which are not probability surveys, whose composition may not be entirely transparent. A recent report from the American Association of Public Opinion Research¹ emphasized the importance of full and complete disclosure of sample selection methods for online surveys. In this methodological test, we intend to conduct thorough qualitative analyses including nonresponse bias assessments and the impact on the estimates of reweighting the internet portion of the NHCIS sample to represent the civilian, noninstitutionalized US population. This exercise will enable us to evaluate the feasibility of using the internet panel alone for further research. Additional protocol detail is in Attachment 8.

Because most programs resulting from the Affordable Care Act will be implemented by the States, high quality surveys that can produce state-level estimates will provide vital information. The NHIS data have been used to provide estimates on key health care coverage information for the nation and 20 to 30 states. There is keen interest in expanding the number of states for which the NHIS can provide annual estimates. In late 2013, NCHS intends to conduct a test that will enhance NHIS data related to health care reform by increasing NHIS state-level samples in specific geographic areas. The test includes both mode and frame experimentation. Cases will be randomly assigned to telephone or in-person interviews in approximately 10 areas for which there is insufficient NHIS sample to on which to make stable state estimates on key health variables. The address based sample augmentation will come from a commercial vendor. To accommodate the need for a shorter interview for telephone administration, the questionnaire is an abbreviated version of the NHIS (Attachment 6). The study design and analysis plan will be submitted to OMB as a nonsubstantive change request.

Privacy Impact Assessment

The Office of the Chief Information Security Officer (OCISO) has a current copy of the Privacy Impact Assessment.

Overview of the Data Collection System

Under an interagency agreement, the U.S. Census Bureau is the data collection agent for the National Health Interview Survey. NHIS data are collected by Census interviewers, primarily through personal visits to households using laptop computers. Telephone interviews may be attempted when efforts to make personal contact have not been successful, when the respondent requests a telephone interview, when part of the interview needs to be completed and it is not possible to schedule another personal visit, or when road conditions or travel distances would make it difficult to schedule a personal visit. Nationally, the NHIS uses about 600 interviewers, trained and directed by health survey supervisors in the 6 U.S. Census Bureau Regional Offices. Interviewers (also referred to as Field Representatives) receive training on an annual basis in basic interviewing procedures and in the concepts and procedures unique to the NHIS.

The NHIS is conducted using computer-assisted personal interviewing (CAPI). The CAPI data collection method employs Blaise computer software that presents the questionnaire on computer screens to each interviewer. The computer program guides the interviewer through the questionnaire, automatically routing the interviewer to appropriate questions based on answers to previous questions. Interviewers enter survey responses directly into the computer, and the CAPI program determines if the selected response is within an allowable range, checks it for consistency against other data collected during the interview, and saves the responses into a survey data file. This data collection technology reduces the time required for collecting, transferring, processing, and releasing data, and it ensures the accurate flow of the questionnaire. Publically released data sets are available indefinitely on the NCHS internet site.

Responsibility for developing questions and monitoring field work in each of these areas is assigned to NCHS staff. Input to the design of these questions was solicited from experts in a variety of organizations within the federal government, and from outside researchers and public health professionals.

Questionnaire Structure: The Basic Module is repeated every year with little change; this allows for trend analysis and for data from more than one year to be pooled to increase sample size for analytic purposes. The Basic Module contains three major parts: the Family Core (Attachment 3a), the Adult Core (Attachment 3b), and the Child Core (Attachment 3c). The Family Core component collects information on everyone in the family. This allows the NHIS to serve as a sampling frame for additional integrated surveys as needed. Information collected on the Family Core for all family members includes: household composition and sociodemographic characteristics; tracking information;

information for matches to administrative data bases; and basic indicators of health status, health behavior, and health care services. The first part of the Family Core serves as the screener questionnaire. Attachment 3 includes the screener component of the Family Core and the OMB statement at the beginning of the computerized instrument.

The Family Core component is administered to any available adult respondent to obtain information about all household and family members. The Adult Core component is administered to a randomly selected adult family member who must respond for himself or herself. If there are children in the family, one is randomly selected and the Child Core component is administered to an adult family member who is knowledgeable about that child's health. Finally, recontact information is collected from an adult family member to obtain names, addresses, and telephone numbers of persons who might know their whereabouts if they move.

Items of Information to be Collected

This clearance request is for continuing the previously approved Core Modules of the NHIS and for previously approved Topical Modules. To put this request in context, a brief description of the overall questionnaire design is given here.

Four broad content domains and associated sub domains are covered by the Core Module: health status, health care services, health behavior, and sociodemographic characteristics. The sub domains are listed as follows:

Health status

- Conditions
- Injuries/Poisoning
- Activity limitations

Health care services

- Access to care
- Health insurance
- Utilization

Health Behaviors

- Smoking
- Physical Activity
- Alcohol Consumption
- Obesity

- Sleep

Sociodemographics

- Household composition
- Race/national origin
- Education
- Income and assets
- Gender and sexual identity

The previously approved questions for the Core Module are included in Attachments 3a, 3b, and 3c.

Supplementary questions may be embedded within or attached to one of the principal sections (Family, Sample Adult, and Sample Child). The previously approved 2013 supplementary questions are shown in attachment 3e and 3f. Questions in 3e have been in previous NHIS surveys. Questions in 3f include some questions that are new to the NHIS.

Flashcards used in the administration of the questionnaire are included in Attachment 3i.

In addition to the principal questionnaires, a previously approved questionnaire that is used to reinterview a small sample of respondents as a quality control measure is also included (Attachment 3h).

Questions for the multi-mode study are included in Attachment 3g and for the frame augmentation sample, in Attachment 6.

Information in identifiable form (IIF)

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

- Name
- Date of birth
- Last four digits of the Social Security Number
- Mailing address
- Phone numbers
- Medical information
- Military status
- Employment status

2. Purpose and Use of Information Collection

The purposes of the NHIS are (1) to provide national data on an annual basis on the incidence of acute illness and accidental injuries, 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 U.S. report and provides the majority of indicators used in monitoring progress toward the Healthy People goals and for describing health disparities.

A major strength of the NHIS is its ability to display health characteristics by selected demographic and socioeconomic characteristics of the U.S. civilian, noninstitutionalized population. The uses of NHIS data are generally in the areas of program planning and evaluation, public health education and health promotion and epidemiological research.

A summary of the need for each of the topic areas of the NHIS Core Module previously approved by OMB follows:

- Conditions

The NHIS is the major source of information on both acute and chronic conditions in the U.S. population. Since risk factors for many chronic diseases are well known and modifiable, information on their prevalence is needed routinely to evaluate the impact of prevention programs. Acute conditions, while often not fatal, have substantial impact on health care utilization and health care costs; information on major acute conditions is needed to appropriately analyze utilization data.

- Injuries

Injuries are a leading cause of disability and premature mortality in the United States. The NHIS has long been a major source of data on the incidence of nonfatal injuries. However, more detailed population-based data on the causes and circumstances of non-fatal injuries, which are vital for designing and evaluating injury prevention programs, have been lacking. The National Committee on Injury Prevention and Control has pointed out the need to build upon and improve existing injury surveillance data collection systems such as the NHIS. To support these needs, the NHIS expanded injury questions in 1997 to increase the level of detail on the circumstances of nonfatal injuries.

- Limitation of Activities

Limitations in physical functioning and in the ability to perform key activities have long been recognized as major health issues and assessment of activity limitation has been done in previous NHIS questionnaires. With an aging and increasingly diverse population, the need to better understand activity limitation is imperative since it is higher among elderly, minority, and economically disadvantaged persons. The 1990 passage of the Americans with Disabilities Act (ADA) also underscored the need for clear and objective data on activity limitation. Finally, functional assessment measures are widely used to determine eligibility for numerous federal assistance programs. NHIS data on functional limitations can help measure the impact of changes in these programs.

- Health Behaviors

As noted above, many of the risk factors for a number of important chronic conditions are related to lifestyle choices (such as smoking and diet). Many of the national health objectives for the Year 2010 are related to health promotion and risk reduction and the NHIS has been identified as the major data source to track progress toward achieving many of these objectives. Most of the items included in this section have been included in previously fielded supplements to the NHIS. Because of their relevance to many national health promotion efforts, a decision was made to incorporate key health behavior items into the NHIS Basic Module.

- Access to Health Care

Recent debate on the U.S. health care delivery system has focused attention on the need for data to assess the types and sources of health care being utilized as well as problems in getting access to needed health care.

- Health Care Utilization

The NHIS Core questionnaire has always included questions on the utilization of hospital and outpatient care services. This information is important to those making decisions about allocation of health care resources and for evaluating the impact of proposed changes in financing of health care services.

- Health Insurance

Since 1990, the NHIS has collected health insurance information on an annual basis. This data is particularly needed by policy analysts to evaluate the impact of any changes.

- Demographic and Socioeconomic Characteristics

As in the past, the NHIS Basic Module will collect information on socioeconomic and demographic characteristics of respondents. One of the well-recognized and longstanding strengths of the NHIS is its ability to allow examination of health measures by a number of demographic and economic variables.

- Recontact and Matching Information

The NHIS continues to collect, on a confidential basis, data needed to recontact respondents for additional information and to match respondents to administrative records such as the National Death Index. The ability to track respondents and match to other records greatly expands the usefulness of the data at very low cost. Questions related to the use of telephones and cell phones address areas of cell phone usage that are critical for assessment of coverage in telephone surveys.

- Supplementary Questions

A summary of the 2013 supplementary questions follows. A comparison chart (approved by OMB on 10/11/2012) of 2013 supplement questions with similar questions previously used by NHIS is provided in Attachment 7.

Asthma:

The asthma questions (Attachment 3e) that appear in the Sample Child and Sample Adult Questionnaires for 2013 are part of the Healthy People 2020 Initiative and are sponsored by the National Center for Environmental Health (NCEH, CDC) and the National Heart Lung and Blood Institute (NHLBI, NIH). Similar questions were on the NHIS in 2003 and 2008 and provide information on:

- The number of asthma attacks
- Visits to the emergency room
- Number of days of school/work missed
- Use of inhalers
- Asthma action plans
- Advice from health care professionals.

Cancer Screening:

The Cancer Screening supplement (Attachment 3e) is sponsored by CDC's National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP). The purpose of these questions is to determine the practices and knowledge of the public with regard to cancer screening practices, such as Pap tests, mammography, PSA testing and colorectal screening, which are known to reduce mortality from cancer. Many of the questions measure Healthy People 2020 objectives; these items were last on the NHIS in 2010, as part of the Cancer Control Module.

Epilepsy:

The Sample Adult Epilepsy supplement (Attachment 3e) is sponsored by the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP). These questions are embedded within the Adult Conditions (ACN) module in the Sample Adult Module, and were last in the NHIS in 2010.

The purpose of the epilepsy questions is to:

- Monitor the prevalence of epilepsy in adults
- Determine whether medication is taken for epilepsy
- Find out the frequency of epileptic seizures, and whether epilepsy or its treatment interferes with work/school/social activities.

Hepatitis B/C:

Supplement questions on hepatitis screening tests (Attachment 3e) are sponsored by the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP, CDC). These questions complement similar ongoing approved questions (sponsored by NCIRD, CDC) that collect information on hepatitis A and B. The new questions ask about hepatitis B and C screening tests. The

CDC has recently recommended that all persons born between 1945 and 1965 be screened for hepatitis C, thus the new questions ask if the test has been administered and the main reason for the test.

Immunosuppression:

Immunosuppression questions (Attachment 3e) are sponsored by the National Center for Immunization and Respiratory Diseases (NCIRD, CDC). The purpose of the questions is to measure the prevalence of adults with weakened immune systems and to ask about possible reasons for their immune compromised state, i.e., from medication, chronic illness, etc. The general topic of immunosuppression has been covered in previous NHIS supplements, most recently on the 2012 Complementary and Alternative Medicine Supplement for Sample Adults.

HIV testing:

A question on HIV testing, fielded in the 2010 and earlier NHIS surveys, is proposed for inclusion again (Attachment 3e).

Sexual identity module:

Limited data are currently available on health disparities that involve the Lesbian, Gay, and Bisexual (LGB) populations. Many Healthy People 2010 objectives went unmeasured because most general health studies do not include questions on sexual identity and those that do are usually targeted to a specific health-related issue or population subgroup. The introduction of questions on sexual identity to ongoing surveys requires methodological development and testing to assure that the data collected are valid across all population subgroups and can be used for policy and program development and evaluation. The objective of asking a question on sexual identity in the NHIS is to fill the tremendous gap that exists regarding knowledge of general health behaviors, health status, and health care utilization of LGBT persons.

A series of questions was approved for the 5,000 case testing by OMB on June 26, 2012 (OMB 0920-0222). The questions tested and that are proposed starting with the 2013 NHIS include HIV testing, neighborhood characteristics, financial worries, sleep issues, and sexual identity (Attachment 3f). The ACASI content is consistent with the content studied in two smaller approved tests. Cases in the 5,000 case test were randomly assigned to receive the above described questions in either CAPI or ACASI. Prevalence estimates for the sexual identity questions were compared by mode of administration. Since a documented advantage

of ACASI is the enhanced level of privacy it affords, we anticipated higher prevalence estimates of sexual minorities (Lesbian, Gay, Bisexual or Transgender persons) from this mode of administration. Estimates for sensitive items on HIV testing, financial worries, and neighborhood characteristics were also compared. Estimates were similar for the two modes of administration but break-offs were higher and the interviews were longer using ACASI. Therefore, the questions will be administered in CAPI, the more cost efficient mode.

Multi-mode follow-back survey:

Innovative technologies must be considered for HHS surveys which are universally faced with increasing costs and decreasing response rates. The use of the web as a means of data collection could be a useful tool to improve the efficiency of HHS surveys and timeliness of data collection and reporting. Web-based surveys have the advantage of being quick and inexpensive. Computer accessibility and population coverage can be disadvantages, however, if web is the sole mode used and the sample is not representative of the population of interest. The multi-mode study, described further in Attachment 8, uses sample not set aside for MEPS for a follow-back interview one year after the initial interview to identify area of change with regard to access to care, health insurance coverage, and health status. The questionnaire—drawn from the NHIS—is found in Attachment 3g. Respondents will be approached to participate via the internet or telephone. Because it uses both telephone and internet modes for data collection, its coverage is more complete than a followback that uses only the internet. However, this approach allows us to evaluate the quality of the data if internet alone is used for followup.

Addition to Core NHIS:

As required by Section 4302 of the Affordable Care Act (see Attachment 1), a question that addresses English proficiency will be added to the Core NHIS no later than July 2013:

Question Text: How well {fill: do you/does NAME} speak English?
Would you say...

*Read categories below.

- 1 Very well
- 2 Well
- 3 Not well
- 4 Not at all

7 Refused
9 Don't know

Universe Text: All family members age 5+ years

Skip instructions: cycle through all family members age 5+: <1-4,R,D> [go to next section]

Privacy Impact Assessment Information

The Office of the Chief Information Security Officer (OCISO) has a current copy of the Privacy Impact Assessment. The NHIS continues to collect, on a confidential basis, data needed to recontact respondents for additional information and for participation in the Medical Expenditure Panel Survey and to match respondents to administrative records such as the National Death Index. The ability to track respondents and match to other records greatly expands the usefulness of the data at very low cost.

Only those NCHS employees, specially designated agents, including the U.S. Census Bureau, and our full research partners who must use the personal information for a specific purpose can use such data. Everyone else who uses NHIS data can do so only after all identifiable information is removed.

The collection of information in identifiable form requires strong measures to ensure that private information is not disclosed in a breach of confidentiality. All NCHS employees as well as all contract staff receive appropriate training and sign a "Nondisclosure Statement." Staffs of collaborating agencies are also required to sign this statement and outside agencies are required to enter into a more formal agreement with NCHS. The transmission and storage of confidential data are protected through procedures such as encryption and carefully restricted access. See A10 for more details.

3. Use of Improved Information Technology and Burden Reduction

The survey will be conducted by Computer Assisted Personal Interview (CAPI), using Blaise software, which reduces the time required for collecting, transferring data, processing data, and releasing data. CAPI usually reduces the average duration of

interviews, compared to a paper questionnaire with identical content.

4. Efforts to Identify Duplication and Use of Similar Information

During the course of development of the redesigned NHIS, numerous individuals were consulted, both formally and informally. The names and organizations of the most directly involved individuals are cited in Attachment 4a. Consultation included not only issues of design and content but also knowledge of existing surveys or data. In addition, a search was made of the literature to ascertain the uniqueness of the items.

Consultation took place in face-to-face meetings, telephone conferences, electronic mail, and postal mail, and there were multiple contacts with many of the individual consultants.

The Board of Scientific Counselors (BSC) of the National Center for Health Statistics (NCHS) commissioned a panel to review the NHIS. The panel issued a report on 21 November 2008. The report may be found at:

<http://www.cdc.gov/nchs/data/bsc/NHISFinalReportwithexecsumm112108.pdf>

Other surveys were reviewed to determine possible duplication. Because the NHIS is the principle health survey conducted by the Department of Health and Human Services, the Basic Module items are not duplicated in their entirety in any other national data system. In fact other surveys borrow questions from the NHIS for new surveys. To the extent that there is some overlap in content of the Basic Module with other surveys, it is because it is necessary to insure that the full range of relevant variables are included for complex analyses of data on the NHIS sample.

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 tracking of the National Objectives for Health Promotion and Disease Prevention and the prevalence of HIV/AIDS testing. 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 minority groups. Third, the Medical Expenditures Panel Surveys (Household Component and Medical Providers Component, OMB No. 0935-0118) 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. Reducing the frequency of data collection would undermine all of 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

The Federal Register notice announcing the 60-day public comment period for NHIS OMB 0920-0214 appeared in Vol. 77, No. 124, June 27, 2012 on pages 38295-96. A copy of the Federal Notice is included in Attachment 2.

A comment was received. See Attachment 5b.

B. Other consultations outside the agency

Major consultations took place in 1995 and 1996 when the Basic Module content was being developed. In summary, the consultation was very broad and included survey design experts, experts on the substantive health topics covered in the questionnaires, and end users of the data (Attachment 4a).

The survey design experts included several paid consultants who reviewed draft documents and attended monthly redesign staff meetings; they were Thomas Jabine, a Washington DC consultant; James Lepkowski of the University of Michigan; and Floyd Fowler of the University of Massachusetts.

The substantive experts included many scientists on the staffs of NIH and CDC, and university-based researchers; to name just a few

of those who reviewed documents and provided written comments: Barbara Starfield of the Johns Hopkins University; Paul Newacheck of the University of California, San Francisco; and Thomas Achenbach of the University of Vermont.

Consultation took place in face-to-face meetings, telephone conferences, electronic mail, and postal mail, and there were multiple contacts with many of the individual consultants. While not all recommendations by consultants could be accommodated, the content of Basic Module of the NHIS questionnaire was almost entirely selected on the advice of outside consultants. No major problems remained unresolved following the consultations.

The Board of Scientific Counselors (BSC) of the National Center for Health Statistics (NCHS) commissioned a panel to review the NHIS. The panel issued a report on 21 November 2008, which states, "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>

9. Explanation of Any Payments or Gifts to Respondents

No payments will be made to respondents in the basic NHIS.

We request permission to experiment with monetary incentives in the NHCIS to maximize response rates. The design of the experiment is detailed in Attachment 8.

10. Assurance of Confidentiality Provided to Respondents

Confidentiality provided to respondents is assured by adherence to Section 308(d) of the Public Health Service Act (42 USC 242m) as follows (Attachment 5a):

All information which would permit identification of an individual, a practice, or an establishment will be held confidential, will be used for statistical purposes only by NCHS staff, contractors, and agents only when required and with necessary controls, and will not be disclosed or released to other persons without the consent of the individual or the establishment in accordance with section 308(d) of the Public Health Service Act (42 USC 242m) and the Confidential Information Protection and Statistical Efficiency Act (PL-107-347).

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."

Privacy Impact Assessment Information

The NCHS Privacy Act Coordinator has reviewed this request and has determined that the Privacy Act is applicable. The Privacy

Act System of Records name is 09-20-0164 Health and Demographic Surveys Conducted in Probability Samples of the U.S. Population.

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 (Attachment 5b), and will carry through to interviewer training and all communications with potential respondents. Materials will include 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.

To further aid interviewers in guarding the confidentiality and security of data, all data collected in this project will be collected on laptops 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.

In this survey, as in others, NHIS will include a routine set of measures to safeguard confidentiality, including the following: all 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; when confidential materials are moved between locations, records are maintained to insure that there is no loss in transit; 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. Confidential data will never be released to the public. For example, all personal identifiers are removed from the public release files; this includes participant name, address, survey location number, sample person number, and so forth. A concerted effort is made to avoid any disclosures that may allow a researcher to go back and find individuals in the general population. All data releases are reviewed by the NCHS Disclosure Review Board to avoid data breaches, such as release of detailed geographic information that may allow anyone to identify practices or individuals in the general population.

The survey was approved by the Institutional Review Board (the NCHS Research Ethics Review Board) on June 21, 2012 (Attachment 5c).

11. Justification for Sensitive Questions

Some of the NHIS research topics include potentially sensitive questions. In the informed consent procedure, all sample persons are advised of the voluntary nature of their participation in the survey or any of its components. Sample persons are informed that they can choose not to answer any individual questions and may stop the interview at any time.

All questions and procedures are reviewed by the NCHS Research Ethics Review Board for issues of sensitivity (Attachment 5c). The potential sensitivity of questions was an evaluation criterion in determining content of the survey. The multipurpose nature of the NHIS makes it necessary to exclude topics so sensitive that they may interfere with participation.

Questions asked about the following are thought to be of a sensitive nature:

- Social Security and Health Insurance Claim Number (last four digits)
- Citizenship Status
- Intentional Injuries

Social Security Number and Health Insurance Claim Number

The last four digits of the Social Security Number (SSN) is asked on the NHIS questionnaire to allow linkage with administrative and vital records, such as the National Death Index (NDI). 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, father's surname, 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.

The Social Security Number is also used by the Medical Expenditure Panel Study to help track the location of respondents who have changed residence since their NHIS interview. Finding a correct address for respondents is essential to maintaining response levels at an acceptable level in linked surveys, and the Social Security Number is a key item for establishing a correct address.

Medicare beneficiaries are given a health insurance claim (HIC) number that is their (or their spouse's) SSN with an alphabetic prefix. The NHIS also 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.

Before the questions on SSN and HIC are asked, respondents are informed of their purpose and given an assurance of confidentiality:

Finally, we would like the last four digits of your Social Security Number and the last four numbers and any letters of your Medicare number. This information will help us link your survey data with health-related records of other government agencies, and allow us to conduct additional research without taking up your time with more questions. The National Center for Health Statistics uses this information for research purposes only. Providing this information is voluntary. Federal laws authorize us to ask for this information and require us to keep it strictly private. There will be no effect on your benefits if you do not provide this information.

* Read if necessary: The specific federal laws are the Public Health Service Act (Title 42, United States Code, Section 242K) and the Confidential Information Protection and Statistical Efficiency Act (Title V of Public Law 107-347).

If the respondent asks for more information about the purpose and confidentiality of these questions, the interviewer can display a standard help screen on her computer and read it to the respondent.

Citizenship Status

Because changes in welfare legislation affect the health care coverage of some U.S. residents who are not citizens, it is now more important to obtain information about the citizenship status of NHIS sample persons. For that reason, since 1998 the NHIS asked the following question about all members of sample families as part of the Family Core: {Are/Is} {you/subject name} a CITIZEN of the United States?

The respondent will be asked to select a response from this printed list:

- | |
|---|
| <ul style="list-style-type: none">(1) Yes, born in the United States(2) Yes, born in Puerto Rico, Guam, American Virgin Islands, or other U.S. territory(3) Yes, born abroad to American parent(s)(4) Yes, U.S. citizen by naturalization(5) No, not a citizen of the United States |
|---|

If necessary, the Field Representative will read the following

statement:

Information about citizenship is being collected by the Department of Health and Human Services to perform health-related research pertaining to place of birth and length of time in the United States. Providing this information is voluntary and is collected under the authority of the Public Health Service Act. There will be no effect on pending immigration or citizenship petitions.

Intentional Injuries

The questions on injuries and poisoning are intended to elicit a full account of the circumstance surrounding such events, including whether or not they were intentionally caused by another person. Although no direct questions are asked about intentionality or the identity of other persons, it is possible that respondents would report incidents of child abuse to an interviewer. Legal counsel advised NCHS that if that were to occur, Federal law protecting the confidentiality of the interview would take precedence over a State law requiring that evidence of child abuse be reported to authorities.

Furthermore, by analyzing previously collected NHIS data, it was determined that reports of child abuse are extremely rare in NHIS interviews, and that when they occur they almost always refer to events many years past. For those reasons, NCHS decided that it is not necessary to inform respondents in advance that the questions about injury and poisoning could lead to disclosure of child abuse. The NHIS Research Ethics Review Board reviewed and concurred in that decision.

12. Estimates of Annualized Burden Hours and Costs

A. Time Estimates

This submission requests OMB approval for three years of data collection. These data collections will occur within the context of ongoing data collection activities (OMB# 0920-0214). The average burden for each survey component for one complete survey cycle is shown in the table below.

As shown below, the estimated overall average annual burden for the 2013, 2014, and 2015 surveys, including the screening component, the core questions, the supplement questions, the reinterview component, and the medical provider component is 57,099 hours.

The screening component (Line 1 of burden table; Attachment 3) involves asking a short set of questions contained in the NHIS Coverage (COV) and Household (HHC) components of the Core NHIS used to determine whether the household includes a black, Hispanic or Asian person (More detail on the screening component is contained in section B.1). Approximately 12,000 of the screener designated households are not selected into the full NHIS survey. These households spend about 5 minutes to complete the screening components. The total burden for screener households who are not selected into the full survey is about 1,000 hours.

Lines 2-4 of the burden table describe the various sections of the core questionnaire (Attachments 3a, 3b, 3c). Line 5 is for the questionnaires that are sent to the medical care provider of a sample of children and teens to collect immunization information (Attachment 3d). Line 6 and 7 contain the supplemental questions (Attachment 3e and 3f). Line 8 contains the questions for the multi-mode study (Attachment 3g). A small quality control resurvey of about 5,000 participating households is conducted, described in line 9 (Attachment 3h). A methodological sample frame test of 5,000 persons (Attachment 6) is shown on line 10.

Annualized Burden Table

Questionnaire (respondent)	Number of respondents	Number of Responses per Respondent	Average burden per respondent in hours	Total Burden in Hours
Screener Questionnaire	12,000	1	5/60	1,000
Family Core (adult family member)	55,000	1	23/60	21,083
Adult Core (sample adult)	44,000	1	15/60	11,000
Child Core (adult family member)	17,000	1	10/60	2,833
Child/Teen Record Check (medical provider)	10,000	1	5/60	833
Supplements (adult family member)	60,000	1	12/60	12,000

Sexual Identity Module (adult family member)	44,000	1	4/60	2,933
Multi-mode study (adult family Member)	5,000	1	30/60	2,500
Reinterview Survey	5,000	1	5/60	417
Sample Frame Test (adult family member)	5,000	1	30/60	2,500
Total Burden Hours				57,099

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 module. In some sample families the same adult could be the respondent for all of the major components: Family, Adult, and Child; in other families there could be a different respondent for each of the Basic Modules. 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.

B. Cost to Respondents

At an average wage rate of \$21.00 per hour and an average length of interview of about 13.3 minutes for the 257,000 respondents (including those who screen out of the survey), the average cost per respondent is about \$4.67. (Wage rate information is from the Bureau of Labor Statistics: <http://www.bls.gov/ncs/ocs/sp/nctb1344.pdf>. This estimated cost does not represent an out of pocket expense, but represents a monetary value attributed to the time spent doing the interview.

Total Burden Hours	Respondent Wage Rate per Hour	Total estimated costs
57,099	\$21.00	\$1,199,079

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

None.

14. Annualized Cost to the Government

As shown in the table below, the total cost of the 2011 NHIS is estimated to be about \$42 million, which includes costs to NCHS directly and to its fieldwork contractor, the Bureau of the Census. For NCHS, the estimated cost for the 2013 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 2013 NHIS will be about \$33 million, which is transferred to the Census Bureau through an Interagency Agreement.

Total 2013 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

The current NHIS burden is 55,343 hours. For the 2013, 2014, and 2015 NHIS surveys the average total burden is estimated to be about 57,099, an increase of 1,756 hours. The total burden is higher due to the addition of the multi-mode follow back survey and the sample frame methodology study.

16. Plans for Tabulation and Publication and Project Time Schedule

The following are key activities and projected completion dates for the 2013 NHIS:

<u>Activity</u>	<u>Projected Completion Date</u>
o Interviewer training	December 2012
o 2013 data collection	January - December 2013
o Early release of selected estimates (quarter 1)	September 2013
o 2013 data tape available	June 2014

o Publication of summary
statistics

January - March 2015

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

N/A. Not requesting exemption.

**18. Exceptions to Certification for Paperwork Reduction Act
Submissions**

There are no exceptions to the certification.

¹Baker, R. et al. (2010) AAPOR Report on Online Panels. Public Opinion Quarterly. Volume 74, Issue 4. Pp. 711-781.