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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-18-0950; Docket No. CDC-2018-0040]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS)

ACTION: Notice with comment period

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled National Health and Nutrition Examination Survey (NHANES). NHANES programs produce descriptive statistics, which measure the health and nutrition status of the general population.

DATES: CDC must receive written comments on or before [**INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER**].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2018-0040 by any of the following methods:

- Federal eRulemaking Portal: Regulation.gov. Follow the instructions for submitting comments.
- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (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. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal

Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. 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;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. 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 submissions of responses.

5. Assess information collection costs.

Proposed Project

The National Health and Nutrition Examination Survey (NHANES), (OMB Control Number 0920-0950, Expiration Date 12/31/2019) - 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.

NHANES programs produce descriptive statistics, which measure the health and nutrition status of the general population. With 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.

In 2019, a new sampling strategy is being implemented. To increase operational efficiency, NHANES will survey a nationally representative sample over the course of a two-year cycle instead of annually. The change to a two-year cycle will permit more days allocated to each primary sampling unit (PSU), which will result in more time to screen and recruit potential participants, and allow for more exam slots. As in previous years, the base sample will remain at approximately 5,000 interviewed and examined individuals annually.

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 2019-20 NHANES physical examination includes the

following components: 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), and hearing (ages 6-19 and 70+). Starting in 2019, we will collect blood pressure using an automated device, instead of using manual devices.

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. In 2019, we plan to add a Words-In-Noise (ages 70+) exam, genetic testing related to the liver elastography exam, and a balance exam (ages 40+).

The 2019-20 survey will bring back the cognitive function test (ages 60+). NHANES also plans to conduct a 24-hour blood pressure measurement pilot among NHANES participants ages 18 and older.

The bio specimens collected for laboratory tests include urine, blood, and vaginal and penile swabs. Serum, plasma and urine specimens are stored for future testing, including genetic research, if the participant consents. Consent to store DNA is continuing in NHANES. Oral rinse samples for HPV analyses is cycling back into the survey (ages 8-69 years).

The following analytes are being discontinued in 2018 for participants from the smoking sample subset: Aromatic Amines,

Heterocyclic Amines, Urine Cotinine, Tobacco-Specific Nitrosamines, Perchlorate, Nitrates, and Thiocyanate, Urinary Arsenic, Mercury, Iodine and Metals.

Cycling out of NHANES 2019-20 are the blood pressure methodology project, Human Papillomavirus (HPV) in serum, Aldehydes in serum, Volatile N-nitrosamines (VNAs) tobacco biomarkers, Urine heterocyclic amines, urine aromatic amines and urine tobacco-specific nitrosamines

New additions to the survey questionnaires include two questions on WIC participation, a birth to less than 24-month questionnaire module and collecting information on infant formula ingredients. We are also considering modifications to multiple existing questionnaire sections in order to better align with questions asked in the National Health Interview Survey (NHIS) (OMB Control No. 0920-0214, Exp. 12/31/2019) or to streamline the instruments to reduce respondent burden.

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.

In 2019-2020, we plan to continue or expand upon existing multi-mode screening and electronic consent procedures in NHANES. Our yearly goal for interview, exam and post exam components is 5,000 participants. To achieve this goal we may need to screen up to 15,000 individuals.

Burden for individuals will vary based on their level of participation. For example, infants and children tend to have shorter interviews and exams than adults. This occurs because young people may have fewer health conditions or medications to report so their interviews take less time or because certain exams are only conducted on individuals 18 and older, etc. In addition, adults often serve as proxy respondents for young people in their families.

Participation in NHANES is voluntary and confidential. There is no cost to respondents other than their time. The total estimated annual burden hours are 72,917. We are requesting a three-year approval.

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 (in hours)
Individuals in households	Screener	15,000	1	3/60	750
Individuals in households	Household Interview	5,000	1	1.5	7,500
Individuals in households	MEC Exam	5,000	1	4	20,000
Individuals in households	Dietary Interview Phone Follow-Up	5,000	1	30/60	2,500
Individuals in households	Flexible Consumer Behavior Survey Phone Follow-Up	5,000	1	20/60	1,667
Individuals in households	Developmental Projects & Special Studies	3,500	1	3	10,500
Individuals in households	24 hour Blood Pressure Pilot	1,200	1	25	30,000
Total					72,917

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