DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–14–14VS]

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*. Written comments and/or suggestions regarding the items contained in this notice should be directed 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

Developmental Studies to Improve the National Health Care Surveys—New—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 the Secretary of Health and Human Services (DHHS), acting through the Division of Health Care Statistics (DHCS) within NCHS, shall collect statistics on the extent and nature of illness and disability of the population of the United States.

The DHCS conducts the National Health Care Surveys, a family of nationally representative surveys of encounters and health care providers in inpatient, outpatient, and long-term care settings. This information collection request (ICR) is for a new generic clearance to conduct developmental studies to improve this family of surveys. This three year clearance period will include studies to evaluate and improve upon existing survey design and operations, as well as to examine the feasibility of, and address challenges that may arise with, future expansions of the National Health Care Surveys.

Specifically, this request covers developmental research with the following aims: (1) To explore ways to refine and improve upon existing survey designs and procedures; and (2) to explore and evaluate proposed survey designs and alternative approaches to data collection. The goal of these research studies is to further enhance DHCS existing and future data collection protocols to increase research capacity and improve health care data quality for the purpose of monitoring public health and well-being at the national, state and local levels, thereby informing health policy decision-making process. The information collected through this generic ICR will not be used to make generalizable statements about the population of interest or to inform public policy; however, methodological findings may be reported.

This generic clearance would include studies conducted in person, via the telephone or internet, and by postal or electronic mail. Methods covered would include qualitative (e.g., usability testing, focus groups, ethnographic studies, and respondent debriefing questionnaires) and/or quantitative (e.g., pilot tests, pre-tests and split sample experiments) research methodologies. Examples of studies to improve existing survey designs and procedures may include evaluation of incentive approaches to improve recruitment and increase participation rates; testing of new survey items to obtain additional data on providers, patients, and their encounters while minimizing misinterpretation and human error in data collection; testing data collection in panel surveys; triangulating and validating survey responses from multiple data sources; assessment of the feasibility of data retrieval; and development of protocols that will locate, identify, and collect accurate survey data in the least labor-intensive and burdensome manner at the sampled practice site.

To explore and evaluate proposed survey designs and alternative approaches to collecting data, especially with the nationwide adoption of electronic health records, studies may expand the evaluation of data extraction of electronic health records and submission via continuity of care documentation to small/mid-size/large medical providers and hospital networks, managed care health plans, prison-hospitals, and other inpatient, outpatient, and long-term care settings that are currently either in-scope or out-of-scope of the National Health Care Surveys. Research on feasibility, data quality and respondent burden also may be carried out in the context of developing new surveys of health care providers and establishments that are currently out-of-scope of the National Health Care Surveys.

Specific motivations for conducting developmental studies include: (1) Within the National Ambulatory Medical Care Survey (NAMCS) (OMB No. 0920–0234), new clinical groups may be expanded to include dentists, psychologists, podiatrists, chiropractors, optometrists), mid-level providers (e.g., physician assistants, advanced practice nurses, nurse practitioners, certified nurse midwives) and allied-health professionals (e.g., certified nursing aides, medical assistants, radiology technicians, laboratory technicians, pharmacists, dieticians/nutritionists). Current sampling frames such as those from the American Medical Association may be obtained and studied, as well as frames that are not currently in use by NAMCS, such as state and organizational listings of other licensed providers. (2) Within the National Study of Long-Term Care Providers (OMB No. 0920–0912), additional new frames may be sought and evaluated and data items from home care agencies, long-term care hospitals, and facilities exclusively serving individuals with intellectual/developmental disability may be tested. Similarly, data may be obtained from lists compiled by states and other organizations. Data about the facilities as well as residents and their visits will be investigated. (3) In the inpatient and outpatient care settings, the National Hospital Care Survey (NHCS) (OMB No.

0920–0212) and the National Hospital Ambulatory Medical Care Survey (NHAMCS) (OMB No. 0920–0278) may investigate the addition of facility and patient information especially as it relates to insurance and electronic medical records.

Discussion is underway with the DHHS Office of Minority Health on the possibility of conducting a study to collect data on the awareness, adoption and implementation of the Enhanced National Standards on Culturally and Linguistically Appropriate Services (CLAS) in physician offices. The study may be preceded by a feasibility study.

The National Health Care Surveys collect critical, accurate data that are used to produce reliable national estimates—and in recent years, state-level estimates—of clinical services and of the providers who delivered those services in inpatient, outpatient, ambulatory, and long-term care settings. The data from these surveys are used by providers, policy makers and researchers to address important topics of interest, including the quality and disparities of care among populations, epidemiology of medical conditions, diffusion of technologies, effects of policies and practice guidelines, and changes in health care over time. Research studies need to be conducted to improve existing and proposed survey design and procedures of the National Health Care Surveys, as well as to evaluate alternative data collection approaches particularly due to the expansion of electronic health record use, and to develop new sample frames of currently out-of-scope providers and settings of care. There is no cost to respondents other than their time to participate. Average burdens are designed to cover 15–40 min interviews as well as 90 minute focus groups, longer on-site visits, and situations where organizations may be preparing electronic data files. The total estimated annualized burden is 7,085 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Health Care Providers and Business entities	Interviews, surveys, focus groups, experiments (in person, phone, internet, postal/electronic mail).	6,667	1	1
Health Care Providers,State/local government agencies, and business entities.	Interviews, surveys, focus groups, experiments (in person, phone, internet, postal/electronic mail).	167	1	2.5

Leroy 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

Food and Drug Administration

[Docket No. FDA–2014–N–1009]

Agency Information Collection Activities; Proposed Collection; Comment Request; Information Request Regarding pH of Smokeless Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. 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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information regarding pH of smokeless tobacco products.

DATES: Submit either electronic or written comments on the collection of information by September 22, 2014.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: 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. ''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 (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.