

1ATTACHMENT 7

Revised Eligibility and Rules for the Million Hearts Hypertension Control Challenge

0920-0976

Eligibility

The Million Hearts[®] Hypertension Control Challenge is open to public and private individual clinicians, practices, and health systems providing health care services to patients in a US state or territory. To be eligible to win the Challenge, the applicant must

1. Be a US licensed clinician, practicing in any US setting, who provides continuing care for adult patients with hypertension. In the case of an individual, whether participating singly or in a group, the individual must be a citizen or permanent resident of the United States.
2. Or be a US 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.
In the case of a private entity, the private entity shall be incorporated in and maintain a primary place of business in the US.
3. Or be a health system, incorporated in and maintaining a primary place of business in the US that provides continuing medical care for adult patients with hypertension.
4. In the case of a private entity, the private entity shall be incorporated in and maintain a primary place of business in the US.
5. The United States means a State, the District of Columbia, the Commonwealth of Puerto Rico, and any other territory or possession of the United States.

In addition, the clinician, practice, or health system:

1. Must treat all adult patients with hypertension in the practice seeking care, not a select subgroup of patients.
2. Must treat a minimum of 500 adult patients (aged 18 years and older) annually.
3. Must have completed the application in its entirety.
4. Must have a data management system (electronic or paper) that allows for verification of data submitted.
5. Must have a hypertension control rate of at least 80% during the 12-month reporting period preceding the Challenge, among the practice's hypertensive patient population.
6. Must agree to:
 - a. Participate in a data validation process to be conducted by a reputable independent contractor. To the extent applicable law allows, data will be kept confidential by the

contractor and will be shared with the CDC in aggregate form only (i.e., the hypertension control rate for the practice not individual hypertension values).

- b. Sign, without revisions, a HIPAA compliant Business Associate Agreement with the contractor conducting the data validation.
 - c. 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, and attributed to Champions.
 - d. Provide information through a 60 minute, or other similar, interview about their clinical strategies and protocol implementation for the development of a success story document.
7. Individual applicants and individuals in a group practice 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.
 8. Eligibility status of individual applicants with serious sanctions will be determined at the discretion of CDC.
 9. Health systems must have a policy in place that conducts periodic background checks on all providers and takes appropriate action accordingly. The background check should ensure that staff are 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**. The policy must ensure that staff are 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. In addition, a health system background check will include a search for The Joint Commission sanctions and current investigations for serious

institutional misconduct (e.g., attorney general investigation). CDC's contractor may request the policy and any supporting information deemed necessary.

10. Centers for Disease Control and Prevention (CDC) employees are not eligible to apply. Contractors working on a CDC campus are not eligible. Neither the judges nor any individuals or entities participating in the development or implementation of the Challenge are eligible.
11. A federal entity or federal employee acting within the scope of their employment are not eligible to apply.
12. An HHS employee who wishes to submit an application shall not work on their application or submission during assigned duty hours.
13. Champions recognized in a prior Million Hearts® Hypertension Control Challenge retain their designation as a "Champion" and are not eligible to be named a Champion future Challenges.

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

An individual or entity shall not be deemed ineligible because the individual or entity used federal facilities or consulted with federal employees during a competition if the facilities and employees are made available to all individuals and entities participating in the competition on an equal basis.

Rules

1. The Challenge recognizes clinicians, practices and health systems that achieve notable hypertension control rates across their adult patient population, not just for select patients. Applicants submitting research studies, pilot studies, or entries that limit hypertension control data submitted to a subset of the provider or health system population such as treatment cohorts, patients of a specific age range, or patients enrolled in limited quality improvement projects are not eligible.
2. Federal grantees and contractors:
 - a. Federal grantees may not use federal funds to develop COMPETES Act Challenge applications unless consistent with the purpose of their grant award and specifically requested to do so due to competition design, and as announced in the Federal Register.
 - b. Federal contractors may not use federal funds from a contract to develop COMPETES Act Challenge applications or to fund efforts in support of a COMPETES Act Challenge submission. Costs associated with such activities are unallowable and are not allocable to government contracts.
3. According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection or information unless it displays a valid OMB control number. The valid OMB Control number for this information collection is 0920-0976 which expires xx/xx/xxxx. The time required

to complete this information collection is estimated to be 30 minutes, including the time to review the instructions, search existing data resources, gather the data needed and complete and review the information collection. If you have comments concerning the accuracy or the time estimate(s) or suggestions for improving this form, please write to the US Department of Health and Human Services, OS/OCIO/PRA, 200 Independence Ave SW, Suite 336-E. Washington, DC, 20201, Attention: PRA Reports Clearance Officer.

4. By participating in this Challenge:

- a. Individual or organizations 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.
- b. An individual or organization agrees to indemnify the Federal Government against third party claims for damages arising from or related to Challenge activities. Individuals and organizations are not required to hold liability insurance related to participation in this Challenge.
- c. Participants are required to obtain liability insurance or demonstrate financial responsibility in the amount of \$0, for claims by a third party for death, bodily injury, or property damage, or loss resulting from an activity carried out in connection with participation in a challenge. No cash prize will be awarded. Champions will receive national recognition.

General Conditions

CDC reserves the right to cancel, suspend, and/or modify the Challenge, or any part of it, for any reason, at CDC's sole discretion. If the Challenge is cancelled, suspended, and/or modified, CDC will inform the public through the publication of a notice in the Federal Register.

Participation in this Contest constitutes a contestants' full and unconditional agreement to abide by the Contest's Official Rules found at www.Challenge.gov.

Submission Guidelines

To enter the Challenge, participants must complete the application form by clicking the link at the bottom of this page. The application form is a combination of short answer responses, checkbox responses, and assurances.

Application information includes:

1. The size of the applicant's adult patient population defined as the number of adult patients (age 18 years and older) served during the reporting year regardless of diagnosis, a summary of known patient demographics (e.g., age distribution), and any noteworthy patient population characteristics. The reporting year (continuous 12 months) should reflect the most currently available data with an end date no earlier than 3 months prior to the date of submission.
2. The percent of the applicant's adult patient population identified above that were seen during the reporting year and had a hypertension diagnosis (i.e., hypertension prevalence). There are an estimated 14 million people who are unaware of their hypertension. Most of these people are hiding in plain sight—they are in clinical treatment with elevated blood pressure documented, but hypertension neither diagnosed nor treated. Applicants selected as finalists will have their reported hypertension prevalence (i.e., percentage of their practice or system population with the condition) assessed for alignment with their predicted hypertension prevalence. Initially, a rough estimate of the applicant's predicted hypertension prevalence will be calculated using the reported age distribution of their patient population and hypertension prevalence findings from national studies, using the **Million Hearts® Hypertension Prevalence Estimator Tool [Excel-88K]**. If the applicant's reported prevalence varies considerably from this rough estimate, the applicant may be asked to describe possible reasons for this disparity during the data validation process. If the reported hypertension prevalence is extreme and there is not a justifiable reason, the applicant may be excluded from further participation in the Challenge.
3. The hypertension control rate should be for the provider's or health system's entire adult hypertensive population identified above during the reporting year. 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), or patients enrolled in limited scale quality improvement projects.
4. In addition, the hypertension control rate during the previous reporting year is also required. For example, if the current reporting year is January 1, 2018, to December 31, 2018, then the previous reporting year should be January 1, 2017, to December 31, 2017.

5. In determining the hypertension control rate, CDC defines "hypertension control" as a blood pressure reading <140 mmHg systolic and <90 mmHg diastolic among adult hypertensive patients ages 18-85.
6. A description of clinic systems or processes that support hypertension control. Checkbox responses may be supplemented by a short answer response. Supporting information about clinic systems is encouraged but not required. Sustainable systems may include provider or patient incentives, dashboards, staffing characteristics, electronic record keeping systems, reminder or alert systems, clinician reporting, service modifications, etc.
7. The applicant must agree to:
 - o Participate in a data validation process, accept the award if selected, and participate in award activities.
 - o To complete, without revisions, a required Business Associate Agreement form and/or other forms that may be required by applicable law.
 - o Participate in a 60-minute interview or similar activity to gather information about their hypertension control strategies, and work with CDC on the review of material to share clinical strategies. Strategies used by Champions that support hypertension control may be written into a success story, placed on this website, and attributed to Champions.
 - o Assume any and all risks and waive claims against the federal government and its related entities except in the case of willful misconduct, for any injury, death, damage, or loss of property, revenue or profits, whether direct, indirect or consequences, arising from participation in this prize contest, whether the injury, death, damage or loss arises through negligence or otherwise.
 - o Indemnify the federal government against third party claims for damages arising from or related to competition activities.

Applicants not agreeing to each of these items on the application form will be excluded from the Challenge.

Paper responses will not be accepted.

The estimated burden for completing the application form is 30 minutes.

Data Validation Process

The application will be scored based on the hypertension control rate for your most recent 12-month reporting period ending not earlier than December 31, 20XX.

Applicants with the highest score will participate in a two-phase process to verify their data. Applicant who are non-compliant or non-responsive with requests or timelines will be removed from further consideration.

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, phase 2 consists of a medical chart review. Phase 1 of the verification of hypertension prevalence and blood pressure control rate data is estimated to take 1 hours. In addition, background checks will be conducted by an independent source for individual or small practice applicants to ensure there are no serious sanctions or that other misconduct has occurred (as outlined in the Eligibility section). For large providers or health systems, their background check policy and implementation will be reviewed for compliance with the individual background check protocol. In addition, a health system background check will include a search for The Joint Commission's sanctions and current investigations for serious institutional misconduct (e.g., investigations for professional medical misconduct).

Phase 2 of the validation, for applicants whose Phase 1 data is verified as accurate, consists of hypertension control validation via medical chart review.

Applicants must provide documents showing the criteria used to include patients as "controlled" and a list with each hypertensive patient found to have blood pressure in control. Thirty patient records will be selected randomly for file review for compliance. For the thirty records selected, electronic copies of all of the pertinent medical records will be submitted through a secure FTP site with a secure login. Criteria for compliance with the measure include having documentation of having at least one outpatient encounter with a diagnosis of hypertension during the first 6 months of the measurement period and evidence that the patient's most recent blood pressure is adequately controlled (a reading of <140/<90 mmHg).

Performance categories: HIGH (90% – 100% of the records are in compliance with the review criteria); MEDIUM (60% – 89% in compliance); or LOW (less than 60% in compliance).

Prizes

Up to 35 Champions will be recognized.

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

In addition to recognition on the Million Hearts® and CDC websites, national press releases will be initiated to recognize and congratulate Champions. Documentation of clinical systems and strategies champions adopted that support hypertension control will be housed on this website and attributed to Champions.

Selecting the Champions

A CDC-sponsored panel of three to five experts consisting of CDC staff will review the applications that pass phase 1 and phase 2 to select Champions. Final selection of Champions will take into account all the information from the application form, the background check, and data verification and validation. In the event of tied scores at any point in the selection process, geographic location may be taken into account to ensure a broad distribution of champions.

The first Round Finalists will be selected based on a composite score generated from the information on the application form. These applicants will participate in a data validation process.

The application will be scored based on the hypertension control rate for your most recent 12-month reporting period ending not earlier than December 31, 20XX.

Judges will confirm that there are no conflicts of interest with any applicants being considered as a Champion.

Some Champions will participate in a post-challenge telephone interview. The interview will include questions about the strategies employed by the individual 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 two hours, which includes time to review the interview protocol with the interviewer, respond to the interview questions, and review a summary data about the Champion's practices. The summary may be written as a success story and posted on the Million Hearts® website.

CDC Judges Panel

Judges will be selected by CDC based on their knowledge of hypertension and hypertension control strategies. Judges may include at least three of the following:

- Million Hearts® Executive Director
- Million Hearts® Senior Advisor
- A representative of the CDC Director's Office
- Other CDC employees

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