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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-16-0950; Docket No. CDC-2016-0044]

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 to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on the proposed revision of the National Health and Nutrition Examination Survey (NHANES). NHANES programs produce descriptive statistics which measure the health and nutrition status of the general population.

DATES: Written comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2015-0044 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. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the 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 OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or

provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

The National Health and Nutrition Examination Survey (NHANES), (OMB No. 0920-0950, expires 12/31/2017) - 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 2017-2018 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+).

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 2017 we plan to add a liver elastography (ultrasound) exam with a set of alcohol questions to complement this exam, an Oral Human Papilloma Virus (HPV) follow-up, and cycle back in bone density for hip and spine into the Dual X-ray Absorptiometry (DXA) exam for (ages 50+). The osteoporosis questionnaire will also cycle back into NHANES to complement the changes to the DXA exam. These questions will be asked of those 40+ In addition, the age range for the existing DXA total body scan will be changed from 6-59 years to 8-69 years.

NHANES plans to conduct a blood pressure methodology study. The study population will be NHANES participants aged 6 and older who agree to come to the Mobile Examination Center (MEC). The survey would also like to conduct an Ambulatory Blood Pressure Pilot Study among NHANES participants ages 18 and older.

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, including genetic research, if the participant consents. NHANES 2017-18 plans to add three Phthalates in urine (ages 3+), nine Urinary flame retardants in urine (ages 3+), one Insect repellent in urine (ages 3+), one Volatile organic compound (VOC) metabolite in urine (ages 3+), eighteen Tobacco biomarkers in urine (ages 3+), two Metals in urine (ages 3+), Vitamin C in serum (ages 6+), Vitamins A, E, and carotenoids in serum (ages 6+), Unsaturated Iron Binding Capacity (UIBC)/Total Iron Binding Capacity (TIBC) in serum (ages 12+), and Congenital cytomegalovirus (CMV) in sera (ages 1-5). Consent to store DNA is cycling back into NHANES.

In addition metals in whole blood are changing from a one-half sample to a full sample (ages 1+). Polycyclic Aromatic Hydrocarbons (PAHs) are being discontinued in the smoker oversample subgroup, however testing will continue in a 1/3 subsample of general NHANES participants.

The 2017-18 survey will also bring back the Flexible Consumer Behavior Survey Phone follow-Up questionnaire for participant ages 1+. This takes place in the home after the second dietary recall is completed.

The following major examination or laboratory items, that

had been included in the 2015–2016 NHANES, were cycled out for NHANES 2017–2018: pubertal maturation, oral glucose tolerance test (OGTT), dual X-ray absorptiometry scans for vertebral fractures and aortic calcification, three metals in serum and three hormones and binding proteins.

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 2017–2018, we also plan to conduct a Dietary Supplement Imaging pilot study, as well as implement multi-mode screening and electronic consent procedures in NHANES. The consent for birth certificate linkage that had been included in previous NHANES will be dropped from NHANES 2017–2018.

There is no cost to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per respondent	Average Burden per Respondent (in hours)	Total Burden Hours
Individuals in households	NHANES Questionnaire	14,410	1	2.5	36,025
Individuals in households	Blood Pressure Methodology Study Phase 1	1,404	1	30/60	702
Individuals in households	Blood Pressure Methodology Study Phase 2	2,000	1	30/60	1,000
Individuals in households	Ambulatory Blood Pressure Pilot Study	1,200	1	25	30,000
Individuals in households	Oral HPV rinse Follow-up Study 6 months (estimated 80% of original sample of 3600)	2,880	1	10/60	480
Individuals in households	Oral HPV rinse Follow-up Study 12 Months (estimated 70% Of original sample)	2,520	1	10/60	420
Individuals in households	Oral HPV rinse Follow-up Study 18 months (estimated 60% Of original sample)	2,160	1	10/60	360
Individuals in households	Oral HPV rinse Follow-up Study 24	1,800	1	10/60	300

	Months (estimated 50% Of original sample)				
Individuals in households	Flexible Consumer Behavior Survey Phone Follow-Up	5,000	1	20/60	1,667
Individuals in households	Special Studies	3,500	1	3	10,500
Total					81,454

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