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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-14-0950]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639-5960 or send an email to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 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 11/30/2015—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 15,411 respondents participate in some aspect of the full survey. About 10,000 complete the screener for the survey. About 142 complete the household interview only. About 5,269 complete both the household interview and the Mobile Examination Center (MEC) examination. Up to 4,000 additional persons might participate in tests of procedures, special studies, or methodological

studies (see line 2 of Burden Table). Participation in NHANES is completely voluntary and confidential. A two-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, risk factors, and environmental exposures. 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 2013-2014 NHANES physical examination includes the following components: Oral glucose tolerance test (ages 12 and older), grip strength (ages 6 and older), anthropometry (all ages), 24-hour dietary recall (all ages), physician's examination (all ages, blood pressure is collected here), taste and smell (60 and older), oral health examination (ages 1 and older, fluorosis photos ages 6-19), 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 physical activity monitor is placed for 7 days of wear (ages 3 and older) and instructions are provided for mailing it back; a second 24-hour dietary recall (all ages) is scheduled to be conducted by phone 3-10 days later; and supplies and directions for a home urine collection (ages 20-69) is explained (this urine is mailed back).

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.

For the 2013-14 NHANES some major additions to the laboratory component include the following: Additional laboratory tests related to tobacco exposure, laboratory content related to fluoride exposure, and collection of HPV swabs for males.

The following major examination or laboratory items, that had been included in the 2011-2012 NHANES, were cycled out for NHANES 2013-2014: Tuberculin skin testing, the respiratory health, and hearing examination components, and collection of a genetic specimen for future testing.

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 2014, 24-hour urine will be collected from interested NHANES participants who have completed the NHANES examination. This information is designed to better understand sodium intake and provide a population baseline for use in monitoring trends in sodium intake in the future. This special study will be limited to a one-half sample of participants ages 20-69. One half of those successfully completing this initial collection will be asked to complete second 24-hour urine. In addition to sodium levels, potassium, chloride and creatinine levels will be measured. Other analyses of the urine are being considered: Fluoride, micro-albumin, phosphorus and iodine.

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 to participate. The total estimate of annualized burden is 48,986 hours.

ANNUALIZED BURDEN HOURS AND COSTS

Type of respondent	Form	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Individuals in households	NHANES Questionnaire	15,411	1	2.4
Individuals in households	Special Studies	4,000	1	3

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-14-0955]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-7570 or send comments to LeRoy Richardson, at 1600 Clifton Road, MS D74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

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; and (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. Written comments should be received within 60 days of this notice.

Proposed Project

Early Hearing Detection and Intervention—Pediatric Audiology Links to Service (EHDI-PALS) Survey

(OMB No. 0920-0955, Expiration 02/28/2014)—Revision—National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Division of Human Development and Disability, located within NCBDDD, promotes the health of babies, children, and adults, with a focus on preventing birth defects and developmental disabilities and optimizing the health outcomes of those with disabilities. Since the passage of the Early Hearing Detection and Intervention (EHDI) Act, 97% of newborn infants are now screened for hearing loss prior to hospital discharge. However, many of these infants have not received needed hearing tests and follow up services after their hospital discharges. The 2011 national average loss to follow-up/loss to documentation rate is at 35%. This rate remains an area of critical concern for state EHDI programs and CDC-EHDI team's goal of timely diagnosis by 3 months of age and intervention by 6 months of age. Many states cite the lack of audiology resources as the main factor behind the high loss to follow up. To compound the problem, many pediatric audiologists may be proficient evaluating children age five and older but are not proficient with diagnosing infants or younger children because children age five and younger require a different skill set. No existing literature or database was available to help states verify and quantify their states' true follow up capacity until this project went live in 2013.

Meeting since April 2010, the EHDI-PALS workgroup has sought consensus on the loss to follow up/loss to documentation issue facing the EHDI programs. A survey based on standard of care practice was developed for state EHDI programs to quantify the pediatric audiology resource distribution within their state, particularly audiology facilities that are equipped to provide follow up services for children age five and younger. After nine months of data collection, preliminary data suggested that children residing in certain regions of the United States who were loss to follow up were due to the distance

parents had to travel to reach a pediatric audiology facility. For example, parents who reside in western region of Nebraska and Iowa on average have to drive over 100 miles to reach a pediatric audiology facility.

CDC is requesting an Office of Management and Budget (OMB) approval to continue collecting audiology facility information from audiologists or facility managers so both parents, physicians and state EHDI programs will have a tool to find where the pediatric audiology facilities are located. This survey will continue to allow CDC-EHDI team and state EHDI programs to compile a systematic, quantifiable distribution of audiology facilities and the capacity of each facility to provide services for children age five and younger. The data collected will also allow the CDC-EHDI team to analyze facility distribution data to improve technical assistance to State EHDI programs.

Two additional questions will be added to the existing survey. The two questions will ask for more information from audiology facilities that provide services by remote telepractice technology. This information will be of vital interest and benefit for both parents who live in remote regions of the US and state EHDI programs to maximize resource coverage. Respondents will all be audiologists who manage a facility or provide audiologic care for children age five and younger. To minimize burden and improve convenience, the survey will continue to be available via a secure password protected Web site. Placing the survey on the internet ensures convenient, on-demand access by the audiologists. Financial cost is minimized because no mailing fee will be associated with sending or responding to this survey.

EHDI-PALS currently has 882 facilities in the database since the beginning of the data collection. All 882 facilities' contacts will receive a brief email from University of Maine to remind them to review their survey answers. It is estimated that approximately 800 audiologists will do so. It takes approximately two minutes per person to review the survey