

**Leroy A. Richardson,**  
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 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