

Centers for Medicare & Medicaid Services  
Center for Medicare and Medicaid Innovation  
The Million Hearts® Cardiovascular Disease (CVD)  
Risk Reduction Model  
Request for Applications

---

09/09/2015

### Model Abstract

**Objectives:** The Million Hearts® CVD risk reduction model promotes CVD prevention, improved CVD outcomes, and accountability for costs among Medicare beneficiaries through risk assessment and risk management. The model financially incentivizes providers to use the American College of Cardiology/American Heart Association (ACC/AHA) Atherosclerotic Cardiovascular Disease (ASCVD) risk calculator to prevent heart attacks and strokes.

**Methods:** The model will recruit approximately 720 practices who develop plans to use the ACC/AHA ASCVD calculator to risk stratify Medicare Fee for Service (FFS) beneficiaries and propose innovative service delivery models that reduce risk across the entire population. Half of all selected applicants (n=360 intervention practices) will be randomly assigned to the intervention group with the remaining selected applicants assigned to the control group.

*Intervention* practices will be paid a one-time \$10 per beneficiary fee to calculate a beneficiary's ASCVD risk score and to engage the patient in shared decision-making. In year one, an additional \$10 monthly Cardiovascular Care Management (CVD CM) payment per beneficiary will be made for risk management for the highest risk patients. During years two through five, practices can receive a monthly CVD CM payment of up to \$10 based upon the reduction of their high-risk beneficiary ASCVD risk scores.

*Control* practices will not be asked to implement ASCVD risk calculation but will be asked to submit clinical data on Medicare beneficiaries for comparison against intervention practices. Data collection will occur in years 1, 2, 3, and 5. Practices will be paid a \$20 per-beneficiary payment (based on the estimated costs of preparing and transmitting the required data) for each reporting cycle.

### Eligible Applicant:

Eligibility criteria for applicants include:

- Practices must have at least 1 practitioner. Practitioners are defined as Medical Doctors, Doctors of Osteopathic Medicine, Physician Assistants, and Nurse Practitioners.
- Practitioners are required to be enrolled in and eligible to bill for Medicare part B

- Practices must be using an Office of the National Coordinator (ONC) certified Electronic Health Record system
- Participating physician or other eligible professionals within the practice must have met the criteria for the EHR Incentive Programs in performance year 2014, also known as “meaningful use,” of a certified electronic health record.

**Letter of Intent:**

Interested applicants must submit a non-binding letter of intent (LOI) no later than 11:59 EDT September 10, 2015. Applicants will be unable to access the application without first submitting an LOI. An LOI template is provided in *Appendix A*. To file an LOI, applicants may access the electronic portal at <http://innovationgov.force.com/MHLOI>.

The estimated time to complete the LOI is less than 5 minutes.

**Application:**

Applications to the RFA must be submitted electronically no later than 11:59 p.m. EDT September 10, 2015.

The RFA application can be accessed at <https://innovationgov.secure.force.com/mhcvdrrrfa/>. You will need your LOI confirmation number to access the application.

The estimated time to complete the application is 1-2 hours.

**Key Dates:**

- Date of Issue: May 28, 2015
- LOI Due Date: September 10, 2015, by 11:59 p.m. Eastern Daylight Time
- Application Due Date: September 10, 2015, by 11:59 p.m. Eastern Daylight Time
- Anticipated Awardee Announcements: November 2015
- Anticipated Model Participation Agreement award: December 2015
- Anticipated Period of Performance: January 04, 2016 to December 31, 2020. (5 years)

# Table of Contents

Model Abstract.....	1
Objectives .....	1
Methods.....	1
Eligible Applicant: .....	1
Eligibility criteria for applicants include: .....	1
Key Dates: .....	2
I. Background and Introduction.....	4
II. Statutory Authority.....	5
III. Scope and General Approach .....	5
IV. Deadline for Applications.....	6
V. Description of Million Hearts Model .....	7
VI. Eligibility of Medicare Beneficiaries .....	9
Beneficiaries.....	9
VII. Defining the Attributed Population .....	10
VIII. Applicant Eligibility and Participation Requirements .....	14
Applicant Eligibility .....	14
Randomization.....	16
Participation in Other Medicare Programs, Models, or Demonstrations.....	16
IX. Payment Model .....	17
Intervention Group Payments .....	17
Control Group Payments .....	19
X. Evaluation of Million Hearts Model .....	20
XI. Quality and Metrics Reporting .....	21
XII. Million Hearts® CVD model Program Monitoring.....	23
XIII. Application Selection.....	25
Application Questions .....	25
Review and Selection Process .....	26
Length of Agreement.....	27
XIV. Learning Systems Strategy.....	27
XV. Termination.....	28
XVI. Legal Waivers .....	28
XVII. Agency Contacts .....	29
Programmatic Questions .....	29
Administrative Questions .....	29
XVIII. Appendix A: Non-Binding Letter of Intent Template.....	30

## I. Background and Introduction

The Centers for Medicare & Medicaid Services (CMS) is committed to improving quality and reducing expenditures for Medicare, Medicaid, and the Children’s Health Insurance Program (CHIP). The Million Hearts® CVD risk reduction model pursues these goals with the prevention of cardiovascular disease (CVD) through reductions in the number of heart attacks and strokes.

Evidence shows that prevention of CVD can significantly reduce both cardiovascular-related and all-cause mortality.<sup>1</sup> Historically, providers focus on the individual components of CVD risk such as hypertension control, cholesterol control, and smoking cessation. While this approach has shown some effectiveness, CVD continues to be the leading cause of death in the United States and the largest contributor to healthcare costs.<sup>2,3</sup>

The Million Hearts® Cardiovascular Disease Risk Reduction model, herein referred to as the Million Hearts® CVD model, seeks to bridge a gap in cardiovascular care by providing targeted incentives to engage in individual CVD risk calculation and population-level risk management. Instead of focusing on the individual components of risk, participating practices will engage in risk stratification across a patient panel to identify those at highest risk for Atherosclerotic Cardiovascular Disease (ASCVD). The model attempts to prevent first-time heart attacks and strokes by paying practices to identify their patients at highest risk and engaging these patients in a systematic program to reduce their CVD risk.<sup>4</sup>

Participating practices in the Million Hearts® CVD model will risk stratify their Medicare fee-for-service (FFS) beneficiaries by using the American College of Cardiology/American Heart Association (ACC/AHA) 10-year pooled cohort ASCVD risk calculator. Based on their 10-year risk score, high-risk beneficiaries will be identified. Beneficiaries who are over age 79, who have had a prior heart attack or stroke, or who are receiving hospice care will be excluded. Practice care teams will work collaboratively and employ shared decision-making to decrease cardiovascular risk. Interventions should address each person’s individual risk and contribute to a population level risk reduction.

---

<sup>1</sup> Farley, Thomas A. et al. Deaths Preventable in the U.S. by Improvements in Use of Clinical Preventive Services

*American Journal of Preventive Medicine*, Volume 38, Issue 6, 600 – 609.

<sup>2</sup> Soni, A. Top 10 Most Costly Conditions among Men and Women, 2008: Estimates for the U.S. Civilian Non institutionalized Adult Population, Age 18 and Older. Medical Expenditure Panel Survey Statistical Brief #331. 2011. Available at: [http://meps.ahrq.gov/mepsweb/data\\_files/publications/st331/stat331.pdf](http://meps.ahrq.gov/mepsweb/data_files/publications/st331/stat331.pdf). Accessed: October 28, 2014.

<sup>3</sup> <http://www.cdc.gov/chronicdisease/overview/>

<sup>4</sup> Shared decision-making is a collaborative process between patients and providers to make care decisions that are based on patient education, intervention options available, and the potential harms and benefits of specific intervention options.

## II. Statutory Authority

Section 1115A of the Social Security Act (added by section 3021 of the Affordable Care Act) (42 U.S.C. 1315a) authorizes the Center for Medicare and Medicaid Innovation (the Innovation Center) to test innovative health care payment and service delivery models that can lower Medicare, Medicaid, and CHIP expenditures while maintaining or enhancing the quality of care.

The Million Hearts® CVD Risk Reduction Model, described in this Request for Applications (RFA), will use the CMS Innovation Center's authority to test a new model of care delivery and payment that targets heart attacks and strokes among Medicare beneficiaries. The model will test whether financial incentives and accountability for the average ASCVD risk score across a provider's Medicare population are effective in reducing heart attacks, strokes, and total cost of care.

## III. Scope and General Approach

The Million Hearts® CVD risk reduction model supports prevention of CVD, improved health outcomes, and healthcare cost savings or cost neutrality through systematic implementation of beneficiary risk calculation and stratification.

The Million Hearts® model will incentivize practices to calculate risk for all eligible Medicare beneficiaries by using the American College of Cardiology/American Heart Association (ACC/AHA) Atherosclerotic Cardiovascular Disease (ASCVD) 10-year pooled cohort risk calculator and to develop risk modification plans based on beneficiary risk profiles.

The model will use a randomized controlled design to identify successful prevention and population health interventions implemented within the following framework:

- Universal risk stratification of all Medicare eligible beneficiaries who meet the inclusion criteria using the ACC/AHA ASCVD Pooled Cohort 10 year risk calculator
- Evidenced-based risk modification using shared decision making between beneficiaries and care teams in order to reduce ASCVD risk scores
- Use of prevention and population health management strategies based on needs identified during risk stratification of beneficiaries
- Reporting of continuous risk calculator variables, ASCVD 10-year risk score, and a cardiovascular Physician Quality Reporting System (PQRS) measure set through a Data Registry that will be provided as part of the model test. As an added benefit, participating practices will also have the option of reporting on additional PQRS measures within the Data Registry to meet both the PQRS and physician value-based payment modifier (VM) reporting requirements.

The model will recruit approximately 720 practices who develop plans to use the ACC/AHA ASCVD calculator to risk stratify beneficiaries and propose innovative service delivery models

that reduce risk across the entire population. Half of all selected applicants (n=360 intervention practices) will be randomly assigned to the intervention group with the remaining selected applicants assigned to the control group.

The model will continue over five years. While CMS is committed to improving care for beneficiaries, the Agency reserves the right to terminate the Million Hearts® CVD model testing for any reason, as is true for all models tested under Section 1115A authority. Similarly, as implementation of the model ensues, CMS reserves the right to terminate the overall model test or model testing at any individual site if it is determined that it is not achieving the goals and aims of the model, and may be required to terminate or modify the model as directed by Section 1115A(b)(3)(B).

#### **IV. Deadline for Applications**

Interested applicants must submit a letter of intent (LOI) no later than September 10, 2015 11:59 pm EDT. Letters of intent will be used only for planning purposes and the content of the LOI will not be binding. An LOI template is provided in *Appendix A*.

To file an LOI, applicants may access an electronic portal at

<http://innovationgov.force.com/MHLOI>

The estimated LOI total completion time is less than **5** minutes.

***CMS will not consider applications from organizations that do not submit a Letter of Intent.***

Applications to the RFA must be submitted electronically no later than September 10, 2015 11:59 pm EDT. Application questions are provided in section *XIII*.

To submit an application, applicants will need their LOI confirmation number and the e-mail used to submit the LOI to receive access to the application.

The RFA application can be accessed at <https://innovationgov.secure.force.com/mhcvdrrrfa/>

The estimated total completion time of this application is **1 to 2** hours.

***CMS reserves the right to request additional information from applicants in order to assess their applications and eligibility for participating in the model test.***

Applicants seeking to withdraw their application must submit an electronic withdrawal request to CMS via the following mailbox: MHmodel@cms.hhs.gov. The request must be submitted as a PDF on the organization's letterhead and signed by an authorized corporate official. It should include: the applicant organization's legal name; the organization's primary point of contact; the full and correct address of the organization; and a description of the nature of the withdrawal. Applicants seeking to withdraw only specific CMS Certification Numbers (CCNs) and/or National Provider Identifier (NPI) numbers from a pending application must follow the same process outlined above.

## V. Description of Million Hearts Model

The model will employ a randomized controlled design and require the following characteristics for those practices assigned to the intervention group:

- Risk Stratified Care
- Population Health Management
- Shared Decision Making
- Individual Risk Modification Planning
- Team-Based Care
- Quality and Clinical Data Reporting

These characteristics are described in further detail in the sections below.

### Risk Stratified Care and Population Health Management

Participating practices will use the ACC/AHA ASCVD Pooled Cohort Equation 10-year risk calculator to risk stratify their attributed Medicare FFS beneficiaries.

The tool requires users to input the following data:

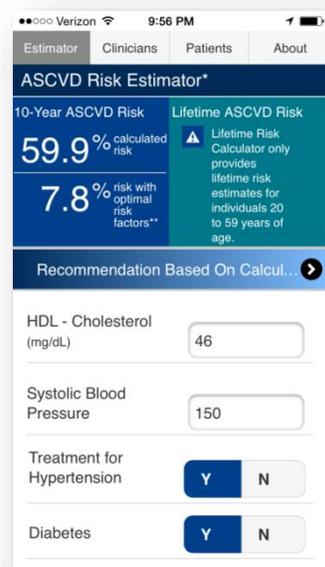
- Age
- Race
- Total cholesterol
- High-density lipoprotein (HDL) cholesterol
- Systolic blood pressure
- Use of antihypertensive medication
- Smoking status
- Diabetes status

Systematic risk calculation will help clinicians understand ASCVD risk across their entire Medicare patient panel.

Practices will be able to identify beneficiaries at the highest risk of an ASCVD event, and can take action to mitigate that risk.

Both the process of documenting ASCVD risk variables and the resulting risk score provides an opportunity for providers to engage high-risk individuals in the development of risk-reduction plans. It also allows practices to develop plans for population health management interventions focused on the most prevalent needs among high-risk beneficiaries. For example, the identification of significant numbers of smokers among high-risk patients could lead to the practice's creation of a smoking cessation program.

Figure 1: ASCVD risk calculator, with hypothetical 67 year old man with several CV risk factors



## **Shared Decision Making and Individual Risk Modification Planning**

Patient-centered care dictates that the provision of care is based on patient's preferences, needs, and values. A central tenet to patient-centered care is the collaborative process of shared decision-making between providers and patients. These collaborative patient/provider decisions are based on patient education, intervention options, and the potential harms and benefits of specific interventions. The process encourages patients to take control of their health, supports them in making individualized care decisions, while allowing providers to feel confident in the care provided.

Using the calculator as a tool to facilitate discussion, intervention practices will be asked to develop individual risk modification plans with each high-risk beneficiary. The format and implementation of the individual risk modification plans will be left to the discretion of each practice. Practices should develop preventative health interventions that are patient-centered and informed by a shared-decision making process. Each beneficiary should leave the visit knowing their risk, the options available to reduce their risk, and a plan of action that meets their values and needs.

CMMI will provide shared decision-making technical assistance during the application process and model implementation.

## **Team-Based Care**

Team-based care involves the use of a multidisciplinary team of providers and other professionals to enhance communication, care coordination, and patient self-management with the aim of improving the quality of care and health outcomes for patients. A team can include, but is not limited to, physicians, physician assistants, nurse practitioners, nurses, pharmacists, dietitians, social workers, or community health workers. Team-based care is implemented by changing the roles of existing staff and/or by adding new staff.

With routine, systematic assessment of high-risk patients, practices will identify those patients who will most likely benefit from additional support to reduce their ASCVD risk. The efforts to reduce this risk may be complex and require comprehensive support. To achieve this goal, practices will utilize a healthcare team to effectively manage their patients' complex and competing needs.

Please note, the only requirement for the care team is that it has one provider defined as a medical doctor, doctor of osteopathic medicine, physician assistant, or nurse practitioner. There are no other specific requirements of numbers and types of individuals involved in the care team. Moreover, members of the care team are not required to be employees of the organization. For example, a pharmacist could be an active member of the care team but would be used through an outside referral.

## **Data Registry**

Intervention practices will be required to report the beneficiary risk calculator variables and ASCVD 10 year risk score biannually. Practices will also be required to report cardiovascular Physician Quality Reporting System (PQRS) measure set annually (see section XI for more information on the required CVD PQRS measures.) Practices will use a Data Registry to report clinical indicator data to CMS and submit PQRS measures. The Million Hearts® Data Registry will be provided to practices for free as a benefit of participation in the Million Hearts® CVD risk reduction model. As an added benefit, participating practices will also have the option of reporting on additional PQRS measures within the data registry to meet the PQRS and VM reporting requirements.

The data submitted by practices will also be used to assist them in their continuous quality improvement efforts and further strengthen their CVD risk reduction programs. At a minimum, intervention practices will be provided a Million Hearts® report card twice a year. This report card will provide them with an aggregate risk score and dependent variables from the most recent reporting period, baseline, and previous reporting period, as well as percentage change from baseline, percent change from the previous reporting period, and other relevant de-identified information such as state and national averages.

More information about the PQRS and VM can be found at the links below:

- PQRS: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html?redirect=/PQRS/>  
VM : <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/ValueBasedPaymentModifier.html>

## **Control Practices**

Practices randomized to the control group will receive a per beneficiary cost-based payment for help covering the costs of preparing and transmitting the data to CMS for those beneficiaries attributed to the practice under the attribution rules noted above.

Unlike intervention group practices, control group practices will not be required to calculate or submit beneficiaries' 10-year ASCVD risk scores. However, they will be required to use the data registry tool to report all information necessary for follow up risk calculation for beneficiaries.

## **VI. Eligibility of Medicare Beneficiaries**

### **Beneficiaries**

The target population for the Million Hearts® CVD model is all Medicare FFS beneficiaries aged 18-79 years of age.

All Medicare FFS beneficiaries 18-79 years of age meeting the inclusion criteria will receive risk stratification using the ACC/AHA CVD risk calculator. The risk calculator uses the following variables to calculate risk: age, race, total and high-density lipoprotein (HDL) cholesterol levels, systolic blood pressure, use of antihypertensive medication, smoking status, and diabetes status.

After the initial risk stratification, **high-risk** beneficiaries will receive ongoing management and treatment, supported by a monthly Cardiovascular Care Management (CVD CM) payment.

**High-risk** is defined as any beneficiary with an ACC/AHA 10 year ASCVD risk score greater than or equal to 30%. Large population-wide studies estimate that approximately 1 in 10 of the target population will be defined as high-risk.<sup>5</sup>

Please note, CMS reserves the right in this model test to change the definition of “high-risk” during the model test. Potential reasons for changing the definition include having a sufficient number of “high-risk” patients among the population of participating practices or changes in clinical guidelines.

Any beneficiary with the following characteristics is **ineligible** to participate in the model:

- Prior heart attack and/or stroke
- Currently receiving care in hospice
- Over the age of 79. (The ACC/AHA risk calculation tool is designed only for individuals 18-79.<sup>6</sup>)
- Medicare Advantage or other health plan coverage as primary payer

## VII. Defining the Attributed Population

Attribution is the process to identify a group of CMS beneficiaries that are being served by a particular practitioner and/or practice. The beneficiaries that are “attributed” to a practice, are the group on which CMS will base payment, monitoring, and evaluation for participating practices.

CMS will use the following attribution methodology to identify Medicare fee-for-service (FFS) beneficiaries for which practices will have accountability.

---

<sup>5</sup> Centers for Medicare and Medicaid Services. Chronic Conditions Warehouse. Cost and Use Data Files and 20% Data Files. 2009-2012.

<sup>6</sup> Goff DC, Lloyd-Jones DM, Bennett G, Coady S et al. 2013 ACC/AHA Guideline on the Assessment of Cardiovascular Risk: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *Circulation* 2014; 129: S49-S73

## Intervention Practices

After selection for participation in Million Hearts® CVD model, CMS will perform beneficiary attribution with claims data using the process outlined below. Once the list of beneficiaries has been identified, CMS will provide intervention group practices an approved panel size. Practices will receive a one-time \$10 per beneficiary Cardiovascular Risk Assessment payment after they conduct baseline ASCVD risk calculation on beneficiaries within the panel. High-risk patients with a 10-year risk greater than 30% will be identified from this pool of patients.

In year one, an additional \$10 monthly Cardiovascular Care Management (CVD CM) payment will be made for risk management among the highest risk patients. During years two through five, practices can receive a monthly CVD CM payment of up to \$10 based upon the reduction of their beneficiary ASCVD risk scores equal to a potential annual payment of \$120 per eligible high-risk beneficiary. Conditions to receive the full monthly \$10 CVD CM payment are described in section IX.

Assume a three provider practice is enrolled in the model. The practice provides services to a panel of 500 Medicare beneficiaries that meet the definition of the target population. The practice conducts the risk stratification and identifies 50 beneficiaries as being high risk. This practice has the potential to receive \$11,000 in year one of the model. In years 2-5, the practice has the potential to earn a maximum of \$6,000 each year if meeting the conditions to receive the full \$10 monthly CVD CM payment. Over the life of the model, a practice could earn \$35,000 for their cardiovascular disease reduction work.

Beneficiary attribution will be conducted at the beginning of performance year one. To identify the estimated panel size for a practice, CMS will conduct attribution using the 2 previous years of retrospective claims data. Attribution will occur annually at the beginning of each year for the four subsequent performance years for intervention practices.

Assume a practice is enrolled into the model. Also assume that the performance year of the model begins September 1, 2015. CMS will use the methodology outlined below to assess Medicare claims that were billed September 1, 2013 – August 30, 2015. CMS will run this attribution methodology at 4 different points within this 2 year window to gain an understanding of the practice's average panel size of beneficiaries meeting the inclusion criteria of the model.

The process for conducting beneficiary attribution is outlined below:

1. CMS will acquire the following information about the practice from the practice's application:
  - a. Legal Business Name, Tax Identification Number, and Type 2 NPI, and HCCN if applicable;
  - b. Type 1 NPI of participating clinicians;

2. CMS will review 2 years of claims for billing organization EIN/Type 2 NPI combinations to identify beneficiaries who meet the eligibility criteria.
3. Beneficiaries will be attributed to the EIN of the health care organization that billed for the plurality of Evaluation and Management (E & M) charges during the most recent 24-month period. If a beneficiary has an equal number of qualifying visits to more than one practice, the beneficiary will be attributed to the practice with the most recent visit.

Intervention practices will be required to notify CMS if an attributed beneficiary has died or is no longer receiving care at the practice. A beneficiary will be classified as no longer receiving care if the beneficiary has not had a visit to the practice within the last year. Beneficiaries who experience a heart attack and/or stroke are no longer eligible to participate in the model, however CMS will continue to track their claims data for evaluation and monitoring purposes. Although the practices will no longer receive payment, they will also not be penalized if beneficiaries opt out of the model for clinical indication, terminal cancer, enrolling hospice care, or other personal reasons.

Intervention practices will be required to sign a Model Participation Agreement (MPA) that will set forth the terms and conditions of the model. Each participating intervention practice must be a Medicare-enrolled entity that is identified by a TIN and bills for items and services furnished by one or more Medicare-enrolled individuals identified by an NPI. The practice will be required to identify the name and NPI of each individual who bills under the TIN of the practice and has agreed to participate in the model. Not all NPIs within the practice must agree to participate in the model. CMS will evaluate the model based on the results generated by each participating practice, as defined by its TIN and participating NPIs. Practices that intend to use the data registry to meet some of the requirements for PQRS and the VM will need to align their practice/organization participation in the Million Hearts CVD Model with the program requirements of the VM.

### **Control Practices**

After selection for participation in the control group, CMS will perform beneficiary attribution with the same process used for intervention practices. Once beneficiaries have been identified, CMS will provide control group practices an approved panel size for whom they can receive a \$20 per beneficiary payment after the submission of clinical and demographic data described in section XI. Failure to submit data to CMS will result in a forfeiture of the payment. The initial Control group attribution will occur at the same time as the intervention attribution process.

Assume a one provider solo practice is randomized to the control group. The practice provides services to a panel of 300 Medicare beneficiaries that meet the definition of the target population. This practice will be compensated \$6,000 for each reporting year upon the completion of successful reporting.

Control group practices will also have patients attributed. The process for attribution for control group practice is the same process outlined above for intervention practices

### **Beneficiary Inclusion in the Model**

Participating intervention practices in the Million Hearts® CVD model will manage the care of high-risk beneficiaries over the life of the model. As new beneficiaries begin receiving care at the practice, the practice will need to calculate their CVD risk and risk stratify them using the ACC/AHA ASCVD risk calculator. High-risk beneficiaries will be included into the model and included in the practice's composite risk reduction. The practice will have a 6 month grace period before a new beneficiary would be included in their absolute risk reduction performance.

The baseline performance for a practice is established by taking the individual level 10-year CVD risk scores and calculating the average for the practice. When a new patient begins receiving care at the practices, his or her baseline risk will be calculated, but his or her risk will not be included in the average risk calculation until the 6 month grace period has elapsed. This will prevent practices from being detrimentally affected by new beneficiaries who may have extremely high 10-year ASCVD risk.

Practices will be expected to submit a high-risk beneficiary file to CMS identifying their high-risk beneficiaries at the beginning of each performance year. The enrollment file will include new beneficiaries who have begun receiving care at the practice and beneficiaries who have left the practice or are deceased. CMS will monitor the enrollment files across model participants to identify duplication of beneficiaries and to confirm that beneficiaries are appropriately attributed to practices.

### **Beneficiary Notification**

Practices in the intervention group will be required to inform all beneficiaries identified as high-risk of their inclusion in in the Million Hearts® model. Notification must include information related to the practices' sharing of Protected Health Information (PHI) with CMS. Beneficiaries will not be provided with an opt-out option for data sharing.

Eligible beneficiaries will automatically be included in the Million Hearts® CVD model when they begin receiving services at participating practices. Practices in the intervention group, however, will be given a six month grace period before new beneficiaries are counted towards their population level cardiovascular risk baseline. Practices will be required to report a baseline score in the second 6 month reporting period in which a beneficiary is attributed but are allowed to report the baseline risk in the first six months and potentially receive subsequent payments for high risk beneficiaries within the initial year; such reporting in the first six months will not, however, count towards baseline performance. For example, if the program year begins January

1, practices would engage in risk stratification January 1 – June 30. Practices will report to CMS on the required data elements by July 31. Practices will receive their payment for the initial Risk Stratification and 6 months of cardiovascular care management fees in August.

Million Hearts® CVD model intervention practices must send letters or provide written notification to newly attributed beneficiaries using approved text provided by CMS. Notifications should be performed prior to the start of each performance year and inform beneficiaries of their alignment status. Practices must notify beneficiaries if they are added to the attributed list after the annual attribution period. All beneficiary correspondence related to Million Hearts® CVD model must use CMS pre-approved form letters.

All letters must include CMS approved language with the following elements:

- a short description of the model;
- an explanation that the beneficiary retains full Medicare FFS benefits and the freedom to choose his or her providers;
- data sharing description; and
- contact information for Million Hearts®: Cardiovascular Risk Reduction model and 1-800-Medicare for questions and/or concerns.

CMS will engage a contractor to conduct an independent audit of randomly selected practices to ensure accuracy and validity of the data being submitted to CMS. In addition, separate audits of individual practices may be conducted as needed. Noncompliance with the terms and conditions with this model test discovered during an audit will result in a Corrective Action Plan. CMS reserves the right to terminate a practice from the model based on an audit finding.

## **VIII. Applicant Eligibility and Participation Requirements**

### **Applicant Eligibility**

The Million Hearts® CVD model seeks a diverse range of practices—varying in size, clinical focus, geographic distribution, and patient demographic factors. Examples of practices include general/family practice, internal medicine, geriatric medicine, multi-specialty groups, nephrology, and cardiovascular medicine. Applicants could be private practices (physicians, nurse practitioners, or physician assistants who work in private practices), hospital-owned physician practices, large medical networks, hospital/physician organizations, or independent practice associations.

The basic eligibility criteria include:

- Practice must have at least one practitioner. Practitioners are defined as Medical Doctors, Doctors of Osteopathic Medicine, Physician Assistants, and Nurse Practitioners.
- Practitioners are required to be enrolled in and eligible to bill for Medicare part B

- Practices must be using an Office of the National Coordinator (ONC) certified Electronic Health Record system
- Participating physician or other eligible professionals within the practice must have met the criteria for the EHR Incentive Programs in performance year 2014, also known as “meaningful use,” of a certified electronic health record.

Practices will apply to the model through an online application. Every practice that submits a complete application and meets the eligibility criteria will be placed into a pool of eligible applicants. Approximately 720 practices will be selected from the pool of eligible applicants. Approximately 360 intervention and 360 control group practices will be selected from the final pool of eligible applicants. Although the application will not be scored based on the quality of responses, applications will be reviewed for completeness and eligibility as well as program integrity checks. Please refer to section XIII to understand the criteria for a complete application.

The pool of approximately 720 practices will be selected based on a mix of factors including practice size, clinical focus, patient population, geographic distribution, and patient demographic diverse range of practices.

If considerably more than 720 practices apply and meet the eligibility criteria, practices will be selected based on:

1. Number of practitioners and number of Medicare beneficiaries served to ensure the model has adequate funds for payments to control group practices throughout the five year project period.
2. Other factors such as clinical focus, geographic distribution and patient demographic to support collaborative learning among diverse partners and a robust evaluation.
3. Application submission date to provide an unbiased decision aid for choosing between similar practices.

The ultimate selection of practices to participate in the model will be at the discretion of CMS.

CMS reserves the right to (1) prohibit categories of providers/suppliers from participating in the model testing should CMS determine that the participation of such categories of providers/suppliers would pose an elevated program integrity risk to the Medicare program, and (2) not select otherwise-qualified applicants on the basis of information found during a program integrity review.

The Million Hearts® CVD Model application will request information about the applicant so that the CMS can conduct Medicare provider vetting. This will involve collecting the following for each participating site:

- Full name and address (including ZIP code)
- CCN (facilities only)

- Tax Identification Number (TIN); and
- NPI (participating providers and organizational)

Applications will also require applicants to disclose any sanctions, investigations, probations or corrective action plans that the applicant is currently undergoing or have undergone in the last three years.

### **Randomization**

The Million Hearts® CVD Model is using a randomized controlled design to evaluate the effectiveness of payment incentives to reduce cardiovascular risk. Applicants will enter into an MPA with CMS under which they agree to the terms and conditions of the model, including the agreement to abide by the results of randomization and the provision of data to CMS. Data submissions to CMS will include beneficiary level clinical indicators used to calculate 10 year risk. Once applicants have been selected and MPAs have been signed, practices will be randomized to the intervention or the control group. More information on the evaluation design can be located in section XII.

### **Participation in Other Medicare Programs, Models, or Demonstrations**

The Affordable Care Act presents multiple opportunities for improving the delivery and financing of health care. The interventions supported through this model must complement and support other health reform efforts, while still maintaining sufficient independence for the intervention to be effectively evaluated. CMS is not seeking to fund interventions that compete or interfere with existing models, programs and demonstrations. CMS, however, may fund testing of complementary payment and service delivery models under the authority of section 1115A of the Social Security Act.

Applicants who are currently participating in other CMS models are eligible to participate in Million Hearts® CVD model, which may complement other CMS models and programs including the Shared Savings Program, the Pioneer ACO Model, the Financial Alignment Demonstration, and the Comprehensive Primary Care (CPC) model. The pay-for-outcomes approach in this model does not involve shared savings, and participation in shared savings programs would not constitute an overlap. CMS will consider participants in other CMMI models as eligible applicants for the Million Hearts model. Applicants will be required to disclose in their application if they are participating in existing CMS models or demonstrations. This information will be used for information purposes only. Applicant's participating in other CMMI programs should ensure the requirements and policies of said program allow for participation in other CMMI models.

Many services rendered under the Chronic Care Management (CCM) code may be duplicative with the actions taken to manage 10-year CVD risk. Therefore, participating practitioners will be prohibited from billing the CCM code for beneficiaries receiving CVD CM payments in the model.

## IX. Payment Model

### Intervention Group Payments

The Million Hearts® CVD model has identified 2 types

- Cardiovascular Disease Risk Assessment (CVD RA) payment
- Cardiovascular Care Management (CVD CM) payment

#### ***The Cardiovascular Disease Risk Assessment (CVD RA) Payment***

The CVD RA Payment is a onetime payment to risk stratify eligible beneficiaries using the American College of Cardiology/ American Heart Association/ (ACC/AHA) ASCVD Pooled Cohort 10 year risk calculator. The risk score will be calculated in a face-to-face office visit with a member of the care team. The Care Team delivering the CVD RA and CVD CM services is comprised of at least one EP, defined as Medical Doctors, Doctors of Osteopathic Medicine, Physician Assistants, and Nurse Practitioners and any additional clinical staffing including but is not limited to: Nurses, Pharmacists, Dietitians, Social Workers, Patient Navigators, and/or Community Health Workers.

After the first 12 months of the model a practice is considered non-participatory in the model if a practice at the end of each reporting period has not risk stratified more than 25% of its eligible patients. If the lowest quintile (lowest 20%) of participating practices has risk stratified more than 25% eligible patients, than the lowest quintile of practices is considered non-participatory. It is allowed one 6 month report period to become compliant.

The 10-year risk score will be calculated using the clinical indicators outlined in Section XI. The care team will order the necessary clinical tests and labs needed to calculate the 10-year risk score. Based on the calculated risk score, each beneficiary is assigned into a risk category of a high-risk or non-high risk, outlined in section V.A. High-risk is defined as any beneficiary with an ACC/AHA 10 year ASCVD risk score greater than or equal to 30%. This group of beneficiaries will receive ongoing management and treatment supported by the monthly Cardiovascular Care Management (CVD CM) payment described below.

In addition to the calculation of 10-year ASCVD risk, providers will attest to the provision of the following services:

- Shared Decision Making – Jointly identify a risk factor(s) to improve. Practices should utilize a decision aid, such as a shared decision support tool that can be found online, paper, or integrated into the EHR;
- Individual Risk Modification Plan - This is an electronic summary of the beneficiary's risk score, ACC/AHA risk calculator variables, record of all recommended preventive care services, and medication reconciliation with review of adherence and potential interactions, and medication compliance and self-management.

#### ***Cardiovascular Disease Care Management (CVD CM) Payment***

The CVD CM payment is a monthly payment to support the management, monitoring, and care of beneficiaries identified as *high-risk*. To receive the ongoing CVD CM payment, practices will attest to the provision of the following services between each 6 month reporting period:

- Conduct at least one annual in-person re-assessment of the ACC/AHA ASCVD Pooled Cohort 10 year risk score utilizing the Treatment Benefit Equation;
- A minimum of two annual follow-up beneficiary encounters
  - Assess progress and make updates of individual risk modification plan and re-engagement in shared-decision making where necessary.

The three contact points outlined above can be conducted by any member of the care team through a face-to-face or non-face-to-face encounter. The face-to-face encounter can be conducted in the practice's service site or in a location identified by mutual agreement with the patient. Non-face-to-face encounters can occur via phone, mobile device, or secure electronic patient portals.

Practices are required to document any patient interaction in the EHR and/or official medical record by a member of the care team. Practices will attest to the provision of these services and documentation through the bi-annual reporting of their clinical & quality measures.

If no recalculation of the risk score has occurred after three 6 month reporting periods and the high-risk beneficiary remains an attributed patient of the practice, the high-risk beneficiary's risk score reverts back to the original baseline risk score.

If a practice has not fulfilled the requirements of the CVD CM payment outlined above for more than 25% of their high-risk beneficiaries after the second year of the model and after any 6 month reporting period thereafter, the practice is considered non-participatory in the model and it is allowed one 6 month report period to become compliant.

If the lowest quintile (lowest 20%) of participating practices has fulfilled the requirements of the CVD CM payment for more than 25% eligible patients, than the lowest quintile of practices is considered non-participatory. The quintile is calculated from the previous 6 month reporting period. It is allowed one 6 month report period to become compliant.

The Million Hearts® Cardiovascular Risk Reduction model is designed to incentivize absolute ASCVD risk reduction through the use of financial payments. Practices will receive a one-time \$10 per-beneficiary payment for each eligible beneficiary that is assessed for ASCVD risk using the ACC/AHA CVD risk calculator, regardless of each beneficiary's assigned risk category. Ongoing monthly CVD payment will be available for beneficiaries that were categorized as high-risk in the initial assessment for whom data elements have been reported. In the first year of the model, practices will receive a monthly \$10 CVD CM payment in year 1 of the model. This allows practices to focus on identifying eligible beneficiaries and establish the necessary systems and protocols to deliver care management services as outlined below.

Following the initial risk stratification, practices will use an ASCVD treatment-benefit tool to measure longitudinal performance in absolute risk reduction. For years 2-5 of the model, practices will receive up to a \$10 monthly CVD CM payment for those beneficiaries identified as high risk, contingent on the practice's performance in ASCVD risk reduction of the high-risk beneficiaries reflected in the longitudinal treatment benefit tool; these performance benchmarks are outlined in Table 1.

**Table 1 – Million Hearts® CVD Model Incentive Structure**

Aggregate Absolute Risk Reduction	Cardiovascular Care Management Fee Paid
<2 percentage points	\$0
2-10 percentage points	\$5
> 10 percentage points	\$10

The payment model will be implemented according to the following schedule:

- Year 1: One time \$10 per beneficiary payment for risk score calculation for each eligible Medicare FFS beneficiary, plus a monthly \$10 CVD CM payment for those beneficiaries identified as high risk.
- Year 2-5: One time \$10 per beneficiary payment for risk score calculation for each new eligible Medicare FFS beneficiary served by the practice.
- Year 2-5: Monthly CVD CM payment for those beneficiaries identified as high risk, variable based on the average cumulative absolute risk reduction of the practice’s high-risk beneficiary population.

Practices will be required to report the clinical indicators outlined in Table 2 every 6 months and the Core Cardiovascular PQRS measures, discussed further in section XI, annually throughout the life of the model. The performance in absolute risk reduction will be calculated using data submitted following every 6 month reporting period.

CMS will not make payments to practices for non-Medicare covered services, other than as specified in this RFA or in an agreement specifying the terms and conditions of the model. Any non-Medicare covered interventions employed by model practices must comply with all applicable federal and state laws and regulations.

All payments for practices in the intervention group will be made from the Part B Supplementary Medical Insurance Trust Fund, and will not be subject to coinsurance or the Part B deductible.

### **Control Group Payments**

Practices randomized to the control group will receive a per beneficiary cost-based payment to help cover the costs of preparing and transmitting the data to CMS. Unlike intervention group

practices, control group practices will not calculate or submit beneficiaries' 10-year ASCVD risk scores. However, they will be required to use the Data Registry tool to report all information necessary for follow up risk calculation for beneficiaries. This includes the following, but not limited to, indicators: systolic blood pressure, total cholesterol, HDL cholesterol, diabetes mellitus status, smoking status, age, gender, and race, as well as the cardiovascular health PQRS measure set. Additional data elements may be added over time as clinical practice evolves. Control group practices will be asked to submit this data for all eligible beneficiaries to CMS at the beginning of years 1, 2, 3, and 5 of the model.

## **X. Evaluation of Million Hearts Model**

CMS will contract with a third party entity to conduct an independent evaluation of the model. This evaluation will inform the objective of achieving better care, better health, and lower cost when program incentives are aligned with outcomes. Both qualitative and quantitative methods will examine progress towards and challenges to achieving model objectives.

### **Analytic Design**

To maximize comparability among intervention and control practices with respect to practice characteristics and interest in participating in the Million Hearts® CVD model, a randomized controlled trial of eligible practices will be used to evaluate the effectiveness of the model. The model's impact on health care outcomes, utilization, and costs will be assessed by comparing results between the intervention and control groups.

The two primary outcome measures will be 1) the reduction in ASCVD risk based on the treatment-benefit equation; and 2) the reduction in the number of heart attacks, strokes, and transient ischemic attacks (TIAs), based on claims data. However, additional effects will also be analyzed, including:

- Other health outcomes (*e.g.*, incidence and prevalence of cardiovascular disease: myocardial infarction or unstable angina, stroke, congestive heart failure, aneurysm; chronic kidney disease and other chronic conditions; death from cardiovascular causes; all-cause mortality);
- Health care utilization (*e.g.*, ED visit rates, hospitalizations, readmissions, office visits, and procedures such as, percutaneous coronary intervention/angioplasty and coronary artery bypass grafting); and
- Total cost of care, and changes in expenditure subcategories (*e.g.*, inpatient, office visits, ED visits, and procedures).

## Data Collection

The evaluation will include multi-pronged data collection in order to understand the context of each program intervention. Data for the analyses will come from sources including, but not limited to: self-reported program monitoring information; interviews with participant providers; Medicare claims; and site visits with Million Hearts® CVD model participants. All participating practices will be required to comply with the model evaluation.

## XI. Quality and Metrics Reporting

The Million Hearts® CVD model reporting strategy intends to facilitate the reporting of CVD indicators, support the payment model and encourage participation in CMS quality measure programs. Practices participating in the Million Hearts® CVD model will receive access to a Data Registry at no cost. For all participating practices, this Data Registry will be used to report measures required for the model.

Practices participating in the Million Hearts® CVD Model will be required to report two sets of measures outlined below in Tables 2 and 3. The submission of both measure sets will fulfill requirements for the Million Hearts® CVD model. Utilizing the Data Registry platform, practices can also report additional measures to satisfy PQRS and VM reporting requirements.

The first set of measures, referred to as the clinical indicators, is beneficiary level clinical indicators needed to calculate the 10-year ACC/AHA risk score and follow-up longitudinal treatment benefit risk reduction. The clinical indicators are outlined in Table 2 below.

<b>Table 2 – Clinical Indicators for 10-year Risk Calculation</b>
Age
Race
Total cholesterol
High-density lipoprotein (HDL) cholesterol
Low-density lipoprotein (LDL) cholesterol
Systolic blood pressure
Use of statin therapy
Use of antihypertensive medication
Use of aspirin therapy
Smoking status
Diabetes status
10-year ACC/AHA Risk Score

Practices will also be required to submit cardiovascular health related measures from the existing PQRS measure set. The mandatory cardiovascular PQRS measures are outlined below in Table 3. Practices will have the option of selecting additional measures from the Data Registry in order to satisfy PQRS reporting requirements.

Table 3- Core Cardiovascular PQRS Measure Set		
Category	PQRS Number	Measure Description
Aspirin Use	#204	Percentage of patients 18 years of age and older who were discharged alive for acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period and who had documentation of use of aspirin or another antithrombotic during the measurement period
Blood Pressure Screening	#317	Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.
Blood Pressure Control	#236	Percentage of patients 18-85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90 mmHg) during the measurement period
Smoking Cessation and Screening	#226	Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.
Statin Therapy for Prevention and Treatment of CVD	TBD	TBD

Clinical and quality measures may be added or changed by CMS to ensure compliance with clinical guidelines throughout the life of the model.

### Reporting

All metrics for the model will be submitted using a Data Registry. The registry will be provided to practices at no cost and will serve as an additional incentive for participation in the model. CMS will only mandate reporting of the clinical indicators needed to calculate the 10-year ACC/AHA risk score and the treatment benefit equation (see Table 2) and the Cardiovascular PQRS core measure set as listed in Table 3 for practices that participate in the model. Beneficiary-level data will be identified using the Health Insurance Claim Number (HICN). Data can be populated from the practice's Electronic Health Record. Practices have the option to use the Data Registry to

receive credit for participation in the PQRS and VM programs by selecting and reporting additional measures that meet their respective program requirements.

Intervention group practices will be required to report twice a year throughout the 5 year model lifecycle and control group practices will report once a year in years 1, 2, 3 and 5. A table of the current reporting timelines can be found in the Appendix.

More information about the Data Registry and how data can be report is available at <http://innovation.cms.gov/initiatives/Million-Hearts-CDRRM/> . CMS and its contractors will provide technical assistance during model with data reporting throughout the life of the model.

## **XII. Million Hearts® CVD model Program Monitoring**

CMS will closely monitor the Million Hearts® CVD model as it is being implemented and tested. Practices that do not meet the model requirements as outlined in the terms and conditions may be terminated. Annual evaluations and a summative evaluation at the close of the period of performance will be performed.

The purpose of monitoring is to ensure that implementation is occurring safely and appropriately at the practice level, and that adequate patient protections are in place. CMS will monitor practices participating in this model to ensure that access to care is not being compromised, that practices are either building or have built the capacity and infrastructure to deliver quality cardiovascular care services, and that data received from practices demonstrates their engagement in continuous improvement.

One hypothetical risk of this model is that participating practitioners may exclude challenging patients from the Million Hearts® CVD Model. This risk will be mitigated through the attribution process during which CMS will verify the EHR generated beneficiaries identified as high-risk lists with claims data. We will closely follow patterns of high-risk beneficiaries who have been dropped from the model to ensure the absence of adverse selection, dropping of beneficiaries, and inappropriate non-inclusion of beneficiaries.

Program monitoring will also assess whether CMS and its contractors are providing adequate service, resources, and technical assistance for participating practices.

### **Program Reporting**

In addition to submitting clinical data to the Data Registry, practices will be asked to report annually to CMS on their efforts and approach to implement this model test. The self-reported program monitoring will be collected in a brief annual survey comprised primarily of brief free-text qualitative questions on the following core components of this project:

- Risk Stratified Care

- Population Health Management
- Shared Decision Making
- Individual Risk Modification Planning
- Team-Based Care
- Data Registry Reporting

This annual requirement will have an average reporting burden of **one** hour.

### **Monitoring**

The CMS Innovation Center will employ a range of methods to monitor and assess Million Hearts® CVD model practice performance including, but not limited to:

Analysis of specific financial and quality performance data, care delivery interventions, and population health management strategies reported by sites;

- Analysis of beneficiary and provider complaints including, but not limited to, those submitted through 1-800 Medicare call center and internal processes;
- Random audits that include but are not limited to claims data mining, medical chart review, beneficiary survey data, coding audits, on-site compliance reviews, and review of financial transactions through bi-annual reporting involving Million Hearts® sites and/or Model participants.

If a participant practice is found to be non-compliant through the use of the described monitoring activities, it will receive notification from CMS about specific deficiencies. Upon notification by letter of non-compliance, participant practices will work with CMS to identify the root cause and determine steps needed to achieve compliance within the terms and conditions of the Model Participant Agreement. CMS and the participant will create a corrective action plan with timelines for completion.

CMS can employ a variety of response tactics based on the severity and type of issue, including:

- Corrective Action Plans (CAPs) – A CAP could result from a 6 month period of non-compliance with the Terms and Condition of the MPA and/or a negative audit finding;
- Termination of the Million Hearts® CVD model site – Termination from the program could result from failure to fulfill the requirements of the CAP within the time frame established by CMS, a negative audit finding, or activity resulting in beneficiary harm; and
- Referral to law enforcement – Practices who break state and federal law will be referred to law enforcement.

These remediation responses do not limit or restrict Office of the Inspector General’s (OIG) authority to audit, evaluate, investigate, or inspect a Million Hearts® practice, its participants,

and other individuals or entities performing functions or services related to the Million Hearts® model.

CMS may add additional program integrity safeguards and requirements to the program as it develops the Model design, evaluates applications for participation in the Model, and finalizes the Million Hearts® CVD Model Participation Agreement.

### **XIII. Application Selection**

#### **Application Questions**

A response is required for all questions list below for an application to be considered complete.

#### **1) Practice Characteristics**

Estimated Completion Time: 15-30 minutes

Applicants will be required to address the following questions related to their practice’s demographics and other program participation

- How many total service sites are there in your practice? (whole number)
- How many total providers are employed at your practice? (whole number)
- Is your organization located in a geographically rural area? (Yes/No/Not Sure)
- How many total patients does your practice serve? (whole number)
- How many Medicare beneficiaries does your practice serve? (whole number)
- Please provide estimated patient population percentage data for race, ethnicity, insurance type, and age. (table provided: estimated percentage)
- Are you currently participating in any other CMS models or demonstrations? (Y/N)
  - If yes which programs? (list of programs provided)

#### **2) Population Health Management & Quality and Clinical Data Infrastructure**

Estimated Completion Time: 3-5 minutes

Applicants are required to address the following questions related to their health information technology infrastructure necessary to support the core components: ***population health management*** and ***quality and clinical data reporting***.

- Does your practice have an Electronic Health Record (EHR)? (Y/N)
- Have participating providers met the criteria for the EHR Incentive Programs, also known as “meaningful use,” in performance year 2014? (Y/N) Will they continue to meet the criteria for performance year 2015?

#### **3) Design of Project**

Estimated Completion Time: 45 minutes- 1.5 hours

Complete responses are required for each of the core components (risk stratified care, shared decision-making, individual risk modification planning, and team-Based Care) of the project design and responses are limited to a maximum of 2500 characters including space.

Your purposed methods to address the core components *population health management* and *quality and clinical data reporting* can be discussed in your response but are not required.

**Note:** There are no specific length requirements for complete response apart from the maximum character limit.

### **Team-Based Care**

Describe your health care team for this model and outline the roles and responsibilities of the team members. (2500 character limit)

### **Shared Decision-Making & Risk Modification Planning**

Describe your shared decision-making strategy and how you will ensure beneficiaries will leave the clinical encounter knowing their risk, options available to reduce their risk, and a plan that meets their values and need. (2500 character limit)

### **Review and Selection Process**

CMS staff will review all applications for completeness and eligibility. Applications that arrive late, that fail to meet the eligibility requirements, or that do not include the required forms will not be reviewed.

Every practice that submits a complete application and meets the eligibility criteria will be placed into a pool of eligible applicants. Approximately 720 practices will be selected from the pool of eligible applicants. Although the application will not be scored based on the quality of responses, applications will be reviewed for eligibility and program integrity checks.

If considerably more practices apply and meet the eligibility criteria than 720, practices will be selected based on:

1. Number of providers and number of Medicare beneficiaries served to ensure the model has adequate funds for payments to control group practices throughout the five year project period.
2. Other factors such as clinical focus, geographic distribution, and patient demographic to support collaborative learning among diverse partners and a robust evaluation.
3. Application submission date to provide an unbiased decision aid for choosing between similar practices.

The ultimate selection of practices to participate in the model will be at the discretion of CMS.

Approximately 360 intervention and 360 control group practices will be selected randomly from the final pool of eligible applicants. The randomization process will take into account practice size, clinical focus, patient population, geographic distribution, and patient demographic factors.

## Length of Agreement

Agreements will have an initial term consisting of five 12-month performance periods. CMS expects the first performance period to begin in January 2016 and the fifth performance period to end by December 2020. Additionally, CMS may terminate the agreement at any point due to non-compliance with the Million Hearts® CVD model Participation Agreement, performance or program integrity issues, or in accordance with section 1115A(b)(3)(B) of the Social Security Act.

## XIV. Learning Systems Strategy

A benefit of practices participating in a CMS model test is access to education and resources of CMS the learning system. The learning systems will support participating practices throughout the five-year model by convening learning collaborative on a national scale.

Components of the learning system will include remote and distance learning methods such as webinars, video conferences, and dissemination of promising practices. The aim of the learning system is to accelerate achieving the results for the model through sharing lessons learned and promising practices. An example of a learning system activity is presentation of the creative methods of shared-decision making or team-based care among practices with high rates of CVD risk reduction.

To best support the broad range of anticipated innovators for this initiative, CMS will create a national learning network to improve care, achieve better health outcomes and reduce the total cost of care. The goal of these learning networks is to allow model participants to learn from their peers and to improve their outcomes throughout the duration of the model's existence.

CMS will require model participants to be engaged in learning events and to contribute actively to the learning system by providing technical expertise that will accelerate national improvement in the risk reduction of heart attacks and strokes of high-risk patients.

Each practice will be required to participate in the model's learning system. It is expected that there will be required learning activities/events for a minimum of **1-2 hours** every other month. Where appropriate, continuing medical education (CME's) will be available to providers in participating practices. However, there may be additional optional learning opportunities to participate in throughout the life of the model.

Example formats of potential for required or optional learning activities includes: webinars, video conferences, telephone conferences, and web-based collaboration site. Additional technical assistance and shared learning resources may be disseminating list serves, blogs, and case studies that will assist in collaboration and disseminating promising practices.

Part of practices' expected involvement in the learning system is to participate in results-driven small groups or learning communities that will be formed as a result of this model. These smaller learning communities may be formed around a specific aspect of the model or target a specific population subgroup such as women or rural patients.

## **XV. Termination**

Continued monthly payments are dependent on satisfactory performance against goals and performance expectations delineated in the requirements of the agreement and, if applicable, approved operation plans. CMS reserves the right to terminate the agreement if it is determined to be in the best interests of the Million Hearts® CVD Risk Reduction model. Projects will be funded subject to meeting terms and conditions of the award, and subject to Section 1115A(b)(3)(B) of the Social Security Act, which requires the Secretary to terminate or modify the design and implementation of a model unless it is determined after testing has begun that it is expected to improve quality of care without increasing spending, reduce spending without reducing quality of care, or improve quality of care and reduce spending for CMS programs .

CMS also may terminate or modify an agreement based upon CMS review of the participant's progress, including a review of whether or how well quality and savings targets are met consistent with Section 1115A(b)(3)(B). In such cases CMS staff will make a recommendation to the CMMI Leadership based on the best interests of CMS including consideration of the Innovation Center's mission to test and evaluate new payment and service delivery models. Practices are required to abide by the results of the random assignment.

## **XVI. Legal Waivers**

The authority for Million Hearts® CVD model is section 1115A of the Social Security Act (SSA). Under section 1115A(d)(1) of the SSA, the Secretary of Health and Human Services may waive such requirements of Titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), and 1903(m)(2)(A)(iii) as may be necessary solely for purposes of carrying out section 1115A with respect to testing models described in section 1115A(b). For this model and consistent with this standard, the Secretary may consider waivers of certain fraud and abuse provisions in sections 1128A, 1128B, and 1877 of the SSA. Waivers are not being issued in this document; waivers, if any, would be set forth in separately issued documentation.

Thus, notwithstanding any other provision of this Request for Applications (RFA), and except as included in any waivers issued for this model, individuals and entities participating in the Million Hearts® CVD model must comply with all applicable laws and regulations. Any such waiver will apply solely to the Million Hearts® CVD model and could differ in scope or design from waivers granted for other programs or models. Waivers issued for any other model or pilot programs do not apply to the Million Hearts® CVD model.

Applicants will be screened to determine eligibility for further review using criteria detailed in this solicitation and in applicable law, including 2 CFR Parts 180 and 376. In addition, CMS may deny funding to an otherwise qualified applicant on the basis of information found during a program integrity review regarding the applicant, its affiliates, or any other relevant individuals or entities. Applicants will be required to disclose sanctions, investigations, probations or corrective action plans that have been imposed on the applicant in the last three years.

## **XVII. Agency Contacts**

### **Programmatic Questions**

Programmatic questions about the Million Hearts® CVD Model should be directed by e-mail to our program staff at: [mhmodel@cms.hhs.gov](mailto:mhmodel@cms.hhs.gov).

### **Administrative Questions**

Administrative questions about the Million Hearts® CVD Model may be directed to:

Center for Medicare & Medicaid Innovation

Attn: Nina Brown

Mail Stop: WB 06-05

7500 Security Blvd.

Baltimore, MD 21244-1850

XVIII. **Appendix A: Non-Binding Letter of Intent Template**  
**Million Hearts®: CVD Model Letter of Intent**

---

**Organization Contact Information**

**Organization Name**

**Street Address**

**City**  **State**  **Zip Code**

**Organization TIN/EIN**  **Organization NPI Number**   
(if applicable)

**Primary Contact Information**

**First Name**  **Last Name**

**Bus. Phone**  **Bus. Email**

(if applicable)

(if applicable)

## Organization Contact Information

## Organization General Information

Please mark an 'X' next to one of the types of organization below

**Type of Organization**

- Academic/Universities
- Advocacy/Founds/Faith/Comm-Based Org
- Assisted Living Facility/Nursing Home
- Dental Clinic/Office
- FQHC/Community Health Center
- Integrated Health System
- Local/Reg. Collaborative or Health Dept.
- Hospital
- Pharmacy Physician Groups/IPAs/Phys. Office
- Primary or Specialty Care Clinics
- Rehabilitation/Skilled Nursing Facility
- Urgent Care/Retail/Convenience Clinics
- Other (Please Specify)

**What is the size of your practice?**

Please mark an 'X' next to **one** practice size below

	Small (5 or fewer providers)
	Medium (6-10 Providers)
	Large (More than 10 providers)

**Does your practice have an Electronic Health Record(EHR)?**

Please mark an 'X' next to **Yes** or **No** below

	Yes
	No

**Have participating providers met the criteria for the EHR Incentive Programs, also known as "meaningful use," in performance year 2014**

Please mark an 'X' next to **one** practice size below

	Yes
	No

**Reporting Frequency**  
**Intervention Group**

<b>Performance Year (PY)</b>	<b>Measurement Period</b>	<b>Current NPI List Submission Deadline</b>	<b>Data Submission Period</b>
PY1 (6 months)**	January 1, 2016- June 30, 2016	May 20, 2016	July 1, 2016-July 15, 2016
PY1 (6 months)**	July 1, 2016- December 31, 2016	November 21, 2016	January 2, 2017- January 16, 2017
PY2 (6 months)**	January 1, 2017- June 30, 2017	May 20, 2017	July 1, 2017-July 15, 2017
PY2 (6 months)**	July 1, 2017- December 31, 2017	November 21, 2017	January 2, 2018- January 16, 2018
PY3 (6 months)**	January 1, 2018- June 30, 2018	May 20, 2018	July 1, 2018-July 15, 2018
PY3 (6 months)**	July 1, 2018- December 31, 2018	November 21, 2018	January 2, 2019- January 16, 2019
PY4 (6 months)**	January 1, 2019- June 30, 2019	May 20, 2019	July 1, 2019-July 15, 2019
PY4 (6 months)**	July 1, 2019- December 31, 2019	November 21, 2019	January 2, 2020- January 16, 2020
PY5 (6 months)**	January 1, 2020- June 30, 2020	May 20, 2020	July 1, 2020-July 15, 2020
PY5 (6 months)**	July 1, 2020- December 31, 2020	November 21, 2020	January 2, 2021- January 16, 2021
<p>** Attestation that implementing project and clinical indicators needed to calculate the 10-year ACC/AHA risk score (Gender, Age, Race, Total cholesterol, High-density lipoprotein (HDL) cholesterol, Low-density lipoprotein (LDL) cholesterol, Systolic blood pressure, Use of statin therapy, Use of antihypertensive medication, Use of aspirin therapy, Smoking status, and Diabetes status.) and the 10-year ACC/AHA Risk Score.</p>			

**Control Group**

<b>Performance Year (PY)</b>	<b>Measurement Period</b>	<b>Submission Period</b>
Baseline	January 1 – December 31 2015, 2016	January 4 – March 31, 2016
PY1	January 1 – December 31, 2016	January 2 – January 31, 2017
PY2	January 1 – December 31, 2017	January 2 – January 31, 2018
PY5	January 1 – December 31, 2020	January 2, 2021-January 31, 2021