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 Disease Control and Prevention

[60Day–16–0234; Docket No. CDC–2015–0086]

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 Ambulatory Medical Care Survey (NAMCS). The purpose of NAMCS is to meet the needs and demands for statistical information about the provision of ambulatory medical care services in the United States.

DATES: Written comments must be received on or before December 7, 2015.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2016–0026 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 NE., 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, NE., MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *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 Ambulatory Medical Care Survey (NAMCS), (OMB No. 0920–0234, 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, acting through NCHS, shall collect statistics on the utilization of health care provided by non-federal office-based physicians in the United States. On December 19, 2014, the OMB approved data collection for three years from 2015 to 2017. This revision is to request approval to continue NAMCS data collection activities for three years from 2016–2018 and to add questions to the physician interview that pertain to policies, services, and experiences related to the prevention and treatment of sexually transmitted infections (STIs) and HIV prevention among adolescents and others. Small modifications will also be made to questions on the use of electronic health records. This notice also covers a decrease in the sample size resulting from smaller budget allocations. Due to this decrease, selected state estimates will not be available for 2016–2018 data.

The National Ambulatory Medical Care Survey (NAMCS) has been conducted intermittently from 1973 through 1985, and annually since 1989. The purpose of NAMCS, a voluntary survey, is to meet the needs and demands for statistical information about the provision of ambulatory medical care services in the United States. Ambulatory services are rendered in a wide variety of settings, including physicians' offices and hospital outpatient and emergency departments.

The NAMCS target universe consists of all office visits made by ambulatory patients to non-Federal office-based physicians (excluding those in the specialties of anesthesiology, radiology, and pathology) who are engaged in direct patient care. In 2006, physicians and mid-level providers (*i.e.,* nurse practitioners, physician assistants, and nurse midwives) practicing in community health centers (CHCs) were added to the NAMCS sample, and these data will continue to be collected.

To complement NAMCS data, NCHS initiated the National Hospital Ambulatory Medical Care Survey (NHAMCS, OMB No. 0920–0278, expires 02/28/18) in 1992 to provide

data concerning patient visits to hospital outpatient and emergency departments. NAMCS and NHAMCS are the principal sources of data on ambulatory care provided in the United States.

There is no cost to the 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.)	Total burden (in hrs.)
Office-based physicians	Physician Induction Interview (NAMCS–1)	2,590	1	45/60	1,943
	Patient Record form (NAMCS–30) (Physician abstracts).	259	30	14/60	1,813
	Prepare and transmit EHR (MU On-Boarding)	130	1	1	130
	Pulling, refiling medical record forms (FR abstracts).	2,201	30	1/60	1,101
Community Health Centers.	Induction Interview—service delivery site (NAMCS–201).	104	1	30/60	52
	Induction Interview—Providers (NAMCS–1)	234	1	30/60	117
	Patient Record form (NAMCS–30) (Provider abstracts).	23	30	14/60	161
	Pulling, refiling medical record forms (FR abstracts).	211	30	1/60	106
Reabstraction study	Pulling, refiling medical record forms abstracts)	72	10	1/60	12
Total					5,435

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1622]

Submitting Food Canning Establishment Registration Form and Food Process Filing Forms to the Food and Drug Administration in Electronic or Paper Format: Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a guidance entitled ''Submitting Form FDA 2541 (Food Canning Establishment Registration) and Forms FDA 2541d, FDA 2541e, FDA 2541f, and FDA 2541g (Food Process Filing Forms) to FDA in Electronic or Paper Format: Guidance for Industry.'' This guidance describes the administrative procedures to be used by commercial processors that manufacture, process, or pack acidified foods (''AF'') and/or thermally processed low-acid foods packaged in hermetically sealed containers (historically referred to as ''low-acid canned foods'' or ''LACF''). These changes include new registration and food process filing forms and a new ''smart form'' system for electronic submission of the process filing forms. Registration and process filing are required by the AF and LACF provisions of our regulations. This guidance also provides general information about how to use FDA's systems for electronic submission of the applicable forms. In addition, this guidance describes administrative procedures for voluntary registration and voluntary submissions when a commercial processor has determined that its product is not an acidified food or a low-acid canned food, and is therefore not subject to our regulations for AF and LACF. Further, this guidance describes a voluntary process whereby, upon request, we review data and other information that relate to a new processing method or new equipment.

DATES: Submit either electronic or written comments on FDA guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions: Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions: Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2013–D–1622 for Submitting Food Canning Establishment Registration Form and Food Process Filing Forms to the Food and Drug Administration in Electronic or Paper Format: Guidance for Industry; Availability. Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets