

Prevention and the Agency for Toxic Substances and Disease Registry.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)

Announcement of Requirements and Registration for Million Hearts® Hypertension Control Challenge

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC) located within the Department of Health and Human Services (HHS) announces the launch of the Million Hearts® Hypertension Control Challenge.

Million Hearts® is a national initiative to prevent one million heart attacks and strokes by 2022. Achieving this goal means 10 million more Americans must have their blood pressure under control. Million Hearts® is working to control high blood pressure through clinical approaches, such as using health information technology to its fullest potential and integrating team-based approaches to health care, and community approaches, such as strengthening tobacco control and promoting physical activity. For more information about the initiative, visit <https://millionhearts.hhs.gov/>.

To support improved blood pressure control, HHS/CDC is announcing the 2017 Million Hearts® Hypertension Control Challenge. The challenge will improve understanding of successful implementation strategies at the health system level by motivating clinical practices and health systems to strengthen their hypertension control efforts. 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.

DATES: The Challenge will run from April 7, 2017 through June 2, 2017.

FOR FURTHER INFORMATION CONTACT: Division for Heart Disease and Stroke Prevention, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Hwy NE., Mailstop F-73, Chamblee, GA 30341, Telephone: 770-488-2424, Email: millionhearts@cdc.gov; subject line of email: Million Hearts Hypertension Control Challenge; Attention: Mary George.

SUPPLEMENTARY INFORMATION:

Award Approving Official: Anne Schuchat, MD, Acting Director, Centers for Disease Control and Prevention, and Administrator, Agency for Toxic Substances and Disease Registry

Subject of Challenge Competition: 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).

Entrants to 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 your most recent 12-month reporting period and a previous rate for a 12 month period 1 to 2 years before the current rate. Entrants will also be asked to provide the prevalence of hypertension in their population, describe some population characteristics that might present significant challenges and barriers in controlling hypertension. Entrants with patients presenting with these challenges, as well entrants with systems and processes in place that support hypertension control and are likely to endure, such as electronic reminder systems or team based care, will be taken into consideration in selection.

Nominations will be scored and judged separately by size and type of nominee in the categories listed below. CDC does not guarantee that a specific proportion of Champions will be selected from each category.

- Small individual providers or practices (500-49,999 covered lives)
- Large providers or practices (50,000 or more covered lives)
- Health Systems

Eligibility Rules for Participating in the Competition:

To be eligible to be recognized as a Hypertension Champion under this challenge, an individual or entity—

- (1) Shall have completed the nomination form in its entirety to

participate in the competition under the rules developed by HHS/CDC;

(2) Shall have complied with all the requirements in this section and;

a. Be a U.S. licensed clinician, practicing in any U.S. setting, who provides continuing care for adult patients with hypertension. The individual must be a citizen or permanent resident of the U.S.

b. Or 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. Or 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 seeking care, not a selected subgroup of patients;

(4) Must have a data management system (electronic or paper) that allows HHS/CDC or their contractor to check data submitted;

(5) Must treat a minimum of 500 adult patients annually and have a hypertension control rate of at least 70%;

(6) May not be a Federal entity or Federal employee acting within the scope of their employment;

(7) Shall not be an HHS employee working on their applications or submissions during assigned duty hours;

(8) Shall not be an employee 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 (*i.e.*, the hypertension control rate for the practice not individual hypertension values);

(10) Must agree to sign a Business Associate Agreement with the contractor conducting the data validation.

(11) Must have a written policy in place regarding conducting periodic background checks on all providers and

taking appropriate action based on the results of the check. CDC's contractor may also request 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., investigations for professional medical misconduct). 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® Web site. Strategies used by Champions that support hypertension control may be written into a success story, placed on the Million Hearts® Web site, and attributed to Champions.

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.

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.

Individual nominees 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, prescribing, or dispensing of controlled substances as verified through the Office of the Inspector General List of Excluded Individuals and Entities. <http://oig.hhs.gov/exclusions/background.asp>.

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

Champions previously recognized through the 2013, 2014, and 2015 Million Hearts Hypertension Control Challenge retain their designation as a

“Champion” and are not eligible to be named a Champion in the 2017 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.

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 or 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 local and national recognition.

Registration Process for Participants:

To participate, interested parties should go to <https://millionhearts.hhs.gov/>. On this site, nominees will find the entry form and the rules and guidelines for participating. Information required of the nominees on the nomination form includes:

- The size of the nominee's adult patient population, a summary of known patient demographics (e.g., age distribution), and any noteworthy patient population characteristics.
- The number of the nominee's adult patients who were seen during the past year and had a hypertension diagnosis (i.e., hypertension prevalence).
- The nominee's current hypertension control rate for their hypertensive population. In addition, the hypertension control rate during the previous year is required. In determining the hypertension control rate, CDC defines “hypertension control” as a blood pressure reading <140 mmHg systolic and <90 mmHg diastolic among patients with a diagnosis of hypertension.

The hypertension control rate should be for the provider's or health system's entire adult hypertensive patient

population, not limited to a sample. 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.

- 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 nomination form is 30 minutes.

Amount of the Prize:

Up to a total of 40 of the highest scoring clinical practices or health systems will be recognized as Million Hearts® Hypertension Control Champions.

Basis upon Which Winner Will Be Selected:

The nomination will be scored based on hypertension control rate (at least 90% of score); and sustainable systems in the practice that support hypertension control (up to 5% of score); and patient population that is high risk (up to 5% of score).

Nominees with the highest score will be required to participate in a two-phase process to verify their data. Nominees who are non-compliant or non-responsive with the data 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 nominees whose Phase 1 data is verified as accurate, phase 2 consists of a medical chart review.

A CDC-sponsored panel of three to five experts consisting of HHS/CDC staff will review the nominations that pass phase 2 to select Champions. Final selection of Champions will take into account all the information from the nomination form, the background check, and data verification. In the event of tie scores at any point in the selection process, geographic location may be taken into account to ensure a broad distribution of champions across rural or more populated areas, representing potentially underserved populations.

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 will be written as a success story and will be posted on the Million Hearts® Web site.

Additional Information:

Information received from nominees will be stored in a password protected file on a secure server. The challenge Web site may post the number of nominations received but will not include confidential or proprietary information about individual nominees, as described further below. The database of information submitted by nominees will not be posted on the Web site. Information collected from nominees will include general details, such as the business name, address, and contact information of the nominee. This type of information is generally publicly available. The nomination will collect and store only aggregate clinical data through the nomination process; no individual identifiable patient data will be collected or stored. Confidential or proprietary data, clearly marked as such, will be secured to the full extent allowable by law.

Information for selected Champions, such as the provider, practice, or health system's name, location, hypertension control rate, and clinic practices that support hypertension control will be shared through press releases, the challenge Web site, and Million Hearts® and HHS/CDC resources.

Summary data on the types of systems and processes that all nominees use to control hypertension may be shared in documents or other communication products that describe generally used practices for successful hypertension control. HHS/CDC will use the summary data only as described.

Compliance with Rules and

Contacting Contest Winners:

Finalists and the Champions must comply with all terms and conditions of these Official Rules, and winning is contingent upon fulfilling all requirements herein. The initial finalists will be notified by email, telephone, or mail after the date of the judging.

Privacy:

If Contestants choose to provide HHS/CDC with personal information by registering or filling out the submission form through the Challenge.gov Web site, that information is used to respond to Contestants in matters regarding their submission, announcements of entrants,

finalists, and winners of the Contest. Information is not collected for commercial marketing. Champions are permitted to cite that they were selected as Champions for the 2017 Million Hearts Hypertension Control Challenge.

General Conditions:

HHS/CDC reserves the right to cancel, suspend, and/or modify the Challenge, or any part of it, for any reason, at HHS/CDC's sole discretion. If the Challenge is cancelled, suspended, and/or modified, HHS/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.

Authority: 15 U.S.C. 3719.

Dated: March 30, 2017.

Sandra Cashman,

Executive Secretary, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-0726]

Antibody Mediated Rejection in Kidney Transplantation; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a public workshop regarding new developments and scientific issues related to antibody mediated rejection (AMR) in kidney transplantation. This public workshop is intended to provide information for and gain perspective from individuals, industry, health care professionals, researchers, public health organizations, patients, patient care providers, and other interested persons on various aspects of clinical development of medical products for prophylaxis and/or treatment of AMR in kidney transplant recipients, including clinical trial design and endpoints. The input from this public workshop will also help in developing topics for future discussion.

DATES: The public workshop will be held on April 12, 2017, from 8 a.m. to 6 p.m. and April 13, 2017, from 8:30 a.m. to 1:30 p.m. Submit either

electronic or written comments on this public workshop by April 27, 2017. Late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 27, 2017. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of April 27, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date. See the **SUPPLEMENTARY INFORMATION** section for registration date and information. Workshop updates and the workshop agenda will be made available at: <http://www.fda.gov/Drugs/NewsEvents/ucm532070> prior to the workshop.

ADDRESSES: The public workshop will be held at the Tommy Douglas Conference Center, 10000 New Hampshire Ave., Silver Spring, MD 20903. The conference center's phone number is 240-645-4000.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food