

completeness of the evidence in the systematic reviews may also address this issue.

The proposed project does not duplicate other available sources of this information. Available study registries and databases may not be complete to sufficiently inform the Program’s research.

The purpose of SEADS requests is not to collect generalizable data, but to supplement the published and grey literature searches EPC investigators are conducting. Furthermore, considering the evidence and data included in responses collected from industry stakeholders, an assessment pertaining to the completeness of the evidence-base will be produced. This, AHRQ

believes, will increase the value of AHRQ’s research reviews to end users and potentially provide stakeholders a better understanding of how their submissions are used.

**Estimated Annual Respondent Burden**

Exhibit 1 presents estimates of the reporting burden hours for the data collection efforts. Time estimates are based on pilot testing of materials and what can reasonably be requested of respondents. The number of respondents listed in “Number of respondents per SEADS request” of Exhibit 1 reflects a projected 80% response rate.

Online Submission Form: A form for submitting scientific evidence and data

related to medical interventions sponsored by organizations and individuals such as pharmaceutical companies and independent researchers. The form has three required fields: The organization’s name, the intervention in question, and whether the information they provide is all the information they know to exist. They may upload documents and they are also provided a data entry form if they wish to offer greater details on their studies.

An Optional Data Entry Form is available as an alternative to the Online Submission form. The time requirements for response would be same as the Online Submission Form.

**EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS**

Form name	Number of respondents per SEADS request	Number of responses per respondent	Hours per response	Total burden hours per SEADS
Online Submission Form (OSF) .....	70	1	15/60	17.5
Total .....	70	1	15/60	17.5

**EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN**

Form name	Number of SEADS requests	Total burden hours per SEADS	Average hourly wage rate*	Total cost burden
OSF .....	70	17.5	<sup>a</sup> \$55.48	\$970.90
Total .....	70	17.5	55.48	970.90

\* Occupational Employment Statistics, May 2014 National Occupational Employment and Wage Estimates United States, U.S. Department of Labor, Bureau of Labor Statistics. [http://www.bls.gov/oes/current/oes\\_nat.htm#b29-0000](http://www.bls.gov/oes/current/oes_nat.htm#b29-0000).

<sup>a</sup>Based on the mean wages for *Public Relations and Fundraising Managers, 11–2031*, the occupational group most likely tasked with completing the OSF.

**Request for Comments**

In accordance with the Paperwork Reduction Act, comments on AHRQ’s information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ’s estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and

included in the Agency’s subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

**Sharon Arnold,**  
*Deputy Director.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[30Day–16–0950]

**Agency Forms Undergoing Paperwork Reduction Act Review**

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request

to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of

the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to *omb@cdc.gov*. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

**Proposed Project**

The National Health and Nutrition Examination Survey (NHANES), (OMB No. 0920-0950, expires 11/30/2016)—Revision—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

Section 306 of the Public Health Service (PHS) Act (42 U.S.C. 242k), as amended, authorizes that the Secretary of Health and Human Services (DHHS), acting through NCHS, shall collect statistics on the extent and nature of illness and disability; environmental, social and other health hazards; and determinants of health of the population of the United States.

The National Health and Nutrition Examination Surveys (NHANES) have been conducted periodically between 1970 and 1994, and continuously since 1999 by the National Center for Health Statistics, CDC. Annually, approximately 14,410 respondents participate in some aspect of the full survey. Up to 3,500 additional persons might participate in tests of procedures, special studies, or methodological studies (Table 1). Participation in NHANES is completely voluntary and confidential. A three-year approval is requested.

NHANES programs produce descriptive statistics which measure the health and nutrition status of the

general population. Through the use of physical examinations, laboratory tests, and interviews NHANES studies the relationship between diet, nutrition and health in a representative sample of the United States. NHANES monitors the prevalence of chronic conditions and risk factors. NHANES data are used to produce national reference data on height, weight, and nutrient levels in the blood. Results from more recent NHANES can be compared to findings reported from previous surveys to monitor changes in the health of the U.S. population over time. NCHS collects personal identification information. Participant level data items will include basic demographic information, name, address, social security number, Medicare number and participant health information to allow for linkages to other data sources such as the National Death Index and data from the Centers for Medicare and Medicaid Services (CMS).

A variety of agencies sponsor data collection components on NHANES. To keep burden down, NCHS cycles in and out various components. The 2015–2016 NHANES physical examination includes the following components: Oral glucose tolerance test (ages 12 and older), anthropometry (all ages), 24-hour dietary recall (all ages), physician’s examination (all ages, blood pressure is collected here), oral health examination (ages 1 and older), hearing (ages 20–59), dual X-ray absorptiometry (total body composition ages 6–59 and osteoporosis, vertebral fractures and aortic calcification ages 40 and older).

While at the examination center additional interview questions are asked (6 and older), a second 24-hour dietary recall (all ages) is scheduled to be conducted by phone 3–10 days later, and an appointment is made to return to the MEC to begin a 24-hour urine collection (one-half sample of ages 20–69). In 2014, a 24-hour urine collection was added to the NHANES protocol to better understand sodium intake and provide a population baseline for use in monitoring trends in sodium intake in the future. In 2015, FDA is scheduled to implement a plan to promote broad, gradual reduction of added sodium in the food supply. One half of those successfully completing the initial

collection will be asked to complete a second 24-hour urine. After completing the 24-hour urine participants are asked to provide 2 home urine collections (first morning and an evening) and mail them back. The urines collected in the morning and evening will be compared to the 24-hour urine collection.

NHANES also plans to conduct a waist circumference methodology study. The study population will be NHANES participants aged 20 and over who participate in the body measurements component in the Mobile Examination Center (MEC).

The bio-specimens collected for laboratory tests include urine, blood, vaginal and penile swabs, oral rinses and household water collection. Serum, plasma and urine specimens are stored for future testing if the participant consents.

The following major examination or laboratory items, that had been included in the 2013–2014 NHANES, were cycled out for NHANES 2015–2016: Physical activity monitor, taste and smell component and upper body muscle strength (grip test).

Most sections of the NHANES interviews provide self-reported information to be used either in concert with specific examination or laboratory content, as independent prevalence estimates, or as covariates in statistical analysis (e.g., socio-demographic characteristics). Some examples include alcohol, drug, and tobacco use, sexual behavior, prescription and aspirin use, and indicators of oral, bone, reproductive, and mental health. Several interview components support the nutrition monitoring objective of NHANES, including questions about food security and nutrition program participation, dietary supplement use, and weight history/self-image/related behavior.

NHANES data users include the U.S. Congress; numerous Federal agencies such as other branches of the Centers for Disease Control and Prevention, the National Institutes of Health, and the United States Department of Agriculture; private groups such as the American Heart Association; schools of public health; and private businesses. There is no cost to respondents other than their time.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)
Individuals in households .....	NHANES Questionnaire .....	14,410	1	2.5
Individuals in households .....	Waist Circumference Methodology Study .....	3,000	1	8/60

## ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)
Individuals in households .....	Special Studies .....	3,500	1	3

**Leroy A. Richardson,**

Chief, Information Collection Review Office,  
Office of Scientific Integrity, Office of the  
Associate Director for Science, Office of the  
Director, Centers for Disease Control and  
Prevention.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS–8550, CMS–  
10438 and CMS–10439]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare &  
Medicaid Services, HHS.

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: the necessity and utility of the proposed information collection for the proper performance of the agency's functions; the accuracy of the estimated burden; ways to enhance the quality, utility, and clarity of the information to be collected; and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments must be received by February 9, 2016.

**ADDRESSES:** When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and

recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for “Comment or Submission” or “More Search Options” to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number \_\_\_\_\_, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).

3. Call the Reports Clearance Office at (410) 786–1326.

**FOR FURTHER INFORMATION CONTACT:** Reports Clearance Office at (410) 786–1326.

#### SUPPLEMENTARY INFORMATION:

##### Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

#### CMS–8550 Medicare Registration Application

#### CMS–10438 Data Collection To Support Eligibility Determinations and Enrollment for Employees in the Small Business Health Options Program

#### CMS–10439 Data Collection To Support Eligibility Determinations and Enrollment for Employers in the Small Business Health Options Program

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term “collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

1. *Type of Information Collection Request:* Revision of a currently approved information collection; *Title of Information Collection:* Medicare Registration Application; *Use:* The primary function of the CMS–8550 is to gather information from a physician or other eligible professional to help CMS determine whether he or she meets certain qualifications to be enrolled in the Medicare program for the sole purpose of ordering or certifying certain Medicare items or services and/or prescribing Medicare Part D drugs for Medicare beneficiaries. The application allows a physician or other eligible professional to enroll in Medicare without being approved for billing privileges. The required information is submitted when the applicant requests enrollment in Medicare for the sole purpose of ordering and certifying certain Medicare items and services or for prescribing Medicare Part D drugs. The application is used by Medicare contractors to collect data to help ensure