

**SUPPORTING STATEMENT FOR THE
MILLION HEARTS® HYPERTENSION CONTROL CHALLENGE**

OMB No. 0920-0976

Expiration Date 12/31/2019

Part B

Revision

February 25, 2019

Program Official/Contact:
Mary G. George, MD, MSPH, FACS
Telephone: (770) 488-8092
E-mail: mgeorge@cdc.gov
National Center for Chronic Disease
Prevention and Health Promotion
Centers for Disease Prevention and Control
Atlanta, Georgia

TABLE OF CONTENTS

B. Statistical Methods

1. Respondent Universe and Sampling Methods
2. Procedures for the Collection of Information
3. Methods to Maximize Response Rates and Deal with No Response
4. Tests of Procedures or Methods to be Undertaken
5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

List of Attachments

1. Authorizing Legislation: Public Health Service Act
- 1b. Authorizing Legislation: COMPETES Act
2. 60-Day Federal Register Notice
- 2a. Public Comment 1
- 2b. Public Comment 2
- 3a. Revised Application Form
- 3b. Confirmation email (unchanged)
4. Verification Form (unchanged)
5. Interview Guide (unchanged)
6. Screenshot of 2019 Challenge website
7. IRB Determination
8. Proposed changes
9. Example Business Associate's Agreement
10. IRB Determination

B. STATISTICAL METHODS

1. Respondent Universe and Sampling Methods

Statistical sampling methods are not applicable and cannot be used to accomplish the Million Hearts Hypertension Control Challenge. The Million Hearts® Hypertension Control Challenge aims to recognize medical practices and healthcare systems that have achieved exemplary rates of hypertension control in adult patients ages 18-85. Respondents are single practice providers, group practice providers or healthcare systems that include clinicians providing direct services to adult patients. Information collection is based on a convenience sample of respondents who voluntarily apply and agree to be considered.

The Challenge will be open to:

- Licensed clinicians or medical practices providing primary care, family practice, internal medicine, osteopathic, obstetrics/gynecology, or cardiovascular care, for adults.
 - An individual clinical practice represents one to two licensed clinicians practicing in any setting who provide continuing care for patients with hypertension.
 - A group practice includes any practice with three or more licensed clinicians who, by formal arrangement, share responsibility for a common panel of patients and practice at the same site, defined as a physical location or street address.
- Licensed healthcare systems providing direct services to a patient population within a geographic area in an effort to provide more efficient care.
 - A healthcare system provides medical care for participants and/or their dependents. It may be a complete network of agencies, facilities, and all providers of health care in a specified geographic area. In a healthcare system, medical centers and clinics may work together to more efficiently offer a range of services. Healthcare systems managed on a regional basis should submit an application for the region as a whole.

Detailed eligibility and exclusion criteria for respondents are provided in **Attachment 7, Revised Eligibility and Rules for Participation**. Applicants are deemed ineligible if the clinician's license is not current or is questionable, if there are actions pending against the clinician, such as actions for inappropriate billing, as documented on the Office of the Inspector General Exclusions website at <http://exclusions.oig.hhs.gov>, criminal activities, patient abuse or neglect, healthcare fraud offenses; or if the provider does not respond to requests for data validation. Applicants must be free from convictions 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, prescription, or dispensing of controlled substances as verified through the **Office of the Inspector General List of Excluded Individuals and Entities**. Individual applicants must be free from serious sanctions, such as those for misuse or mis-prescribing of prescription medications. Such serious sanctions will be determined at the discretion of the agency consistent with CDC's public health mission. CDC's contractor may perform background checks on individual clinicians or medical practices.

To estimate the number of respondents to the Challenge, CDC investigated the number of providers recognized by the NCQA Heart/Stroke Recognition (over 4000 since 2003) and the number of providers recognized by the Bridges to Excellence Hypertension Control Program (285). As there are no reimbursement incentives attached to Million Hearts® recognition such as with other programs, **and based on the number of applications received for previous Million Hearts® Challenges, CDC estimates a maximum number of respondents to be approximately 200 applicants.**

CDC plans to recognize up to **35** Million Hearts® Hypertension Control Champions each year. From the pool of 200 applicants, up to 40 finalists may be selected for further consideration. Because finalists may voluntarily decide to discontinue their participation, or may be deemed ineligible, the number of finalists may exceed the number of selected Champions.

2. Procedures for the Collection of Information

The Million Hearts® Hypertension Control Challenge will be hosted through a unique URL: <https://www.challenge.gov/challenge/2018-million-hearts-hypertension-control-challenge/>. The Million Hearts® Hypertension Control Challenge platform will have no content directed at children less than 13 years of age.

Application information will be collected electronically once per year through a web-based online portal (**Attachment 6a, Attachment 6b**), while verification information will be collected by phone and through electronic review or paper review once per year (**Attachment 4**).

Applicants will enter the Challenge by completing the application form that includes information about the population served by the practice or healthcare system and sustainability. Estimated time required to complete the form is less than 30 minutes or less (see **Attachment 3a**).

- Applicants will create a free account on an external web platform

- On this external web platform, the applicant will find the Million Hearts® Hypertension Control Challenge Application Form.
- After submitting an application on the challenge web platform, a confirmation email will be sent to the email address provided by the applicant (**Attachment 3b**).
- Applicants will submit the Application Form during the submission period, (anticipated to begin in February of each year, and end 45-60 days later).

When submitting an application, the applicant agrees to be recognized if selected, and to participate in data verification **and validation** which includes a phone interview and/or site visit to assure accuracy and reasonableness of the information, e.g., that newly diagnosed patients are added to control rate calculations (**Attachment 4**) and **validation** of blood pressure control rate through de-identified electronic medical record review or paper review. CDC intends that verification will be planned and conducted by an independent organization with expertise in data verification **and validation, and conforms to standards** to protect privacy, such as the National Committee on Quality Assurance.

Applicants also agree to participate in an interview regarding their blood pressure control strategies and how they are implemented. The interview will be by phone (see **Attachment 5**).

3. Methods to Maximize Response Rates and Deal with Nonresponse

Maximizing response rate will rely heavily on promotion of the Challenge. Promotion will be through the Million Hearts® website, the Challenge.gov website, social media, and Million Hearts® partners, meetings, and promotions.

Because response is voluntary and based on a convenience sample, CDC does not perform non-response analysis.

4. Test of Procedures or Methods to be Undertaken

Prior to the initial Challenge, the Application Form and interview guide were reviewed and pilot tested by a small group of CDC staff. **One non-substantive change to a question is proposed for the currently approved Application Form.** No changes are proposed for the Data Verification Form or the Interview Guide.

Prior to release of the web portal, testing of the Application Form will be undertaken to ensure that there are no flaws in the Application Form, form submission, or access to submitted information.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Information

The individuals that participated in the design of the information collection include:

Judy Hannan, MPH, RN, Senior Advisor to Director on Million Hearts
Division for Heart Disease and Stroke Prevention, CDC
Telephone (770) 488-4572, jat5@cdc.gov

Hilary Wall, MS, Million Hearts Science Lead
Division for Heart Disease and Stroke Prevention, CDC
Telephone (770) 488-8172, ifx0@cdc.gov

Janet Wright, MD
Million Hearts Executive Director
Division for Heart Disease and Stroke Prevention, CDC
Telephone (410) 786-6503, Janet.Wright@cms.hhs.gov

The individual responsible for overseeing information analysis is:

Matthew Ritchey, PT, DPT, OCS, MPH, Epidemiologist
Division for Heart Disease and Stroke Prevention, CDC
Telephone (770) 488-7232, hha7@cdc.gov

The individual responsible for overseeing information collection is:

Mary G. George, MD, MSPH, FACS, Deputy Assoc. Director for Science & Sr.
Medical Officer
Division of Heart Disease and Stroke Prevention, CDC
Telephone (770)488-8092, coq5@cdc.gov