

**Leroy A. Richardson,**  
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 Office of Scientific Integrity, Office of the  
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 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](mailto: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