



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-25-0976; Docket No. CDC-2025-0020]

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 effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled the Million Hearts® Hypertension Control Challenge. This program is a national initiative to prevent one million heart attacks and strokes by 2027.

DATES: CDC must receive written comments on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2025-0020 by any of the following methods:

- Federal eRulemaking Portal: www.regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21-8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number.

CDC will post, without change, all relevant comments to www.regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal

(www.regulations.gov) or by U.S. mail to the address listed above.

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 Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21-8, Atlanta, Georgia 30329; Telephone: 404-639-7118; E-mail: 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 the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. 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;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. 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 submissions of responses; and

5. Assess information collection costs.

Proposed Project

Million Hearts® Hypertension Control Challenge (OMB Control No. 0920-0976, Exp. 3/31/2026) – Revision – National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Million Hearts® is a national initiative to prevent one million heart attacks and strokes by 2027. To prevent one million cardiovascular events (e.g., heart attacks and strokes), people need to decrease smoking, sodium consumption and physical inactivity by 20%; improve performance on quality-of-care measures for appropriate aspirin use, blood pressure control, cholesterol management, and smoking cessation to 80%; and improve outcomes for priority populations disproportionately burdened by cardiovascular disease. Over the last nine years, we have seen tremendous progress by providers and health care systems that focus on improving their performance in controlling patients' blood pressure. Getting to 80% blood pressure control (defined as <140/<90 mm Hg) would mean that 10 million more Americans with hypertension would have their blood pressure under control, and be at substantially lower risk for strokes, heart attacks, kidney failure, and other related cardiovascular events. For more information about the initiative, visit <https://millionhearts.hhs.gov/> Million Hearts® is a registered trademark of the Department of Health and Human Services (HHS).

The challenge is an important way to call attention to the need for improved hypertension control, provides a powerful motivation and target for clinicians, and will improve understanding of successful implementation strategies at the health system level. It will identify clinicians,

clinical practices, and health systems that have exceptional rates of hypertension control and recognize them as Million Hearts® Hypertension Control Champions. To support improved quality of care delivered to patients with hypertension, Million Hearts® will document the systems, strategies, processes, and staffing that contribute to the exceptional blood pressure control rates achieved by Champions.

The challenge is authorized by Public Law 111-358, the America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education and Science Reauthorization Act of 2010 (COMPETES Act). Applicants for the Million Hearts® Hypertension Control Challenge will be asked to provide two hypertension control rates for the practice's or health system's hypertensive population: a current rate for the most recent 12-month reporting period (e.g., 1/1/2024-12/31/2024) and a previous rate for the 12-month period immediately preceding the most recent reporting period (e.g., 1/1/2023-12/31/2023). Applicants will also be asked to provide the prevalence of hypertension in their population (more details provided below), describe some population characteristics (such as urban/rural location, percent minority, % enrolled in Medicaid, % with no health insurance, and % whose primary language is not English) and strategies used by the practice or health system that support improvements in blood pressure control. A copy of the application form will be available on the Challenge website for the duration of the Challenge.

To be eligible for recognition as a Million Hearts® Hypertension Control Champion under this challenge, an individual or entity

- (1) Shall have completed the application form in its entirety to participate in the competition under the rules developed by HHS/CDC;
- (2) Shall have complied with all eligibility requirements and satisfy the requirements in one of the following subparts:
 - a. Be a U.S. licensed clinician (i.e., MD, DO, nurse practitioner, or physician assistant), practicing in any U.S. setting, who provides ongoing care for adult

patients with hypertension. The individual must be a citizen or permanent resident of the U.S.;

- b. Be a U.S. incorporated clinical practice, defined as any practice with two or more U.S. licensed clinicians who by formal arrangement share responsibility for a common panel of patients, practice at the same physical location or street address, and provide continuing medical care for adult patients with hypertension;
- c. Be a health system, incorporated in and maintaining a primary place of business in the U.S., that provides continuing medical care for adult patients with hypertension. We encourage large health systems (those that are comprised of a large number of geographically dispersed clinics and/or have multiple hospital locations) to consider having one or a few of the highest performing clinics or regional affiliates apply individually instead of the health system applying as a whole;

- (3) Must treat all adult patients with hypertension in the practice, not a selected subgroup of patients;
- (4) Must have a data management system (electronic or paper) that allows HHS/CDC or their contractor to verify data submitted;
- (5) Must treat a minimum of 500 adult patients annually and have a hypertension control rate (blood pressure <140 mm Hg systolic and <90 mm Hg diastolic) of at least **80%**;
- (6) May not be a Federal entity or Federal employee acting within the scope of their employment;
- (7) An HHS employee must not work on their application(s) during assigned duty hours;
- (8) Shall not be an employee of or contractor at CDC;
- (9) Must agree to participate in a data validation process to be conducted by a reputable independent contractor. Data will be kept confidential by the contractor to the extent

applicable law allows and will be shared with the CDC, in aggregate form only (e.g., the hypertension control rate for the practice not individual patients' hypertension values);

- (10) Must agree to sign, without revisions, a Business Associate Agreement with the contractor conducting the data validation;
- (11) Must have a written policy in place about conducting periodic background checks on all providers and taking appropriate action based on the results of the check. CDC's contractor may also request to review the policy and any supporting information deemed necessary. In addition, a health system background check will be conducted by CDC or a CDC contractor that includes a search for The Joint Commission sanctions and current investigations for serious institutional misconduct (e.g., attorney general investigation). Eligibility status, based upon the above-referenced written policy, appropriate action, and background check, will be determined at the discretion of the CDC consistent with CDC's public health mission;
- (12) Must agree to be recognized if selected and agree to participate in an interview to develop a success story that describes the systems and processes that support hypertension control among patients. Champions will be recognized on the Million Hearts® website. Strategies used by Champions that support hypertension control may be written into a success story, placed on the Million Hearts® website, used in press releases, publications, and attributed to Champions.

In addition to meeting the requirements listed in parts 1-12 above, to be eligible for recognition in the challenge, an individual or entity also must comply with the conditions or requirements set forth in each of the following paragraphs in this section.

Federal funds may not be used to develop COMPETES Act challenge applications or to fund efforts in support of a COMPETES Act challenge.

Individual applicants and individuals in a group practice must be free from convictions for or pending investigations of criminal and health care fraud offenses such as felony health care fraud, patient abuse or neglect; felony convictions for other health care-related fraud, theft, or other financial misconduct; and felony convictions relating to unlawful manufacture, distribution, prescribing, or dispensing of controlled substances as verified through the Office of the Inspector General List of Excluded Individuals and Organizations at <http://oig.hhs.gov/exclusions/background.asp>.

Individual applicants must be free from recent serious sanctions, such as those for misuse or mis-prescribing of prescription medications in the past 20 years. Eligibility status of individual applicants with serious sanctions will be determined at the discretion of CDC. CDC or CDC's contractor may perform background checks on individual clinicians and medical practices.

Champions previously recognized through any of the previous Million Hearts® Hypertension Control Challenges retain their designation as a "Champion" and are not eligible to be named a Champion in a new year of challenge.

An individual or organization shall not be disqualified from the Million Hearts® Hypertension Control Challenge for utilizing Federal facilities or consulting with Federal employees during a competition so long as the facilities and Federal employees are made available to all individuals and organizations participating in the competition on an equal basis.

By participating in this challenge, an individual or organization agrees to assume any and all risks related to participating in the challenge. Individuals or organizations also agree to waive claims against the Federal Government and its related entities, except in the case of willful misconduct, when participating in the challenge, including claims for injury; death; damage; or loss of property, money, or profits, and including those risks caused by negligence or other causes.

By participating in this challenge, individuals and organizations agree to protect the Federal Government against third party claims for damages arising from or related to challenge activities.

Individuals or organizations are not required to hold liability insurance related to participation in this challenge.

No cash prize will be awarded. Champions will receive national recognition.

To participate and submit an application, interested parties should go to <https://millionhearts.hhs.gov> or <https://www.challenge.gov>. On this site, applicants will find the application form and the rules and guidelines for participating. Information required of the applicants on the application form includes:

- The size of the applicant's adult primary care patient population, a summary of known patient demographics (e.g., age distribution), and any noteworthy patient population characteristics (such as urban/rural location, percent minority, percent enrolled in Medicaid, percent with no health insurance, and percent whose primary language is not English).
- The number of the applicant's adult primary care patients, ages 18-85, who were seen during the measurement year and had a hypertension diagnosis (i.e. hypertension prevalence).
- The applicant's current hypertension control rate for their hypertensive population ages 18-85 during the measurement year is required. In determining the hypertension control rate for the Million Hearts® Hypertension Control Challenge, CDC defines "hypertension control" as a blood pressure reading <140 mmHg systolic and <90 mmHg diastolic among patients ages 18-85 with a diagnosis of hypertension.
- The hypertension control rate should be for the provider's or health system's entire adult hypertensive patient population ages 18-85, and not limited to a sample. The provider's or health system's hypertensive population ages 18-85 should include only patients in primary care or in cardiology care in the case of a cardiology clinic. Patients seen only in dental care or behavioral health care should not be included. Examples of ineligible data submissions include hypertension control rates that are limited to treatment cohorts from

research studies or pilot studies, patients limited to a specific age range (such as 18-35 only), or patients enrolled in limited scale quality improvement projects.

- Completion of a checklist of sustainable clinic systems or processes that support hypertension control. These may include provider or patient incentives, dashboards, staffing characteristics, electronic record keeping systems, reminder or alert systems, clinician reporting, service modifications, etc.

The estimated burden for completing the application form is 30 minutes. Up to 35 of the highest scoring clinical practices or health systems will be recognized as Million Hearts[®] Hypertension Control Champions. The application will be scored based on two hypertension control rates: one for your most recent 12-month reporting period ending not earlier than December 31, of the previous calendar year, and consistency with a previous rate for the 12-month period beginning 1 year before the current reporting period.

Phase 1 includes verification of the hypertension prevalence and blood pressure control rate data submitted and a background check. For applicants whose Phase 1 data is verified as accurate and who pass the background check without concerns, phase 2 consists of a medical chart review. The medical chart review will verify the diagnosis of hypertension during the reporting year as well as blood pressure being controlled to <140 mmHg systolic and <90 mmHg diastolic. The estimated time for the data verification and validation is two hours.

A CDC-sponsored panel of three to five experts consisting of CDC staff will review the applications that pass phase 2 to select Champions. Final selection of Champions will consider all the information from the application form, the background check, data verification and medical chart validation, and final verified hypertension control rate. In the event of tied scores based on the hypertension control rate at any point in the selection process, geographic location may be considered to ensure a broad distribution of champions. Selected Champions will be notified by phone or email.

Some Champions may participate in a post-challenge telephone interview. The interview will include questions about the strategies employed by the individual practice or organization to achieve high rates of hypertension control, including barriers and facilitators for those strategies. The interview will focus on systems and processes and should not require preparation time by the Champion. The estimated time for the interview is one hour, which includes time to review the interview protocol with the interviewer, respond to the interview questions, and review a summary about the Champion's practices. The summary may be written as a success story and will be posted on the Million Hearts Web site.

CDC requests OMB approval for an estimated 215 annual burden hours. There is no cost to respondents other than their time to participate.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Physician, practices and healthcare systems	Million Hearts® Hypertension Control Champion Application Form	200	1	30/60	100
Finalists	Million Hearts® Hypertension Control Champion Data Verification Form	40	1	2	80
Champions	Interview Guide: Million Hearts® Hypertension	35	1	1	35

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
	Control Champion				
Total					215

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