

## EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN—Continued

Form	Number of respondents	Total burden hours	Average hourly wage rate * (\$)	Total cost (\$)
PSO Disclosure Statement Form .....	3	9	38.06	342.54
PSO Profile Form .....	70	210	38.06	7,992.60
PSO Change of Listing Form .....	61	5.08	38.06	193.34
OCR Patient Safety Confidentiality Complaint Form .....	1	0.33	38.06	12.55
PSO Voluntary Relinquishment Form .....	5	2.50	38.06	95.15
Common Formats .....	1,000	100,000	38.06	3,806,000.00
Total .....				3,833,590.06

\* Based upon the mean of the hourly average wages for health care practitioner and technical occupations, 29-0000, National Compensation Survey, May 2016, "U.S. Department of Labor, Bureau of Labor Statistics." <https://www.bls.gov/oes/current/oes290000.htm>.

### Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility, and; for OCR's enforcement of confidentiality; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

**Karen J. Migdail,**

*Chief of Staff.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[30Day-18-1053]

#### 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 Monitoring and Reporting System for the Division of Community Health's Cooperative Agreement Programs 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 September 16, 2017 to obtain comments from the public and affected agencies. CDC received three comments 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](mailto: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

Monitoring and Reporting System for the Division of Community Health's Cooperative Agreement Programs (OMB No. 0920-1053, expiration March 31, 2018)—Revision—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

### Background and Brief Description

In September 2014, the Division of Community Health (DCH), CDC, announced a new cooperative agreement program, *Racial and Ethnic Approaches to Community Health (REACH)* program, authorized by the Public Health Service Act and the Prevention and Public Health Fund of the Affordable Care Act (Funding Opportunity Announcement (FOA) FOA DP14-1419PPHF14).

REACH awardees include 18 state, local and tribal governmental agencies, and 31 non-governmental organizations. CDC designed the REACH program to address chronic diseases and risk factors for chronic diseases, including physical inactivity, poor diet, obesity, and tobacco use. The program provides support for implementation of broad, evidence- and practice-based policy and environmental improvements in large and small cities, urban rural areas, tribes, multi-sectorial community coalitions, and racial and ethnic communities experiencing chronic disease disparities.

CDC seeks OMB approval to collect information from the 49 REACH awardees during a supplemental fourth year of funding utilizing an electronic management information system, the

DCH-Performance Monitoring Database (DCH-PMD). Forty-four previously funded Partnership to Improve Community Health awardees will no longer be included in this collection due to funding cessation.

The information system collects information to enable the accurate, reliable, uniform and timely submission to CDC of each awardee’s work plan and progress reports. Monitoring allows CDC to: (1) Determine whether an awardee is meeting performance goals; (2) make adjustments in the type and level of technical assistance provided to awardees; and (3) provide oversight of the use of federal funds.

CDC also requests OMB approval to conduct targeted, special purpose information collections on an as-needed basis. Due to substantial interest in the REACH program from a variety of stakeholders, CDC estimates that each REACH awardee may receive an invitation to participate in one special purpose information collection. Methods for these data collections could include telephone interviews, in-person interviews, Web-based surveys, or paper-and-pencil surveys. CDC will submit each special-purpose information collection request to OMB for approval through the Change Request mechanism, and will include

the data collection instrument(s) and a description of purpose and methods.

CDC seeks approval for one year to collect the necessary data. Also, CDC requires cooperative agreement awardee semi-annual progress reporting participation, but voluntary for some special-purpose data collections.

There are no costs to respondents other than their time. CDC estimates no change to the average burden per response for routine, semi-annual reporting (estimated at three hours). The total estimated annualized burden hours for an additional year of information collection are 588.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
DCH Program Awardees (state, local and tribal government sector).	DCH MIS: Semi-annual reporting .....	18	2	3
DCH Program Awardees (private sector) .....	Special Data Request .....	18	1	6
	DCH MIS: Semi-annual reporting .....	31	2	3
	Special Data Request .....	31	1	6

**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.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket Nos. FDA-2013-N-1119; FDA-2010-N-0622; FDA-2011-N-0019; FDA-2010-N-0594; FDA-2011-N-0016; FDA-2009-N-0501; FDA-2014-N-0222; FDA-2017-D-0040; and FDA-2016-N-3585]

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at <https://www.reginfo.gov/public/do/PRAMain>. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Food Canning Establishment Registration, Process Filing, and Recordkeeping for Acidified and Thermally Processed Low-Acid Foods .....	0910-0037	10/31/2020
Color Additive Certification Requests and Recordkeeping .....	0910-0216	10/31/2020
Customer/Partner Service Surveys .....	0910-0360	10/31/2020
Focus Groups as Used by the Food and Drug Administration .....	0910-0497	10/31/2020
Recordkeeping and Records Access Requirements for Food Facilities .....	0910-0560	10/31/2020
Reporting and Recordkeeping Requirements for Reportable Food .....	0910-0643	10/31/2020
Guidance for Industry on User Fee Waivers, Reductions, and Refunds for Drug and Biological Products .....	0910-0693	10/31/2020