CDC plans to conduct the Million Hearts Hypertension Control Challenge annually through 2022. The 2020 Challenge is planned to launch in February 2020, coinciding with American Heart Month. The application period will be open for approximately 45–60 days, with recognition of the 2020 Champions in the fall of 2020. A similar calendar year schedule is planned for 2021 and 2022. Revision for 2020, 2021, and 2022 includes a reduction in the estimated number of respondents. During the period of this revision request, on an annual basis, CDC estimates that information will be collected from up to 200 applicants using the application form, at most 40 data verifications, and at most 35 semi-structured interviews. There is an overall reduction in estimated annualized burden hours.

The overall goal of the Million Hearts initiative is to prevent one million heart attacks and strokes, and controlling hypertension is one focus of the initiative. CDC will use the information collected through the Million Hearts Hypertension Control Challenge to increase widespread attention to hypertension at the clinical practice level, improve understanding of successful and sustainable implementation strategies at the practice or health system level, bring visibility to organizations that invest in hypertension control, and motivate individual practices to strengthen their hypertension control efforts. Information collected through the Million Hearts Hypertension Control Challenge will link success in clinical outcomes of hypertension control with information about strategies that can be used to achieve similar favorable outcomes so that the strategies can be replicated by other providers and health care systems.

OMB approval is requested for three years. Participation is voluntary. The total estimated annualized burden hours are 215. There are no costs 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 hr)
Clinicians, practices, and healthcare systems	Million Hearts® Hypertension Control Champion Application form.	200	1	30/60
Finalists	Data Verification Form	40	1	2
Champions	Semi-structured interview guide	35	1	1

Jeffrey M. Zirger,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30-Day–19–19IJ]

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 ''The Performance Measures Project: Improving Performance Measurement and Monitoring by CDC 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 February 7, 2019 to obtain comments from the public and affected agencies. CDC received one non-substantive 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

The Performance Measures Project: Improving Performance Measurement and Monitoring by CDC Programs—New—Program Performance and Evaluation Office (PPEO), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Each year, approximately 75% of the CDC's congressionally appropriated funding goes to extramural organizations, including state and local partners, via contracts, grants, and, most commonly, cooperative agreements. A cooperative agreement is an award mechanism used when there will be substantial Federal programmatic involvement, meaning that the CDC program staff will collaborate or participate in project or program activities. These funds are distributed from the Office of Grant Services to partners throughout the world to promote health, prevent disease, injury and disability and prepare for new health threats. The availability of funding for cooperative agreements is announced through a Notice of Funding Opportunity (NOFO). CDC awards approximately 65 new domestic, non-research NOFOs each year (each funded

for one to five years). Cooperative agreements may have only a few funded recipients or more than 50 (such as when a CDC program provides funding to all states and territories).

To monitor the performance of recipients and CDC programs toward achieving outcomes specified by cooperative agreements, CDC currently uses the PPMR (OMB Control Number-0920–1132, Expiration Date: 08/31/2019), a progress report form adapted from an information collection owned by the Administration for Children and Families (ACF). This tool may be used to collect information periodically from recipients of CDC funds regarding the progress made on CDC funded projects.

The Performance Measures Project will work with up to 25 CDC programs developing cooperative agreements to address the challenges they face with performance planning, measurement and monitoring. Each cooperative agreement will provide funding to an average of 35 local entities, for a total of up to 875 locally funded entities.

Through participation in this Project, CDC programs and recipients of cooperative agreement funds will: (1) Develop strong performance measurement systems and practices; (2) define and operationalize priority performance measures tailored to a specific cooperative agreement; and (3) establish common data collection and reporting expectations across all recipients for a specific cooperative agreement. The Project focuses on addressing these issues during the early stages of cooperative agreement development and implementation.

The Project proposes a generic clearance adapted from a previously approved generic clearance (OMB Control Number: 0970–0490, Expiration Date 1/31/2020) owned by ACF. This ACF generic clearance replaces the information collection that is the basis of CDC's current PPMR. Project participants will customize sample information collections to meet program-specific needs. The information collected will enable the accurate, reliable, uniform and timely submission to CDC of each recipient's progress and performance measures.

The information collected by the generic information collection is designed to align with, and support the goals outlined for each of the CDC recipients. Collection and reporting of the information will occur in an efficient, standardized, and user-friendly manner that will generate a variety of routine and customizable reports. The generic information collection will allow each recipient to summarize activities and progress towards meeting performance measures and goals over a specified time period specific to each award. CDC will also have the capacity to generate reports that describe activities across multiple recipients. In addition, CDC will use the information collected to respond to inquiries from HHS, Congress and other stakeholder inquiries about program activities and their impact. CDC requests OMB approval for three years. The total estimated burden is 35,000 hours. There is no cost to 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 hours)
CDC Award Recipients	(A) Performance Measures Project Sample Performance Measure Technical Specification Instrument. (B) Performance Measures project Sample Performance Measure Reporting Instrument.	875	1	40

Jeffrey M. Zirger,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–1593]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device Accessories

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by September 12, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0823. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Device Accessories

OMB Control Number 0910–0823—Extension

FDA's guidance document ''Medical Device Accessories—Describing Accessories and Classification Pathways'' (the Accessories guidance) [1] is intended to provide guidance to industry and FDA staff about the regulation of accessories to medical devices, to describe FDA's policy concerning the classification of accessories, and to discuss the application of this policy to devices that are commonly used as accessories to other medical devices. In addition, the guidance explains what devices FDA

[1] The guidance document is available on FDA's website (*https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm429672.pdf*).