

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

**OMB No. 0920-0976**

**Expiration Date 07/31/2016**

**Part A**

**Reinstatement with Change**

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- Goal of the study: To identify medical practices and clinics that achieve high rates of hypertension control and to recognize them as Million Hearts® Hypertension Control Champions for 2016, 2017, and 2018. Information will be collected in 2017, 2018, and 2019.
- Intended use of the resulting data: CDC will use this information to recognize exemplary clinical practices in hypertension control and identify and promote best practices for achieving high rates of control.
- Methods to be used to collect: Clinical practices achieving hypertension control rates of 70% or greater can be nominated, or self-nominate, through the Million Hearts website by completing a Nomination Form that provides de-identified, aggregate information about the nominee’s patient population and rate of control. This information will be used to select finalists who will also participate in a data verification process and a qualitative interview. Data verification will be conducted through the use of an independent chart abstraction contractor or electronic medical record contractor to verify the validity of the data submitted to the Challenge. Qualitative information will be collected through an in-person interview or telephone interview.
- The subpopulation to be studied: Respondents are medical care providers (single physician or group practices) and health care systems reporting on hypertension control in their adult patients ages 18-85.
- How data will be analyzed: Data collected through the nomination and verification processes will be analyzed to calculate and verify the hypertension control rate for the reporting period for the clinical practice. Information collected through qualitative interviews is primarily descriptive. No identifiable, patient-level information will be reported to CDC.

## **A. JUSTIFICATION**

### **A.1. Circumstances Making the Collection of Information Necessary**

CDC’s authority to administer the Million Hearts® Hypertension Control Challenge is provided by the Public Health Service Act (42 USC 241, see **Attachment 1a**), which provides CDC with the authority to conduct investigations and studies relating

to the diagnosis, treatment, and control of diseases, and 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**), which 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® also awards an “Exemplar Prize for Excellence,” recognizing achievement in clinical hypertension control.

### *Background*

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 75 million American adults have high blood pressure and about half (54%) have it adequately controlled. Hypertension and its associated diseases pose approximately \$48.6 billion in medical and lost productivity costs each year.

In September 2011, the Department of Health and Human Services (HHS) launched the Million Hearts® initiative (co-led by the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare and Medicaid Services (CMS)) 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, and will require concerted, system-level strategies to improve the management of hypertension. Phillips et al. first defined clinical inertia (2001) as acknowledgement of the problem, but failure to act.<sup>1</sup> 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.<sup>2</sup> 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

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<sup>1</sup> Phillips LS, Branch WT, Cook CB, et al. Clinical inertia. *Ann Intern Med.* 2001;135(9):825-34

<sup>2</sup> 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>

and communication between physician and staff. Germino<sup>3</sup>, 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.*”

At least some of the system factors needed to address hypertension management can be addressed by identifying and disseminating successful solutions initiated by peers. There is substantial scientific evidence about the types of system changes that improve hypertension control.<sup>4,5</sup> Key levers include incorporating team based care, improving reimbursement, audit and feedback, supporting self-management, using registry data, physician and patient reminders, improving medication compliance, and the use of evidence-based standardized hypertension treatment protocols. What is lacking is implementation expertise with those systems and processes in order to promote best practices.

In 2013, CDC initiated the annual Million Hearts® Hypertension Control Challenge to assist in 1) identifying medical practices that had achieved exemplary levels of hypertension control in their patient populations, and 2) promoting dissemination and adoption of the hypertension control strategies utilized by these practices (OMB No. 0920-0976, exp. 7/31/2016). Information was collected to rate and rank candidates for recognition and to describe their clinical care processes. Million Hearts® Challenges were conducted and supporting information was collected and analyzed in 2013-2014 (for 2013 Million Hearts® Champions announced in 2014), 2014-2015 (for 2014 Champions announced in 2015), and 2015-2016 (for 2015 Champions announced in 2016). Through the Challenges, CDC recognized a total of 59 Million Hearts® Champions in two categories: practices with < 50,000 covered lives and practices with ≥ 50,000 covered lives (<http://millionhearts.hhs.gov/partners-progress/champions/index.html>).

CDC is requesting OMB approval to reinstate the Challenge. Changes to be implemented include:

1. A revised information collection schedule. Information collection for upcoming Challenges will launch in February with selection and recognition of Champions

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<sup>3</sup> Germino, WFJNC 8: Expectations, Challenges, and Wishes—A Primary Care Perspective. *The Journal of Clinical Hypertension*, .2009; 11:573-576.

<sup>4</sup> 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.

<sup>5</sup> 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.

in the fall of the same calendar year. The revised launch date will realign the Million Hearts® Challenge with related activities promoted during February, e.g., National Heart Month. Each Challenge's announcement, application period, application review activities, and recognition awards will all occur during the same calendar year. The information used to calculate the applicant's hypertension control rate will be generated primarily in the preceding calendar year.

2. A reduction in total burden hours. Based on the actual number of nominations received in previous years, the estimated number of nominations for 2017-2019 is being revised downward, resulting in a decrease in total burden.
3. A revised nomination form. Changes to the nomination form are based on feedback from users to improve its usability. One new question has been added about the relationship of the nominator with the nominee. There are six sets of revised questions, 1) identifying the nominee's practice type, 2) identifying rural/urban status of the practice, 3) a set of questions guiding the user on how to identify their hypertension control rate in a standard format, 4) a revised question on the use of an electronic health record system and how the data were obtained, 5) a revised question on the use of clinical quality measures, and 6) a revised section title. Lastly one selection option under clinical system supports was deleted.
4. A minor change to the data verification form (deletion of a sentence).
5. No cash award will be offered.

OMB approval is requested for three years, effective December 2016. Information will be collected annually from approximately 500 nominees and 40 finalists. Up to 40 Champions will be recognized each year.

## **A.2. Purpose and Use of the Information Collection**

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 clinical practice health system level. 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 visibility to a wide range of organizations that invest in hypertension control.

Information collection for the Challenge will be conducted in three steps.

1. The Million Hearts® Hypertension Control Champion Nomination Form (Attachment 3b) will be collected for up to 500 nominees per year. Nominees may self-nominate or be nominated by another party. The web-based nomination form includes contact information for the nominee, demographic information about their clinical practice, data on their hypertension control rate, and information about the clinical system supports used to improve the hypertension control rate. It also includes submission of a minimal amount of data to provide evidence of clinical success in achieving hypertension control.

Based on previous experience, CDC anticipates that the vast majority (greater than 95%) of nominees will already use an existing hypertension control 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. Use of an existing hypertension control measure thus minimizes the respondent burden associated with participating in the Challenge.

Information collected through the nomination process will be used to rate and rank approximately 40 finalists per year for further consideration. Nominees and finalists will receive a preliminary score by CDC staff or contractors based on a structured scoring rubric that considers hypertension control rate (at least 90% of score), sustainable systems (up to 5% of score) and patient population that is high risk (up to 5% of score). A CDC panel of judges will complete a preliminary review of the nominations and assign a preliminary score to each submitted nomination form.

2. Up to 40 finalists with the highest preliminary scores will be asked to participate in a data verification process. The Million Hearts® Hypertension Control Champion Data Verification Form (Attachment 4b) will be used by CDC to verify finalists' nomination information and ensure the accuracy of preliminary ratings. Verification will be conducted by an independent organization such as 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/or site visit with de-identified record review.
3. Up to 40 finalists will be asked to participate in a semi-structured, qualitative interview (see **Attachment 5**, the Million Hearts® Hypertension Control Champion Interview Guide). The purpose of the interview is to obtain in-

depth contextual information about the clinical strategies and facilitators to achieving exemplary hypertension control 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 the clinical supports, systems, and community linkages that support achievement of exemplary hypertension control rates.

CDC plans to recognize up to 40 Champions per year, distributed over two size categories: practices that serve < 50,000 lives, and practices that serve  $\geq$  50,000 covered lives. In any given year the number of finalists may exceed the number of Champions that receive recognition. If a finalist declines to participate in the data verification process or the interview, or is determined to be ineligible, CDC will proceed to the next highest scoring finalist. If time does not permit CDC to continue moving to the next highest scoring participant, CDC will reduce the number of Champions recognized.

The Million Hearts® Challenge is designed to identify currently successful organizations and clinical practices and obtain insights into the ways that they've implemented sustainable changes to maintain high blood pressure control rates. 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 motivate, inspire, and 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 clinical practices and health care systems.

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.

A list of Hypertension Control Champions will be publicly 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.

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

### **A.3. Use of Improved Information Technology and Burden Reduction**

CDC designed this data collection to minimize the burden to nominees. The Sensis challenge platform is an easily accessible, web-based system accessible using a personal computer that supports the collection of a large number of challenge submissions. Having a centralized, consistent method to collect information 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 or multi-select response buttons and short descriptive opportunities through a one-step process.
- Standardize the information collected.

Other information will be collected by telephone interview, personal interview, or site visit.

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

In addition, 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 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 2016 PQRS has only three individual measures related to hypertension. The measures relevant to hypertension are:

- Measure # 122 Adult Kidney Disease: Blood Pressure Management.
- Measure #236 Blood pressure control. 2016 data available in 2018.
- Measure # 317 Screening for hypertension. Available only through electronic health records. 2016 data available in 2018.

None of these measures provide the type of data appropriate to select hypertension control champions except for Measure #236, and this measure will not report 2016 data (the information needed for the Million Hearts Hypertension Control Challenge applications submitted in starting in February 2017 for the 2016 Hypertension Control Challenge) until 2018. Further, of the 2109 measures appropriate for clinician reporting, clinicians are required to report on only nine measures across three domains. This severely limits the number of providers likely to report on hypertension indicators. In 2013<sup>6</sup>, the most popular measures for clinician reporting were: timing of prophylactic antibiotics; tobacco use and screening, BMI screening, pneumococcal vaccine for adults ages 65 and older, and documentation of current medications.

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.<sup>7</sup> 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

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<sup>6</sup> Centers for Medicare and Medicaid Services. 2013 Reporting Experience Including Trends (2007 - 2014) Physician Quality Reporting System and Electronic Prescribing (eRx) Incentive Program. 2015. Downloaded 9/5/2016 at

[https://www.facs.org/~media/files/advocacy/regulatory/2013\\_pqrserx\\_experience\\_report.ashx](https://www.facs.org/~media/files/advocacy/regulatory/2013_pqrserx_experience_report.ashx) .

<sup>7</sup> 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](http://www.hci3.org/sites/default/files/files/files/BTE%20HTN%20Clinician%20Guide_02_02_2012.pdf).

Program is a BTE Clinician Recognition Program intended to identify 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 8 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.

#### **A.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, including federally qualified health centers.

#### **A.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.

#### **A.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.

#### **A.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 May 5, 2016 (Volume 81, Number 87, pages 27136-27137; **Attachment 2**). CDC received 1 non-substantive comment (**Attachment 2a**).

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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National Committee for Quality Assurance

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#### **A.9. Explanation of Any Payment or Gift to Respondents**

Nominees will not receive a payment or gift for participating. Selected Champions will receive public recognition by CDC. The recognition 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.

#### **A.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. 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. 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 an 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. 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. CDC will maintain the provider information and hypertension control data in password-protected files in a secure facility. The 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. For organizations, consent to participate in the Challenge is attested to on the nomination form. Un-attested forms will be excluded from further review. Eligibility and rules for the Challenge are posted on the challenge website (screenshots of the website are in **Attachment 6**) and included in **Attachment 7**.

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

#### **A.11. Institutional Review Board and 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 publicly available. The Challenge will collect information about activities conducted by the practice or healthcare system that led to improved hypertension control, not personal information. No patient level data is collected. CDC has determined that the project is not considered human subjects research and will not require IRB review (see **Attachment 8**).

#### **A.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 500 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 30 minutes.

Nominees will be rated and ranked. Up to 40 finalists will be selected for the data verification process (see **Attachment 4b**), which will be conducted via phone and/or site visit with de-identified record review to verify the information submitted on the nomination form. The verification is estimated to require 1 hour of the provider/administrator's time. CDC may waive the site visits for some or all of the Champions depending upon the consistency of and confidence in submitted data. Burden is estimated on the maximum number of finalists who may be asked to participate in the data verification process.

Up to 40 finalists will also be asked to participate in a semi-structured interview, estimated to take 1 hour (see **Attachment 5**). Interviews may be conducted in person or by telephone. Additional time for the finalist to review the interview summary for accuracy brings the total estimated interview to a maximum of 2 hours.

The total estimated annualized burden is estimated at 370 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	500	1	30/60	250
Finalists	Million Hearts® Hypertension Control Champion Data Verification Form	40	1	1	40
	Interview Guide: Million Hearts® Hypertension Control Champion	40	1	2	80
				Total	370

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 May 2015).

Million Hearts® Hypertension Control Champion Nomination:

- An estimated 75% of respondents will be Administrative/Services managers in a physician’s office. Managers time is valued at \$40.21 per hour.
- An estimated 25% of respondents will be physicians. Using general internists as a standard, physician time is valued at \$102.02 per hour.

- The weighted hourly average value of time applied to the burden is \$55.66.

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 \$102.02 per hour. Data manager time is valued at \$40.51 per hour. Registered nurse, as a representative of clinic staff is valued at \$31.42 per hour.
- The weighted hourly average value of time applied to the burden is \$57.99 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 \$102.02 per hour. Registered nurse time is valued at \$31.42 per hour.
- The weighted hourly average value of time applied to the burden is \$66.72.

The total estimated annualized cost to respondents is \$21,572.20.

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

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Burden per Response (in hours)	Weighted Hourly Wage	Total Cost
Administrator/ Clinician	Million Hearts® Hypertension Control Champion Nomination form	500	1	30/60	\$55.66	\$13,915.00
Data managers, clinic staff, physician	Data Verification Tool	40	1	1	\$57.99	\$ 2,319.60
Clinicians or Clinic staff	Interview Guide:	40	1	2	\$66.72	\$5,337.60

	Million Hearts® Hypertension Control Champion						
						Total	\$21,572.20

**A.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.

**A.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 Sensis, a software company founded in 2002. Sensis 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 are being discontinued), 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 \$235,700.00.

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

Cost Type	Cost
CDC staff. 5% of GS-14 for system oversight.	\$6,700
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.	\$179,000
Total	\$235,700

### **A.15. Explanation for Program Changes or Adjustments**

This is a reinstatement with change. OMB approval is requested for 3 years. Proposed changes are outlined below.

#### 1. Change in the schedule of the Million Hearts ® Hypertension Control Challenge.

CDC is proposing to change the timing of the Challenge to a February launch date to coincide with American Heart Month. We proposed launching in February 2017, with the application period being open for approximately 60-75 days. The timing of recognizing the Champions would correspondingly be awarded in September-October 2017, and a similar schedule for 2018.

#### 2. Changes to Burden Table

- A. In the initial submission to OMB, the burden table was based on expectations without knowledge of actual numbers of submissions. Based on experience over the past three years, we are revising the number of estimated Nominations downward from 1,735 to 500. This results in a reduction of 1,235 responses and a reduction of 618 burden hours.
- B. We are revising the estimated number of finalists who participate in the data verification process from 30 to (up to) 40. This results in an increase of 10 responses and an increase of 10 burden hours.
- C. We are revising the estimated number of finalist interviews upward from 30 to (up to) 40. This results in an increase of 10 responses and an increase of 20 burden hours.

The net changes to the burden table result in a reduction of 1,215 responses and a reduction of 588 burden hours.

Table A.15-1. Summary of changes to Burden Table

Type of Respondents	Form Name	Previous OMB Approval Period		Proposed for This Revision		Net Change	
		No. of Responses	Total burden (in hours)	No. of Responses	Total burden (in hours)	Change in responses	Change in burden hours
Physician (single or Group Practices)/Health-care systems	Million Hearts ® Hypertension Control Champion Nomination Form	1,735	868	500	250	-1,235	-618
Finalists	Million Hearts ® Hypertension Control Champion Data Verification Form	30	30	40	40	+10	+10
	Interview Guide: Million Hearts ® Hypertension Control Champion	30	60	40	80	+10	+20
Total		1,795	958	580	370	-1,215	-588

3. CDC proposes changes to **Attachment 3a** Nomination Form. The proposed revision to the Nomination Form is in **Attachment 3b**. A crosswalk of changes is in **Attachment 3c**. CDC proposes changes to the nomination form are based on feedback from users to improve its usability. One new question has been added about the relationship of the nominator with the nominee. There are six sets of revised questions, 1) identifying the nominee’s practice type, 2) identifying rural or urban status of the practice, 3) a set of questions guiding the user on how to identify their hypertension control rate in a standard format, 4) a revised question on the use of an electronic health record system and how the data were obtained, 5) a revised question on the use of clinical quality measures, and 6) a revised section title. Lastly one selection option under clinical system supports was deleted.
4. A minor editorial change, which does not affect the content of the information collected or the burden estimate, is proposed for the Data Verification Form. The previously approved Verification Form is **Attachment 4a**; the proposed revision of the Verification Form is **Attachment 4b**; and the crosswalk of the change to the Verification Form is **Attachment 4c**.

5. No cash award is being offered.

**A.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 February-March annually. Champions will be announced annually in September 2017, 2018, and 2019.
- B. Publication Plan. Information collected through the Champion interviews will be published on the CDC Million Hearts® website, estimated by October of calendar year, 2017, 2018, and 2019.
- 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 be used by CDC for program improvement. The information collected through qualitative interviews is primarily descriptive.

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

The OMB expiration date will be displayed.

**A.18. Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification statement.