Million Hearts® Cardiovascular Disease Risk Reduction Model FAQs

Intervention Group Participants

Q1. What are the requirements associated with the intervention group participants?

Each participant will use the 10-year American College of Cardiology/American Heart Association (ACA/AHA) Atherosclerotic Cardiovascular Disease risk calculator to risk-stratify all eligible Medicare FFS beneficiaries. For beneficiaries identified as high-risk, the participant will engage in shared decision making, develop individual risk modification plans, and re-assess their risk on an annual basis throughout the 5 years of the Model. Each intervention group participant is also required to complete an annual survey and participate in the model's learning system to provide technical expertise that may accelerate national improvement in the risk reduction of heart attacks and strokes of high-risk beneficiaries. Participants must attend a minimum of one mandatory learning system event per quarter. These learning events can include collaborative activities, virtual meetings, webinars, and affinity/action groups or teams. Continued failure to fulfill model requirements will result in corrective action and/or termination from the model.

Q2. What are the requirements for quality and metrics reporting?

The Million Hearts® Cardiovascular Disease (CVD) Risk Reduction Model will mandate reporting of the clinical indicators needed to calculate the 10-year ACC/AHA risk score and the Treatment Benefit Equation (TBE). Participants in the model will receive free access to the Million Hearts® Data Registry, which houses the beneficiary-level clinical indicators. The beneficiary level clinical indicators needed to calculate the 10-year ACC/AHA risk score and the follow-up longitudinal treatment benefit risk reduction include 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.

Q3. Will CMS change the aforementioned measures during the life of the Model?

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

Q4. What is the reporting frequency for these indicators?

Participants will be required to update the clinical indicators for each high-risk beneficiary on a yearly basis. The Million Hearts® Data Registry will automatically submit all completed beneficiary data on a monthly basis. The performance in aggregate absolute risk reduction will be calculated using data submitted following every six-month reporting period.

Q5. How will data be reported to CMS?

All metrics for the Model will be submitted to CMS using the Million Hearts® Data Registry. The registry will be provided to model participants at no cost and will serve as an additional incentive for participation in the model. The Million Hearts® Data Registry will be populated from the participant's electronic health record (EHR) system or manually entered by the participant in real time.

Q6. How is the care team defined?

The care team delivering the CVD risk stratification and CVD care management services must be comprised of at least one eligible practitioner, which is defined as a medical doctor, doctor of osteopathic medicine, physician assistant, or nurse practitioner, and any additional clinical staff including, but not limited to, nurses, pharmacists, dietitians, social workers, patient navigators, and/or community health workers.

Q7. What services must be provided by the Model participants?

Intervention group participants must attest, in the Data Registry, to having provided the following services:

The Cardiovascular Disease Risk Assessment: The 10-year risk score will be determined using the ACC/AHA ASCVD calculator and documented in a face-to-face office visit with a member of the care team. Participants will be expected to include (i.e., perform an initial ASCVD risk assessment and report) all of their eligible Medicare FFS beneficiaries in the Model.

Ongoing Cardiovascular Care Management: In addition to the calculation of the 10-year ASCVD risk, providers will attest to having at least three annual encounters with each high-risk beneficiary that provide the following services:

- Shared Decision Making: Jointly identify with beneficiaries risk factor(s) to improve in order to reduce overall ASCVD risk scores. Participants should utilize a decision aid, such as a shared decision making support tool that can be found electronically, via 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 information, including a review of adherence and potential interactions, as well as medication compliance and self-management.

Q8: Can the three mandatory ongoing cardiovascular care management encounters be either face-to-face or non-face-to-face?

To receive the ongoing CVD care management payment, intervention group practices will attest to the provisions of the following services each year:

- At least one annual reassessment of the ACC/AHA ASCVD Pooled Cohort 10 Year Risk Score utilizing the Treatment Benefit Equation (TBE) face-to-face
- A minimum of two annual follow-up beneficiary encounters either face-to-face or non-face-to-face

These contact points may be conducted by any member of the care team. The annual risk score reassessment will be calculated during a face-to-face office visit. Physical measurements such as blood pressure would be difficult, or impossible, to do remotely. The two follow-up beneficiary encounters can be done either face-to-face or remotely. Non-face-to-face encounters may occur via phone, mobile device, or secure electronic patient portals. The expectation is that the practice will follow-up with the beneficiary to discuss their progress in risk reduction, modify their risk reduction plan, and/or engage in shared decision making to determine the next best course of action for continuing to reduce or maintain their reduced risk.

Q9. How are beneficiaries assigned for calculation of the risk score?

Model participants will be expected to include (i.e., perform an initial ASCVD risk assessment and report on) all of their eligible Medicare FFS beneficiaries (aged 40-79, no prior heart attack or stroke, no ESRD, not currently enrolled in hospice care, and does not have Medicare Advantage or other health plan coverage as primary payer). The 10-year risk score will be determined using the ACC/AHA ASCVD and documented in a face-to-face office visit with a member of the care team.

Based on the calculated risk score, each beneficiary will be assigned into a risk category of a high-risk or non-high risk. High-risk is defined as any beneficiary with an ACC/AHA 10-year ASCVD risk score greater than or equal to 30%, which is roughly the top decile of risk in the target population. The cut-off for high risk may be increased or reduced depending on the clinical profile of beneficiaries included in the model.

Practices in the intervention group will be required to inform all beneficiaries identified as high-risk of their inclusion in the Model using approved text provided by CMS.

Q10. What are the requirements for annual operations reporting?

In addition to submitting clinical data to the Data Registry, intervention group participants will be required to complete an annual survey provided by CMS regarding the methodology utilized by each participant around the implementation of the model test. The self-reported monitoring will

be collected in a brief annual survey comprised primarily of brief free-text qualitative questions on the following core components of this model: Risk Stratified Care; Population Health Management; Shared Decision Making; Individual Risk Modification Planning; Team-Based Care; and Data Registry Reporting.

Q11. What is the payment process and reimbursement for participants?

The Model will offer two types of payment for intervention group participants: the Cardiovascular Disease Risk Stratification (CVD RS) payment, and the Cardiovascular Care Management (CVD CM) payment. First, participants 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.

Next, ongoing monthly CVD CM payments will be available for beneficiaries that were categorized as high-risk in the initial risk assessment and for whom data elements have been reported. In the first year of the model, participants will receive a monthly $10 CVD CM payment for each high-risk FFS Medicare beneficiary included in year 1 of the model—regardless of performance. This allows participants to focus on identifying eligible beneficiaries and establishing the necessary systems and protocols to deliver care management services as outlined below:

Following the initial risk stratification, participants shall use an ASCVD treatment-benefit tool to measure longitudinal performance in absolute risk reduction. For years 2–5 of the model, participants may receive up to a $10/month CVD CM payment for those beneficiaries identified as high risk, contingent on the participant's performance in ASCVD risk reduction of the high-risk beneficiaries reflected in the longitudinal treatment benefit tool.

Million Hearts® CVD Model Incentive Structure

Aggregate Absolute Risk Reduction Across Entire High-Risk Panel	Per Member Per Month Cardiovascular Care Management Fee Paid
<2 percentage points	$0
2-10 percentage points	$5
> 10 percentage points	$10

Q12. What happens if a beneficiary is lost to attrition?

The same provider cannot receive the initial risk-stratification payment twice for the same beneficiary if a beneficiary is again included in the Model after becoming temporarily ineligible or lost to attrition. If a beneficiary is reassigned, the new provider will be back paid for risk stratification and reporting on the beneficiary after the reassignment has been made.

Q13. How are payments distributed?

Payments for baseline risk stratification and subsequent care management payments will only be made for beneficiaries attributed to the practice. Payments will be distributed to the TIN/EIN of the participant organization. The participant organization is expected to distribute payments to participating providers; this is subject to an audit. Intervention group payments will be treated as claims and are subject to regular Medicare adjustments including sequestration.

Q14. Three of the data points are related to the beneficiary's cholesterol level. Is it sufficient to use the beneficiary's most recent cholesterol test to report this data, even if the test was conducted four years ago? Given that Medicare only covers cholesterol screening every five years for most beneficiaries, would a practice need to use a cholesterol test from the current year to report to CMS?

CMS encourages practices to provide services in line with what is covered by Medicare. If the cholesterol level was obtained in the previous five years, it will be acceptable. If a beneficiary has high cholesterol, Medicare will cover the test once a year.

Q15. Can the model be integrated with an office documentation system or a standalone system?

CMS requires practices to have an Electronic Health Record (EHR), but there are multiple options. CMS will provide a stand-alone web based portal which will provide all functions that are necessary. The only option that is not allowed is the submission of paper-based claims.

Q16. What is the definition of a high–risk beneficiary?

For the purposes of the Model, CMS is defining "high-risk" beneficiaries as individuals with an ACC/AHA 10-year ASCVD risk score of greater than or equal to 30%. The ACC/AHA guidelines still hold true that all individuals should have a risk score of less than 7.5%. CMS is attempting to intervene on the critically high-risk group. It is expected that practices will provide the necessary care as clinically appropriate for beneficiaries with risk scores between 7.5-29%.

Q17: Does the provider's baseline aggregate absolute risk score adjust to what was reported during the year? For example, if a provider achieved an aggregate risk score of 49% during the second year, down from 60%, does the provider have to reduce to less than 47% to get paid the PBPM payment after the next reporting milestone?

No. The aggregate absolute risk reduction is calculated as the difference between the current year and the provider's baseline. If the baseline is 60%, it will remain 60% over the life cycle of the model.

Q18. How will CMS approach recoupment of overpayments?

If, as a result of any later inspection, evaluation, investigation, or audit, it is determined that the amount of payments made to the participant pursuant to the Payment Process and Reimbursement Agreement has been made in error, CMS shall recoup any overpayments. In

the event an overpayment is made, CMS will offset subsequent payments.

CMS will engage a contractor to conduct an independent audit of randomly selected participants to ensure accuracy and validity of the data being submitted to CMS. In addition, separate audits of individual participants may be conducted as needed. Noncompliance with the terms and conditions, specific to this model, discovered during an audit will result in a Corrective Action Program (CAP). CMS reserves the right to remove a participant from the model based on an audit finding.

Control Group Participants

Q19: Are practices selected to be in the "control group" able to proceed with a CVD risk reduction program for their beneficiaries, including the possible use of Million Hearts programming and education while also participating as a member of the control group during the five-years of the model?

Control group practices can proceed with CVD risk reduction programming, but the programming specific to the Model would not be available to the control group during the five-year life cycle of the model.

Q20: If a provider is selected as a control practice, is the provider prevented from providing risk reduction interventions for their beneficiaries?

Control group participants will not be required to provide any services to their attributed Medicare FFS Beneficiaries outside of standard care appropriate for their beneficiaries.

Q21. What are the reporting requirements associated with the Control Group Participants?

Control group participants will be required to provide Medicare Health Insurance Claim Numbers (HICN) for all eligible FFS Medicare beneficiaries. In addition, they will be required to report the following clinical quality measures for these beneficiaries: 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. Clinical and quality measures may be added or changed by CMS to ensure compliance with clinical guidelines throughout the life cycle of the model.

Q22. What is the reporting frequency for these measures?

Control group participants will be required to report to CMS the clinical indicators for all eligible FFS Medicare beneficiaries at the beginning of performance years 1, 2, and 3, and at the end of year 5.

Q23. How will data be reported to CMS*?*

All metrics for the Model will be submitted using the Million Hearts® Data Registry. The registry will be provided to control group participants at no cost.

Q24. What services will be provided to Control group beneficiaries?

Control group participants will not be required to provide any services to their attributed Medicare FFS Beneficiaries outside of standard care appropriate for their beneficiaries.

Q25. What is the Payment Process and Reimbursement for Control group participants?

Participants randomized to the control group will be required to report data on their eligible FFS Medicare beneficiaries. Participants will receive a one-time $20 per beneficiary cost-based payment (based on the estimated costs of preparing and transmitting the data), when they submit data during the reporting period. Control group participants will not calculate or submit beneficiaries' 10-year ASCVD risk scores. Control group participants will be required to use the Data Registry tool to report all information necessary for follow up risk calculation by CMS for beneficiaries, specifically, the clinical indicators described elsewhere. Payments will be distributed to the TIN/EIN of the participant organization.

Q26. Are there are any requirements for control group participation in the Learning System?

Control group participants do not participate in the Learning System.

General Questions

Q27. How will the enrollment and validation methodology be applied to Medicare FFS beneficiaries?

The Model will use the following methodology to attribute Medicare FFS beneficiaries to providers in the Model. It is based on providers reporting into the Million Hearts® Data Registry and validation against claims:

- Providers in both the intervention and control arms include FFS beneficiaries on a continuous basis as they are seen throughout the year. New beneficiaries can continue to be included throughout the Model after Year 1.
- On a monthly basis, CMS will look back at claims submitted by the provider to check for any beneficiaries who were seen by the provider but not included in the Model during the period of performance. If CMS identifies a discrepancy between the data reported and CMS's records, CMS may share limited information with the practice to resolve the discrepancy.
- Beneficiaries who are included by more than one provider will be attributed to the provider who included the beneficiary first.
- Beneficiaries who are included by more than one provider in the same reporting period will be attributed to the provider who has the plurality, or largest number, of E&M charges over a two-year look back period from the last date of service.

- Beneficiary attrition will be recognized by the absence of reporting and a billed encounter claim over two consecutive reporting periods (each reporting period is 6-months in duration).
- Beneficiaries who are in the Model and newly risk stratified by a different provider can only be reassigned to the new provider if the beneficiary is not reported on by the original provider for two reporting periods.
- Beneficiaries who are lost to attrition or become ineligible, but are reported on or become eligible again, will be included again in the Model and counted towards providers' performance and incentive payments.
- Beneficiaries will not be provided with an opt-out option for data sharing (this point will be further explained in a separate Q&A).

Q28. What beneficiaries are ineligible to participate in the model?

Any Medicare FFS beneficiary participant with the following characteristics **must be excluded** from the Model:

- Prior heart attack and/or stroke

- End-Stage Renal Disease

- In hospice, institutionalized, or incarcerated

- Under age of 40 or over the age of 79 at time of initial risk-stratification

- Has Medicare Advantage or other health plan coverage as primary payer

If a beneficiary develops any of these characteristics during the Model, the participant should exclude the beneficiary from the Model.

Q29. What are the requirements for evaluation of Intervention Group and Control Group participants?

CMS will contract with an independent evaluator to study the design and implementation of the Model and to evaluate outcomes under the Model. The evaluation will include multi-pronged data collection in order to understand the context of each intervention. Data for the analyses will come from sources including, but not limited to: self-reported monitoring information; interviews with participant providers; Medicare claims; and site visits with Million Hearts® CVD Model participants. All participants shall be required to comply with the Model evaluation. Participants will need to cooperate fully with the organization CMS engages to evaluate the Model. This will include, but is not limited to, allowing site visits as requested and providing information and data, including beneficiary identifiable information; participant level data, including agency operations and processes; and beneficiary interventions and communications. The participant will also be required to submit clinical performance data to the CMS evaluator during the life cycle of the Model.

Q30. Are there any restrictions on publishing or distributing Model-Related Information?

Prior to use, participants must submit the information to their CMS Project Officer (PO) for approval at least 7 calendar days prior to dissemination: copies of all press releases, education and outreach materials that reference the Model, including, but not limited to, brochures; letters to physicians and/or beneficiaries; media advertisements; and any other press releases, education or outreach materials that include Model results or financial information, projections of payments under the Model, projected values of Model services, or projected or actual savings. In addition, the participant must ask the CMS Project Officer for written approval at least 30 calendar days prior to presenting, publishing, or disseminating any report or statistical/analytical material based on information obtained through participation in the Model. Presentation includes, but is not limited to, papers, articles, professional publication, speeches, and testimony. For 1 year after the Model's five-year lifecycle ends, the participant will notify the Project Officer of any report or any analytical material based on information obtained through participation in the Model.

Q31. What would cause a participant to be considered out of compliance?

A participant will be considered non-compliant and put on a Corrective Action Program (CAP) for any of and not limited to the following reasons:

- Failure to conform to the terms and conditions.
- Implementation of a change to terms and conditions without notifying CMS.
- Failure to notify Project Officer of updates to participant information within 30 calendar days of the change.
- Failure to satisfactorily report clinical indicator data.
- Failure to comply with an audit.
- Unapproved use of education and outreach material.
- Unapproved use of model information.
- Inadequate maintenance of privacy and security of Model-related information that identifies individual beneficiaries in accordance with HIPAA.
- Less than 90% consistency between the list of Medicare FFS beneficiaries included in the Model by the participant and a CMS-generated list of Medicare FFS beneficiaries seen by participant in same reporting period.

Intervention Group participants will also be considered non-compliant and put on a Corrective Action Program (CAP) for the following reasons:

- Failure to complete the annual evaluation survey.
- Failure to participate in the learning system. Requirement to participate in at least one learning system event each quarter.
- Failure to attest to care management encounters.
- Failure to document beneficiary encounters and updates to shared decision making and modification plan in EHR.
- Less than 95% of expected high-risk beneficiaries risk-reassessed in reporting period.

Continued deficiencies after being placed on a Corrective Action Program (CAP) will result in the participant being terminated from the Model.

Q32. Can a participant be terminated from the Model?

CMS may terminate the participant at any point throughout the model's life cycle. CMS will promptly notify the Participant of such termination and the reasons for it, together with the effective date. Cause for termination from the Model may include (but not limited to): failure to meet performance expectations; pervasive beneficiary or provider dissatisfaction; commitment of Medicare fraud; failure to cooperate with CMS contractors; aberrant billing patterns; or failure to attend and actively participate in learning system events. In addition, CMS may terminate this agreement at any time for (i) participant's failure to comply with the terms and conditions of this agreement, or (ii) the best interests of CMS or the Model.

Q33: Is there guidance regarding the need for an IRB/ethics review of an institution's participation in the Million Hearts® model, seeing as participating sites will be randomized into either "intervention" or "control" groups?

The Center for Medicare and Medicaid Innovation (CMMI) evaluation research is in all but very rare cases exempt from the IRB process.

Q34: Do participants have to notify or receive written consent from our beneficiaries to participate in the model?

Written consent from the beneficiary is not required for them to be included in the model. However, we do require intervention group practices to send a notification letter to high-risk beneficiaries who will be included in the model. If you need a template notification letter, please contact us at mhmodel@cms.hhs.gov.