

Leroy A. Richardson,
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 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