respondents. Seven-month quit rates have been previously estimated for all Quitline callers except those that call the ASQ. Based on previous literature and a review of the follow-up evaluation data previously collected by the NQDW, seven-month quit rates are not expected to change significantly over time. Data on the quitline call volume, number of tobacco users served, and the services offered by state quitlines will be provided by state health department personnel who manage the quitline, or their designee, such as contracted quitline service providers, using the NQDW Quitline Services Survey.

Data collected from the NQDW is analyzed with simple descriptive data tabulations, and trends are currently reported online through the CDC State Tobacco Activities Tracking and Evaluation (STATE) System website. More complex statistical analyses, including multivariate regression techniques will be utilized to assess quitline outcomes such as quitline reach, service utilization, how callers reported hearing about the quitline, and the effectiveness of quitline promotions and the CDC Tips From Former Smokers national tobacco education media campaigns on state quitline call volume and tobacco users receiving services from state quitlines.

CDC uses the information collected by the NQDW for ongoing monitoring, reporting, and evaluation related to state quitlines. Select data from the NQDW are reported online through the CDC's STATE System website (*http://www.cdc.gov/statesystem*). The total estimated annual Burden Hours for NQDW are 82,477.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per respondent (in hours)	Total burden (in hours)
Quitline callers who contact the quitline for help for themselves.	NQDW Intake Questionnaire (English-complete).	488,846	1	10/60	81,474
	ASQ Intake Questionnaire (Chinese, Korean, or Vietnamese-complete).	1,935	1	10/60	323
	ASQ Seven-Month Follow-up Questionnaire.	1,587	1	7/60	185
Caller who contacts the Quitline on behalf of someone else.	NQDW Intake Questionnaire (English-subset).	12,217	1	1/60	204
	ASQ Intake Questionnaire (Chinese, Korean, or Vietnamese-subset).	86	1	1/60	2
Tobacco Control Manager or their Designee/Quitline Service Provider.	Submission of NQDW Intake Questionnaire Electronic Data File to CDC.	54	4	1	216
	Submission of NQDW (ASQ) Seven-Month Follow-up Electronic Data File to CDC.	1	1	1	1
	NQDW Quitline Services Survey	54	4	20/60	72
Total	.....	.....	.....	.....	82,477

Jeffrey M. Zirger,

Acting Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2018–24232 Filed 11–5–18; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–19–18AEJ]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Natural History of *Clostridium difficile* Colonization and Infection to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on May 29, 2018 to obtain comments from the public and affected agencies. CDC received one comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov*. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Natural History of *Clostridium difficile Colonization* and Infection—New—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

A broad 60-day notice was published in the **Federal Register** on May 29, 2018, Vol. 83, No. 103, pp. 24475–24476. This 60-day notice notified the public of the broad agency announcement—Applied Research to Address Emerging Public Health Priorities—being made by CDC. Though not specific to this project, it informed the public of CDC's intent to contract with researchers to carry out a variety of different research projects.

Current estimates from the CDC suggest that *Clostridium difficile* now causes more healthcare-associated infections than any other pathogen. However, only 10% to 60% of those acquiring colonization with toxigenic strains develop *C. difficile* infection (CDI), with the remainder becoming asymptomatic carriers. Current infection control measures focus almost entirely on patients with CDI, but several recent studies suggest that asymptomatic carriers of toxigenic *C. difficile* may be an under-appreciated source of transmission. Unfortunately, the natural history of *C. difficile* colonization is not well described because previous studies have not included long-term follow-up of colonized patients and have not included strain-specific information. Previous studies of *C. difficile* carriage have also rarely included assessments of the burden of carriage, the frequency of skin and environmental shedding, and the impact of antibiotics and other healthcare exposures on colonization.

The primary goal of this project is to develop a better understanding of the natural history of *C. difficile* colonization and infection to develop more effective control measures. The study will answer several questions. How often do patients acquire *C. difficile* colonization and shed the organism in their stool? Once colonization is acquired, how long do patients continue to shed *C. difficile* in their stool? How often do patients who acquire *C. difficile* colonization develop diarrhea? Are some types of *C. difficile* strains more likely to cause diarrhea or more likely to be shed in stool for a long time? Finally, do factors like antibiotic treatment, other medications, and diet affect the duration and amount of *C. difficile* shed in stool?

The results of the study will be used in the design of interventions to prevent transmission by asymptomatic carriers. The findings will be valuable for development of accurate transmission models including estimation of the effects of prevention interventions and the data will be made available for development of mathematical models of *C. difficile* transmission. Finally, the study will provide current information on the incubation period for CDI and the fraction of carriers that progress to CDI.

The study hospitals will include the Cleveland VA Medical Center, MetroHealth Medical Center, and the Medical University of South Carolina (MUSC). We will conduct a one-year cohort study of 1200 total patients, including 800 admitted to the hospital, 300 admitted to a long-term care facility (LTCF), and 100 outpatients with no healthcare admissions within 3 months. Peri-rectal, groin, chest/abdomen/hand, and environmental swabs will be collected weekly while in the hospital or LTCF for up to 4 weeks; for outpatients, swabs will be collected weekly for up to 4 weeks. Our goal will be to identify patients with new acquisition of toxigenic *C. difficile* carriage to study the natural history of carriage. Based on previous studies, we anticipate that ~12% of patients will acquire colonization (145 total). For patients with new acquisition of carriage, additional swabs will be collected up to once each month for six months to determine the natural history of colonization and if CDI is diagnosed, stool specimens will be cultured.

One of our goals is to determine the impact of a variety of factors including antibiotic therapy, medications (*e.g.,* laxatives), diet, and strain type on duration and burden of *C. difficile* colonization. In addition, we will obtain information regarding symptoms of diarrhea. To obtain this information, we will perform chart review and interviews. For all subjects, chart review will be conducted during and after admission to obtain information on demographics, co-morbidities, prior CDI, ward location, devices, incontinence, bathing practices, proton pump inhibitor use, mobility, diarrhea, laxatives, and antibiotics (categorized based upon anti-anaerobic and anti-*C. difficile* activity). To supplement information from chart review, subjects will be interviewed by study personnel at the time of each culture collection to obtain information on diarrhea, medications including antibiotics, proton pump inhibitors, and laxatives, diet, bathing practices, and fecal incontinence.

The information being collected through chart review and interviews will be valuable to identify factors associated with *C. difficile* colonization and infection. If this information were not collected, we would not be able to adequately assess factors that could affect *C. difficile* colonization or infection and/or that could lead to gastrointestinal symptoms.

To supplement information from chart review, subjects will be interviewed by study personnel (contractors) at the time of each culture collection to obtain information on diarrhea, medications including antibiotics, proton pump inhibitors, and laxatives, diet, bathing practices, and fecal incontinence. The questions will be administered by study personnel who will be trained by the principal investigator or co-investigators. All subjects will be interviewed. The respondents will have advance notice or appointments.

Total annualized Burden Hours for this study are 577. There is no burden on respondents other than the time to participate. Authorizing legislation comes from Section 301 of the Public Health Service Act. CDC is seeking one year of clearance to complete this study.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Study participants	Questionnaire	1200	5	5/60
Subjects acquiring C. difficile colonization	Questionnaire	145	6	5/60
Subjects developing CDI	Questionnaire	48	1	5/60

Jeffrey M. Zirger,

Acting Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2018–24231 Filed 11–5–18; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Tribal TANF Data Report, TANF Annual Report, and Reasonable Cause/Corrective Action Documentation Process—Final.

OMB No.: 0970–0215.

Description: 42 U.S.C. 612 (Section 412 of the Social Security Act as amended by Public Law 104–193, the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA)), mandates that federally recognized Indian Tribes with an approved Tribal TANF program collect and submit to the Secretary of the Department of Health and Human Services data on the recipients served by the Tribes' programs. This information includes both aggregated and disaggregated data on case characteristics and individual characteristics. In addition, Tribes that are subject to a penalty are allowed to provide reasonable cause justifications as to why a penalty should not be imposed or may develop and implement corrective compliance procedures to eliminate the source of the penalty. Finally, there is an annual report, which requires the Tribes to describe program characteristics. All of the above requirements are currently approved by OMB and the Administration for Children and Families is simply proposing to extend them without any changes.

Respondents: Indian Tribes.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Final Tribal TANF Data Report	74	4	451	133,496
Tribal TANF Annual Report	74	1	40	2,960
Tribal TANF Reasonable Cause/Corrective	74	1	60	4,440

Estimated Total Annual Burden Hours: 140,896.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments 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) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden information to be collected; and (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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2018–24259 Filed 11–5–18; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–0138]

Questions and Answers Regarding Mandatory Food Recalls: Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a final guidance for industry and FDA staff entitled ''Questions and Answers Regarding Mandatory Food Recalls: Guidance for Industry and FDA Staff.'' The guidance provides information on the implementation of the mandatory food recall provisions of the FDA Food Safety Modernization Act (FSMA). The guidance is in the form of Questions and Answers and provides answers to common questions that might arise about the mandatory recall provisions and FDA's plans for their implementation.

DATES: The announcement of the guidance is published in the **Federal Register** on November 6, 2018.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://www.regulations.gov.*