MILLION HEARTS® HYPERTENSION CONTROL CHALLENGE

SUPPORTING STATEMENT PART A: Justification

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Abstract

The goal of the Department of Health and Human Services' Million Hearts® initiative is to prevent one million heart attacks and strokes by 2017. Achieving this goal means that 10 million more Americans must have their blood pressure under control. Million Hearts™ is working to reach this goal partly through the promotion of clinical practices that are effective in increasing blood pressure control among patient populations. To assist this work, the Centers for Disease Control and Prevention (CDC) proposes to launch the Million Hearts® Hypertension Control Challenge. The Challenge will allow CDC to select and recognize Million Hearts® Hypertension Control Champions to motivate, inspire, and further the agency's mission by attracting more interest and attention to hypertension control. Specifically, identifying and recognizing exemplary clinical practices will (a) lead to deeper understanding about how to achieve better control rates (b) bring widespread attention to achievable exemplar rates (c) motivate clinicians to strive for better hypertension control rates and (d) bring prestige to a wide range of organizations that invest in hypertension control. CDC proposes to formally recognize a small number of Champions, fewer than 30 annually, and develop translation documents that describe processes and sustainable systems that support exemplary clinical hypertension control rates.

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

Background

Chronic diseases – including heart disease, cancer, stroke, diabetes, arthritis, and related risk factors, such as tobacco use, physical inactivity, poor diet, and obesity – are the leading causes of death and disability in the United States, accounting for 7 of every 10 deaths and affecting the quality of life of 90 million Americans. Chronic diseases represent 83% of all U.S. health care spending; medical care costs of people with chronic diseases account for more than 75% of the nation's $2 trillion medical care costs. Cardiovascular disease is a leading cause of death for men and women in the United States, among the most costly health problems facing our nation today, and among the most preventable. Heart disease and stroke also contribute significantly to disability. High blood pressure, also known as hypertension, is one of the leading causes of heart disease and stroke. Currently, about 67 million American adults have high blood pressure and about half (46%) have it adequately controlled.

Hypertension and its associated diseases pose $51 billion in medical and lost productivity costs each year.

In September 2011, the Centers for Disease Control and Prevention (CDC) launched the Million Hearts® initiative to prevent one million heart attacks and strokes by 2017. Achieving this goal means that 10 million more Americans must have their blood pressure under control. Million Hearts® is working to reach this goal partly through the promotion of clinical practices that are effective in increasing blood pressure control among patient populations. There is scientific evidence that provides general guidance on the types of system-based changes to clinical practice that can improve patient blood pressure control, but more information is needed to fully understand implementation practices so that they can also be shared and promoted. Germino[1] , in his discussion of pending revisions to clinical guidelines for hypertension control notes "Attempts to improve BP control rates in this country remain an important aspect of the JNC (Joint National Commission) reports, but how do we do this beyond information? Education of both patient and health care personnel is of paramount importance."

Clinical inertia was first defined by Phillips et al. in 2001 as acknowledgement of the problem, but failure to act.[2] They further explained that it "is a problem of the health care professional and the health care system, and it is separate from patient-related issues of adherence and access to care." O'Connor et al. further explored clinical inertia and hypothesized physician factors account for 50% of clinical inertia, patient factors for 30%, and the remaining 20% due to office system factors.[3] Physician factors include: failure to initiate treatment, reactive rather than proactive care, and failure to identify and manage comorbid conditions. System factors include: no clinical guideline, no decision support, no disease registry, and poor visit planning and communication between physician and staff. At least some of these factors can be addressed by identifying and disseminating successful solutions initiated by peers.

CDC proposes to launch the Million Hearts® Hypertension Control Challenge under the authority of the Public Health Service Act and the COMPETES Act. The Public Health Service Act 42 USC 241 (Attachment 1a) provides CDC with the authority to conduct investigations and studies relating to the diagnosis, treatment, and control

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[1] Germino, WFJNC 8: Expectations, Challenges, and Wishes—A Primary Care Perspective. The Journal of Clinical Hypertension, .2009; 11:573–576.

[2] Phillips LS, Branch WT, Cook CB, et al. Clinical inertia. *Ann Intern Med.* 2001;135(9):825-34

[3] O'Connor PJ, Sperl-Hillen JM, Johnson PE, et al. Clinical inertia and outpatient medical errors. *In: Henriksen K, Battles JB, Marks ES, Lewin DI, editors. Advances in Patient Safety: From Research to Implementation (Volume 2: Concepts and Methodology). Rockville (MD): Agency for Healthcare Research and Quality (US); 2005 Feb.* Available at: http://www.ahrq.gov/downloads/pub/advances/vol2/OConnor.pdf

of diseases . The America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education and Science Reauthorization Act of 2010 (COMPETES Act), Public Law 111- 358 (Attachment 1b) provides authority for CDC to hold challenges that further the Agency's mission and provide cash awards. Based on the Office of Management and Budget March 2010 memo, "Guidance on the Use of Challenges and Prizes to Promote Open Government" (Attachment 1c), Million Hearts® is awarding an "Exemplar Prize for Excellence," recognizing achievement in clinical hypertension control. The Challenge will select and recognize Million Hearts® Hypertension Control Champions to motivate, inspire, and guide others and further the agency's mission by attracting more interest and attention to hypertension control. Specifically, identifying and recognizing exemplary clinical practices will (a) lead to deeper understanding about how to achieve better control rates; (b) bring widespread attention to achievable exemplar rates; (c) motivate clinicians to strive for better hypertension control rates; and (d) bring prestige to a wide range of organizations that invest in hypertension control.

OMB approval is requested for three years to conduct three annual challenges. Up to 30 Champions will be identified each year. CDC will collect the information needed to nominate, rate, and rank candidates for recognition. The Challenge will allow clinicians or clinical programs to voluntarily self-nominate their practice or healthcare system for Million Hearts® recognition using a web-based form, the "Million Hearts® Hypertension Control Champion Nomination" (Attachment 3a). Nomination of providers or healthcare systems for the Hypertension Control Challenge will include submission of a minimal amount of data to provide evidence of clinical success in achieving hypertension control.

Nominations will receive a preliminary score by CDC staff or contractors based on a structured scoring rubric that considers hypertension control rate (90% of score), sustainable systems (5% of score) and patient population that is high risk (5% of score) . A panel of 3-5 experts in hypertension control selected by CDC will review the nominations with the highest preliminary score and rate and rank each proposal. The panel will then provide CDC with a ranked list of nominees recommended for recognition by Million Hearts® . Pending data verification for at most 30 finalists, a small number of Champions, 30 or fewer, divided among two size categories (less than 50,000 covered lives and greater than or equal to 50,000 covered lives) will be recognized and receive a nominal cash award of $5,000 - $15,000.

Finalists will be determined 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; or if the provider does not respond to requests for data validation.

It is anticipated that the number of annual nominations submitted will increase as the Challenge becomes known. The number of champions recognized may start at fewer than 30 and increase annually, depending on the availability of funds and the quality of nominations. Continuation of the Challenge will be assessed annually by CDC's Division for Heart Disease and Stroke Prevention and CDC leaders.

Privacy Impact Assessment

Overview of the Data Collection System

Information collection will consist of completion of an online nomination (Attachment 3a) by all interested participants followed by a data verification process (Attachment 4) for up to 30 finalists to be conducted by phone interview and record review, and an in-person or telephonic interview to collect qualitative data (Attachment 5) from up to 30 champions.

Participation at each data collection point is voluntary. We require attestation that the nominee will participate in data validation and recognition if selected as the first opportunity for a nominee to decline. At the time the nominee is notified of their status as a finalist, the nominee may decline to participate further. If a finalist declines to participate further, CDC will proceed to the next finalist. If time does not permit CDC to continue moving to the next highest scoring participant, CDC will reduce the number of Champions recognized.

Items of Information to be Collected

The Million Hearts® Hypertension Control Champion Nomination Form (Attachment 3a) will be collected from all nominees. Information collected on this form includes:

- Contact information for nominee and nominator that includes name, phone number and e-mail address as well as physical address of the nominee.
- A description of the patient population covered by the practice or healthcare system including number of patients, number of patients aged 18-85, number of patients diagnosed as hypertensive; and demographics that support serving a high risk population. No individual patient level data will be collected through the Challenge or held by any contractor or CDC. Nominations will report only aggregate data. Data verification as necessary for selected champions only will be conducted through the use of independent chart abstraction contractor or electronic medical record

contractor, and only aggregate data will be conveyed to CDC. No individual or patient-level data will be included. If an independent contractor is required for data verification, they will be bound by contract to ensure the privacy of individual patients is secure.

- Two point-in-time measures (collected approximately 12 months apart) of the clinical hypertension control rate for the patient population. The nomination form references NQF18 as the blood pressure control measure supported by Million Hearts®, but does not require its use to minimize respondents burden due to recalculation of hypertension rat.
- A description of how hypertension is measured and how control is defined by the provider.
- A radio button selection of sustainable clinic systems and an opportunity to provide additional descriptive information on each.
- Electronic signature verifying the accuracy of data, agreement to data verification and background check, and agreement to accept the award if selected.

To minimize burden for collecting the information needed to administer the Challenge, CDC recommends a measure for reporting hypertension control that is well known and used by national reporting entities. The measure, NQF18, is promulgated by the National Quality Form (NQF), a nonprofit organization involved in the selection of standardized healthcare performance measures. A clear protocol for alignment with NQF18 is publically accessible at http://www.qualityforum.org/QPS/QPSTool.aspx. CDC anticipates that the vast majority (greater than 95%) of nominees will already use this or a similar measure for reimbursement or quality reporting initiatives and so will have ready access to the data. Practices and healthcare systems use these data for a variety of internal and external purposes such as billing, tracking participant progress, marketing, and others. Thus, the impact of data collection on respondents—including small providers—is expected to be minimal.

Information collected through the nomination process will be used to rate and rank finalists for further consideration. To ensure the accuracy of preliminary ratings, CDC will verify finalists' nomination information (see Attachment 4, the Million Hearts^{TM} Hypertension Control Champion Data Verification Form). Verification will conducted by an independent organization such as Minnesota Community Measures or the National Committee for Quality Assurance, which has expertise in clinical data validation and is sensitive to and has expertise in privacy considerations. The

Verification Form will be completed by the independent organization via phone and de-identified record review.

Each selected Champion will participate in a semi-structured interview (Attachment 5). The purpose of the interview is to obtain in-depth contextual information about the clinical strategies and facilitators to achieving exemplary hypertension that are being used by highly successful organizations. The interview will be guided by three opening questions. The interviewer will guide the remaining discussion to gain in depth information on those questions. The interview will focus on:

- A description of the clinical supports, systems, and community linkages that support achievement of exemplary hypertension control rates.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

CDC initially planned to administer the Million Hearts Hypertension Control Challenge through the Challenge.gov Website. Due to changes in the criteria for Challenge.gov, the Million Hearts Hypertension Control Challenge will be administered through a dedicated Website developed and managed by Skild, a software company with experience in supporting over 150 similar competitions. The URL for the Skild site is http://www.skild.com/platform/contest-platform-overview.shtml).

The Million Hearts® Hypertension Control Challenge will be hosted through a unique URL: www.MHhypertensionchallenge.com on the Skild platform.

The Million Hearts® Hypertension Control Challenge platform will have no content directed at children less than 13 years of age.

2. Purpose and Use of the Information Collected

There is substantial scientific evidence about the types of system changes that improve hypertension control.[4,5] Key levers include incorporating team based care, improving reimbursement, audit and feedback, supporting self-management, using

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[4] Walsh J, McDonald KM, Shojania KG, et al. Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies, Volume 3—Hypertension Care. Technical Review No. 9. (Prepared by Stanford University–UCSF Evidence-based Practice Center under Contract No. 290-02-0017). Rockville, MD: Agency for Healthcare Research and Quality, January 2005. AHRQ Publication No. 04-0051-3.

[5] Glynn LG, Murphy AW, Smith SM, Schroeder K, Fahey T. Interventions used to improve control of blood pressure in patients with hypertension. Cochrane Database Syst Rev. 2010.

registry data, physician and patient reminders, and improving medication compliance. What is lacking is implementation expertise with those systems and processes in order to promote best practices. The Million Hearts™ challenge is designed to identify currently successful organizations and obtain insights into the ways that they've implemented sustainable changes. The information gained will be used to develop examples of successful clinical practices that result in better hypertension control rates. These insights can then be shared with other practices to inform their future activities. For example, although some providers and healthcare systems routinely provide data on hypertension control rates to entities such as quality improvement committees, information is not collected or disseminated about the standard or innovative clinic processes used to achieve hypertension control. The Million Hearts® Challenge will link success in clinical outcomes of hypertension control with information about procedures that can be used to achieve similar favorable outcomes so that the strategies can be replicated by other providers and health care systems.

The information to be collected will support the CDC and Million Hearts® purpose of improving and sustaining the control of hypertension through increased attention to hypertension at the clinical practice level and better understanding of successful implementation strategies at the health system level.

Descriptions of Champion's clinical and community strategies to improve hypertension control will be shared through CDC-developed written documents and other media with the broader goal of improving the quality of care delivered to hypertensive patients.

This data collection will also inform CDC's use of similar challenges to bring attention to and address other public health issues.

Privacy Impact Assessment Information

Each organization seeking recognition must submit contact information, including the organization's name, mailing and e-mail addresses, telephone number, as well as the name, and contact information of the individual submitting the nomination to serve as the challenge contact person. Although the application includes individual information, the information is not considered personal, private, or confidential in nature as provider or healthcare system location is publically accessible through insurer sites, and hard copy and online telephone directories. CDC will maintain the individual and provider information and hypertension control data in password-protected files in a secure facility.

A list of Hypertension Control Champions will be publically available with the consent of Champions. However, the published list will only name the organization and city/state the practice is located in (and Web address, if provided); it will not include the name of the organization's contact person or any other person's name, unless expressly requested by the Champion.

No individual patient level data will be collected through the Challenge or held by any contractor or CDC. Nominations will report only aggregate hypertension control rates. Data verification as necessary for selected champions only will be conducted through the use of independent chart abstraction contractor or electronic medical record contractor, and only aggregate data will be conveyed to CDC. No individual or patient-level data will be included. If an independent contractor is required for data verification, they will be bound by contract to ensure the privacy of individual patients is secure.

3. Use of Improved Information Technology and Burden Reduction

CDC designed this data collection to minimize the burden to nominees. The Skild challenge platform is an easily accessible, web-based system accessible using a personal computer that supports the collection of a wide range of challenge submissions. Having a centralized, consistent method to collect data as an information repository helps to minimize errors and redundancy and is essential to the timely and accurate scoring of nominations. The system allows for increased efficiency through electronic reporting by nominees. Providing a web-based nomination system will:

- Shorten the time period for collection of information using radio button response buttons and short descriptive opportunities through a one-step process.
- Standardize the information collected.

Other data will be collected by telephone.

This data collection provides for 95% of data to be collected electronically. A 5% allowance is made for a potential site visit for data verification in the rare case that it cannot be completed electronically.

4. Efforts to Identify Duplication and Use of Similar Information

CDC examined three sources that collect provider performance data for credentialing, accreditation, or recognition of programs: the National Committee for Quality Assurance (NCQA); the Physician Quality Reporting System (PQRS); and Bridges to Excellence (BTE).

The National Committee for Quality Assurance (NCQA) is a not-for-profit organization dedicated to improving health care quality. NCQA recognizes clinicians who use evidence-based measures and provide excellent care to persons with cardiovascular disease through the Heart/Stroke Recognition Program. Recognition is based on self-reporting of a bundle of indicators related to heart disease and stroke and recognizes excellence based on a composite score. A relatively low proportion of the score is driven by hypertension control.

The fee to apply for recognition is $580 - $3,080, depending on the number of physicians reporting data. While not an exorbitant amount, the fee may pose a barrier to some potential applicants.

The cost to purchase the raw data for Commercial, Medicaid and Medicare Quality Compass HEDIS data from NCQA is approximately $29,000.

The Physician Quality Reporting System (PQRS**)** is a reporting program that uses a combination of incentive payments and payment adjustments to promote reporting of quality information by eligible professionals. The program provides an incentive payment to practices with eligible professionals who satisfactorily report data on quality measures for covered Physician Fee Schedule (PFS) services furnished to Medicare Part B Fee-for-Service (FFS) beneficiaries. The pool of potential applicants using PQRS would be limited to those clinicians accepting Medicare patients. More importantly, the 2012 PQRS has only a few individual measures related to hypertension. The measures relevant to hypertension are:

- Measure # 3: High Blood Pressure Control in Diabetes Mellitus
- Measure # 122 Adult Kidney Disease: Blood Pressure Management
- Measure #201 Ischemic Vascular Disease: Blood Pressure Management Control
- Measure # 235 Hypertension: Plan of Care (for patients diagnosed with hypertension). Available in 2012, but not available beginning in 2013.
- Measure #236 Blood pressure control. New in 2013; data available in 2015.

- Measure #237 Hypertension: Blood Pressure Management. Measures percent of hypertensive patients with a blood pressure measure recorded.
- Measure # 317 Screening for hypertension. New in 2012 available only through electronic health records. Data available in 2014.

None of these measures provide the type of data appropriate to select hypertension control champions except for Measure #236, and this measure will not be reported until 2015. Further, of the 199 measures appropriate for clinician reporting, clinicians are required to report on only three measures to receive an incentive. This severely limits the number of providers likely to report on hypertension indicators. In 2010[6], the most current data report available, the most popular measures for clinician reporting were: timing of prophylactic antibiotics; community-acquired bacterial pneumonia: assessment of oxygen saturation; A1C poor control; ECG performed for non-traumatic chest pain; and adoption/use of EHRs.

Hypertension control is incorporated into a measures group or composite score of several related measures. There are 12 measures groups; clinicians that report are only required to report on one measure group, and are only required to report on 30 patients. The measures group containing hypertension control also includes measures for Low Density Lipoprotein (LDL-C) Control in Diabetes, Use of Aspirin or Another Antithrombotic, Tobacco Use: Screening and Cessation Intervention, Complete Lipid Panel and Low Density Lipoprotein (LDL-C) Control, and Screening for High Blood Pressure. Approximately 2% of eligible physicians reported in 2010.

Bridges to Excellence (BTE) is a not-for-profit organization developed by employers, physicians, health care services, researchers, and other industry experts with a mission to create significant leaps in the quality of care by recognizing and rewarding health care providers who demonstrate that they have implemented comprehensive solutions in the management of patients and deliver safe, timely, effective, efficient, equitable and patient-centered care.[7] Providers who meet performance benchmarks can earn a range of incentives, sometimes including substantial cash payouts. Insurers and employers fund these payouts from the savings they achieve through lower health care costs and increased employee productivity. The Hypertension Care Recognition Program is a BTE Clinician Recognition Program intended to identify

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[6] Centers for Medicare and Medicaid Services. 2010 Reporting Experience Including Trends (2007 – 2011) Physician Quality Reporting System and Electronic Prescribing (eRx) Incentive Program. 2012. Downloaded 1/21/2013 at http://www.facs.org/ahp/pqri/2013/2010experience-report.pdf .

[7] The Health Care Incentives Improvement Institute. Clinician Guide: Bridges to Excellence Hypertension Care Recognition Program. 2012. Downloaded 1/21/2013 at http://www.hci3.org/sites/default/files/files/files/BTE%20HTN%20Clinician%20Guide_02_02_2012.pdf.

clinicians who deliver high-value hypertension care to adult patients. The cost to apply for recognition begins at $95 and increases depending on the number of clinicians reporting and the type of data submission used. The highest level of recognition is a composite score of poor control for hypertensive patients, controlled hypertensive patients and 9 other measures, where a provider must score at least 60 of 100 points for recognition. A BTE contracted data aggregator holds all data and only reports to BTE the level of recognition achieved by a provider or practice, not the actual data points. Extracting hypertension control data would require contracting with several data aggregator contractors, and would be costly.

While each of these existing systems has benefits, none of them fully meet the needs of Million Hearts Hypertension Control Challenge:

- Entry that does not discriminate based on resources to apply.
- Entry that is not limited to a pool of physicians affiliated with a specific reporting system.
- Clear access to provider hypertension control data. While other recognition programs collect hypertension control data, the data would need to be extracted from each application at additional cost.
- A combination of clinical and systems data in a format that allows comparison on a number of key selection criteria. Use of the alternate options would require interviews with a much larger pool of high performing clinicians to assess sustainability, effective systems, and high risk populations, prior to selection of champions, increasing the burden to those providers.
- Encouraging a sense of competition among high performing providers.

Further, use of any of these mechanisms reaches only the select audience that responded to and was accepted by the sponsoring organization. Use of any of these measures would require a solicitation to each potential champion in that system to ascertain interest and approval to participate and access their data, approval and resources to disaggregate the hypertension control data if necessary, and request the same system-related information in the Million Hearts® Hypertension Control Champion Nomination Form. Using any of these mechanisms requires an individual solicitation and consent plan for a potentially large pool of candidates – more than for an open and voluntary nomination. It is likely that for best results, multiple contact attempts by government or contract staff would be required to solicit consent.

5. Impact on Small Businesses or Other Small Entities

Participation in the Million Hearts Hypertension Control Challenge is voluntary and does not impose any new data collection or reporting requirements on respondents. This data collection does aim to provide equal access to both large and small clinical practices and healthcare systems. CDC has established a recognition category for small providers (fewer than 50,000 covered lives) to assure a competitive balance between large and small providers. CDC anticipates that approximately 85% of nominees will be clinic based practices and 15% will be healthcare systems, all from the private sector.

6. Consequences of Collecting the Information Less Frequently

The timeframe for data collection is aligned with an annual recognition program, requiring annual data collection. Provider data collections for other purposes may be used for submission to the Million Hearts® Hypertension Control Challenge as long as aligned with the NQF18 measure and collected within a reasonable timeframe (5 months) of submission. Providers and health systems achieving high hypertension control rates are likely capturing this data through a registry or frequent electronic medical review.

Current information must be collected for each annual challenge because:

- The hypertension control data must be timely. Control rates may change over the course of a year given patient turnover, and financial implications of treatment in a rapidly changing healthcare environment. Collections less frequently than annually may result in inaccurate data and recognition to a provider whose performance has slipped.
- One purpose of the challenge is to draw attention to hypertension control and collecting and reviewing data on a regular basis is an important step.

Less frequent information collection for the Million Hearts™ challenge would have negative consequences for the quality of information used to rate and rank nominees, and the types of best practices that CDC hopes to recognize through this challenge.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances related to the Million Hearts® Hypertension Control Challenge and 5 CFR 1320.5. The request fully complies with the regulation.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

A. Federal Register Notice. A 60-day Notice was published in the Federal Register on December 19, 2012 (Volume 77, Number 244, pages 75168-75169; see Attachment 2a). CDC received one non-substantive comment and provided a courtesy reply (see Attachment 2b).

B. Other Consultations. The Million Hearts® Hypertension Control Challenge was designed collaboratively by CDC staff, and Centers for Medicare and Medicaid Services staff, which includes physicians and epidemiologists and statisticians. National Committee for Quality Assurance staff were consulted on data verification procedures and participation. Ongoing collaboration and evaluation of the Challenge and data collection instruments will continue after each Challenge to refine and improve data collection.

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9. Explanation of Any Payment or Gift to Respondents

Nominees will not receive a payment or gift for participating. Selected Champions will receive a nominal cash award ($5,000 to $15,000) and public recognition by CDC. The cash award is intended to support continued quality improvement, the development of a best practice publication, and encourage participation by a greater pool of nominees in future years.

10. Assurance of Confidentiality Provided to Respondents

A. Privacy Act Assessment. This Information Collection Request has been reviewed by staff in the National Center for Chronic Disease Prevention and Health Promotion, who determined that the Privacy Act is not applicable. Respondents are organizational entities, not individuals. Although each entity identifies one or more contact person(s), the names and contact information for these individuals are publicly available in the context of their roles as representatives of the organization. The data collection does not involve collection of sensitive or identifiable personal information. No patient-level records are reported to CDC, only aggregate statistics about the organization's patient population.

B. Security. Access to the Challenge database will be controlled by a password-protected login and accessible by a minimal number of contract or CDC staff. The Skild challenge platform will post the number of nominations submitted. Selected Champions' practice name, city and state will be publicized post selection with the consent of the Champion.

Information collection will be conducted according to a security plan that has been approved by CDC's Office of the Chief Information Security Officer (OCISO). Data collection risks, mitigating controls, and risk acceptance are documented through a completed CDC Social Media and Third-Party Site Security Survey/Plan and a CDC Third Party Web Application Privacy Impact Assessment on file at CDC.

C. Consent. The Million Hearts® Hypertension Control Challenge data collection is not considered research involving human subjects. For organizations, consent to participate in the Challenge is attested to on the nomination form. Un-attested forms will be excluded from further review.

D. Requirement to Respond. There is no requirement to respond, participation is voluntary.

11. Justification for Sensitive Questions

The Million Hearts® Hypertension Control Challenge instrument does not collect sensitive information. The Challenge will collect a limited amount of information in identifiable form (IIF) for the nominator and nominees (e.g., clinic administrator or clinician), such as name, address, and contact information which is the type of information generally publically available. The Challenge will collect information about activities conducted by the practice or healthcare system, not personal information. No patient level data is collected.

12. Estimates of Annualized Burden Hours and Costs

A. Estimated Annualized Burden Hours

Information is collected once annually. Expected respondents are clinicians or clinic administrators in single or multi-provider practices and clinicians or administrators of healthcare systems.

On an annualized basis, CDC estimates receipt of 1,735 Million Hearts ™ Hypertension Control Challenge Nomination Forms (Attachment 3a). Each nomination will report information on aggregate health outcomes and sustainable systems. Nominations will be submitted electronically through the challenge platform. The estimated burden per response is .5 hours, as estimated by a sample of six CDC employees seeing the form for the first time, and entering the full range of responses. This generous estimate allows time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

CDC reserves the right to conduct a site visit or record review to verify data for potential Champions, although CDC may waive the site visits for some or all of the Champions depending upon the consistency of and confidence in submitted data. The verification is estimated to require 1 hour of the provider/administrators time. A maximum of 30 verifications requiring provider time may be conducted, for an annual burden of 30 hours.

Interested and eligible organizations may submit a new nomination in subsequent years and with current data through the challenge platform. CDC plans to recognize organizations in two size categories: 1) organizations with fewer than 50,000 covered lives, and 2) organizations with greater than or equal to 50,000 covered lives.

CDC will recognize up to 30 Champions per year (4 to 15 champions in each size categories). Selected Champions will participate in a semi-structured interview, estimated to take 60 minutes. Interviews may be conducted in person or by telephone. Additional time for the Champion to review the interview summary for accuracy brings the total estimated interview to a maximum of 2 hours for each of potentially 30 Champions.

The total estimated annualized burden is estimated at 958 hours, as summarized in Table A.12-A.

Table A.12-A. Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hr)	Total Burden (in hr)
Physician (Single or Group Practices)/ Health-care systems	Million Hearts® Hypertension Control Champion Nomination form	1,735	1	.5	868
Finalists – telephone interview and record review	Million Hearts® Hypertension Control Champion Data Verification Form	30	1	1	30
Selected Champion	Interview Guide: Million Hearts® Hypertension Control Champion	30	1	2	60
				Total	958

B. Estimated Annualized Cost to Respondents

Table A.12-B displays estimates of annualized cost to respondents for participation in the data collection. Estimates were derived using an average hourly wage from the Bureau of Labor Statistics (Updated March 2012).

Million Hearts® Hypertension Control Champion Nomination:

- An estimated 75% of respondents will be Administrative/Services managers in a physician’s office. Mangers time is valued at $39.71 per hour.

- An estimated 25% of respondents will be physicians. Using general internists as a standard, physician time is valued at $97.76 per hour.
- The weighted hourly average value of time applied to the burden is $54.22.

Data Verification Tool

- It is estimated that respondents will be comprised of data managers, clinic staff, and physicians in equal proportions of 33.34% each.
- Using general internists as a standard, physician time is valued at $97.76 per hour. Data manager time is valued at $36.46 per hour. Registered nurse, as a representative of clinic staff is valued at $35.04 per hour.
- The weighted hourly average value of time applied to the burden is $56.42 per hour.

Interview Guide: Million Hearts® Hypertension Control Champion

- It is estimated that 50% of respondents will be physicians and 50% will be clinic staff such as a registered nurses.
- Physician time is valued at $97.76 per hour. Registered nurse time is valued at $35.04 per hour.
- The weighted hourly average value of time applied to the burden is $66.40.

The total estimated annualized cost to respondents is $52,712.

Table A.12-B. Estimated Annualized Cost to Respondents.

Type of Respondent	Form Name	Number of Respon-dents	Number of Responses per Respondent	Burden per Response (in hours)	Weight-ed Hourly Wage	Total Cost
Administra-tor/ Clinician	Million Hearts® Hypertension Control Champion Nomination form	1735	1	.5	$54.22	$47,036
Data	Data	30	1	1	$56.42	$ 1,692

managers, clinic staff, physician	Verification Tool					
Clinicians or Clinic staff	Interview Guide: Million Hearts® Hyperten-sion Control Champion	30	1	2	$66.40	$3,984
	Total					$52,712

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

CDC anticipates that clinics or healthcare systems with electronic medical record (EMR) systems are most likely to participate, but it is not a condition for consideration or nomination. The cost of an EMR is one that a growing number of practices and healthcare systems would have as part of routine business. Providers with offsite data management services may be required to submit a data request of the data manager. The 2012 Hypertension Control Champion, selected using a different process, indicated that data management and retrieval is a part of practice and is negligible for one data request. No capital or maintenance costs are expected. There are no additional start-up, hardware or software costs.

14. Estimates of Annualized Cost to the Federal Government

Costs to the Federal government include the cost of CDC personnel time for Challenge oversight, and contractor costs for data site collection set up and maintenance . The data collection and management contractor for this information collection is Skild, a software company founded in 2002. Skild has enabled over 150 competitions and assisted in the awarding of over $40 million in prize funds for Fortune 500 companies, advertising agencies, universities, government agencies such as the Food and Drug Administration and the National Science Foundation, and foundations across a variety of industries around the world.

The total estimated annualized cost to the Federal government does not include the selection of Champions, cash awards to Champions, or development of written products.

A summary of costs is presented in Table A.14-1. The total estimated annualized cost to the Government is $90,000.00.

Table A.14-1. Estimated Annualized Cost to the Federal Government.

Cost Type	Cost
CDC staff. 20% of GS-13 for system oversight.	$20,000
Contractor costs for website and database development, maintenance and download of information in a usable format.	$50,000
Contractor costs for validation of data submitted by selected Champions.	$20,000
Total	$90,000

15. Explanation for Program Changes or Adjustments

This is a new collection request.

16. Plans for Tabulation and Publication and Project Time Schedule

A. Time schedule. OMB approval is requested for three years. Anticipated data collection or nomination period is July and August of 2013. Champions will be announced annually in September 2013, 2014 and 2015.

B. Publication Plan. Information collected through the Champion interviews will be published on the CDC Million Hearts® website, estimated by December of calendar year calendar year, 2013, 2014, and 2015.

C. Analysis Plan. CDC will not use complex statistical methods for analyzing information. All nominations will be scored using a detailed scoring rubric. The top scorers will be reviewed by an expert panel and submitted to the Million Hearts® Advisor and Agency Director for recognition. Statistical analyses planned at this time are descriptive, and include identifying the number of nominations submitted; the type of providers nominated; and the range, median and mean of hypertension control rates. This information will used by CDC for program improvement and improved estimating.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB expiration date will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement.