

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.

[FR Doc. 2015–25646 Filed 10–7–15; 8:45 am]

BILLING CODE 4163–18–P

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

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.

[FR Doc. 2015-25648 Filed 10-7-15; 8:45 am]

BILLING CODE 4163-18-P

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