

Million Hearts®

Cardiovascular Disease Risk Reduction Model

Control Group Orientation Webinar

Frequently Asked Questions

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MODEL TIMELINE AND SYSTEMS ACCESS

Q1. When is Go-Live?

A1. Go-Live and beneficiary enrollment will begin in late 2016/early 2017. Your organization's POCs will receive notice of the model's Go-Live date via email and it will be announced during a later model training event.

Q2. When will we be allowed to announce our participation to the public?

A2. CMS will make a public announcement of all model participants in July 2016. Your designated POCs will receive email notification of this announcement. **As a Control Group member your organization may not further publicize your participation in the MH Model.**

Q3. I don't see timelines for any of these steps, what can we anticipate next?

A3. Your organization's POCs will receive a video walking through the beneficiary enrollment and alignment process in the coming months. Approximately one month before Go-Live, your organization will be able to access a web-based training for the MH Data Registry. Instructions for accessing this training will be sent to your designated POCs via email. After Go-Live, the MH Model Team will hold a live Q&A to address any questions related to beneficiary eligibility or enrollment, data entry, and any other topic suggested by yourself and your Control Group colleagues. Throughout the training period, your organization's POCs may also receive other emails from the MH Model Team from the MH Mailbox soliciting feedback on the model's training events or supplying other model-related resources.

Q4. When and how do we update our practitioner list?

A4. Your organization's POCs will receive an email from the MH Mailbox requesting you update your practitioner list in POST portal prior to Go-Live. Currently, this feature is locked but will be accessible for adding/dropping practitioners once you receive the aforementioned email. After Go-Live, all practitioner list updates will be made through the MH Data Registry. Further training on this will be provided in the near future.

Q5. If several of our original practitioners have left our organization since onboarding, are we allowed to replace them before Go-Live?

A5. Please refer to page 6 of your onboarding packet. If your organization employs **less than 20 practitioners**, your organization is required to update your practitioner list in POST portal prior to Go-Live. The MH Model Team will inform your POCs via email when it is appropriate to update your practitioner list in the POST Portal. If your organization employs **20 or more practitioners**, the list of practitioners your organization uploaded into the POST Portal during registration for the MH Model is considered static and cannot change during the lifecycle of the model. In the event that a selected practitioner leaves your organization, you will be able to access the MH Data Registry after Go-Live to select a replacement practitioner for your organization.

Q6. Will there be an invitation to access the POST portal?

A6. Your organization's designated POCs should have already received information regarding their credentials and access to POST portal. They are the only individuals who will have access to POST portal. If your organization's designated POCs do not have this information please contact the Salesforce HelpDesk by phone: 1-888-734-6433, option 5 or email: CMMIForceSupport@cms.hhs.gov.

Q7. Is there a limit to the number of people who can have access to POST portal?

A7. Your organization's two designated POCs are the only individuals who will be able to access POST portal for the duration of the model. To update your organization's POCs prior to Go-Live, contact the Salesforce HelpDesk by phone: 1-888-734-6433, option 5 or email: CMMIForceSupport@cms.hhs.gov.

BENEFICIARY ELIGIBILITY

Q8. How do we know if a beneficiary is eligible for the MH Model?

A8. Please make sure that your participating practitioners and assisting care team members are familiar with the model's eligibility criteria so they are able to identify eligible beneficiaries. The eligibility criteria is included in your onboarding packets, and is listed below:

- Beneficiary is living
- Beneficiary is enrolled in Medicare Fee-for-Service Parts A and B
- Beneficiary is age 40 -79 at time of enrollment
- Beneficiary is not enrolled in the hospice benefit
- Beneficiary is not enrolled in Medicare Advantage and must have Medicare as primary payer
- Beneficiary does not have End Stage Renal Disease (ESRD)
- Beneficiary has not had a heart attack or stroke

Q9. Does the eligibility criteria exclude beneficiaries experiencing ASCVD (stent or bypass) or those who have not had an actual myocardial infarction (MI)?

A9. The eligibility criteria does **not** exclude beneficiaries experiencing ASCVD including stent or bypass, but does exclude individuals who have experienced a previous heart attack or stroke.

Q10. Can we enroll beneficiaries from our ACO who are not beneficiaries of our organization but are affiliated with us through the ACO?

A10. As stated on page 9 of your onboarding packet, the MH Model requires you to enroll beneficiaries on a continuous basis as they are seen by your participating practitioners. This approach will help reduce the likelihood that enrollment disrupts your normal practice workflow. Therefore, data should not be submitted for beneficiaries who have not been seen during a face-to-face visit by your practitioners and provisionally enrolled. Beneficiaries who are not seen by your organization's participating practitioners should not be enrolled by your organization.

Q11. Can the beneficiaries we enroll in the MH Model also be enrolled in Chronic Care Management (CCM)? Does this impact their eligibility?

A11. Yes, your organization can enroll beneficiaries who are also enrolled in Chronic Care Management. This does not impact their eligibility for enrollment into the MH Model or model payments your organization receives for submitting data on these beneficiaries.

Q12. Do we enroll beneficiaries who have heart disease such as stent or bypass but have not had an MI?

A12. Yes, these beneficiaries should be enrolled in the MH Model by your participating practitioners. The model's eligibility criteria does **not** exclude beneficiaries with heart disease including stent or bypass. Please review the beneficiary eligibility criteria in your onboarding packet and in Q8 above.

Q13. How do you suggest we identify eligible beneficiaries? Why doesn't CMS give us a list of attributed beneficiaries ahead of time?

A13. Your participating practitioners and care team should familiarize themselves with the model eligibility criteria listed on page 9 of your onboarding packet. The MH Model's enrollment approach is designed to reduce the likelihood that enrollment disrupts your normal practice workflow.

Q14. What happens if a beneficiary has a heart attack or stroke after enrollment and no longer meets the model's eligibility criteria?

A14. Your organization should not continue submitting data on any beneficiaries that become ineligible during the lifecycle of the model, including those that have a heart attack or stroke after enrollment.

BENEFICIARY ENROLLMENT

Q15. Who can enroll beneficiaries? Is it just MDs or can midlevel practitioners also seeing beneficiaries in the clinic enroll beneficiaries into the MH Model?

A15. If your organization employs less than 20 practitioners as defined by the MH Model RFA (M.D., D.O., P.A. and N.P.), all practitioners can enroll beneficiaries into the model. If your organization employs more than 20 practitioners, only the 20 practitioners uploaded into POST portal during onboarding can enroll beneficiaries. See page 6 of your onboarding packet for more information on your 20 practitioner list if this applies to your organization.

Q16. If a practitioner was not able to enroll a beneficiary at a face to face encounter, should they refrain from submitting data for that beneficiary to CMS?

A16. As stated on page 9 of your onboarding packet, The MH Model requires you to enroll beneficiaries on a continuous basis *as they are seen by your participating practitioners*. This approach will help reduce the likelihood that enrollment disrupts your normal practice workflow. Therefore, data should not be submitted for beneficiaries who have not been seen by your practitioners during a face-to-face visit and provisionally enrolled.

Q17. Do we have to use the beneficiary notification letter provided in our onboarding packet, or can we revise?

A17. Your practitioners must use the letter provided in your onboarding packet without any revisions, aside from the addition of your organization's contact information.

Q18. Will we need a consent form from enrolled beneficiaries in order to collect their clinical or demographic data for this model?

A18. No, but each beneficiary needs to receive a beneficiary notification letter at the point of enrollment. CMS recommends your care team or participating practitioner review the letter with each beneficiary, and direct him or her to the MH Model Team or Medicare if there are any questions or concerns.

Q19. What do we do if a beneficiary refuses to be enrolled?

A19. Contact your Million Hearts® Project Officer (MHPO) for assistance tailored to your organization's beneficiary panel. Your MHPO will be assigned in the next few months, please contact the help desk at mhmodel@cms.hhs.gov or 1-844-711-2664, option 3 for any further questions on this topic prior to Go-Live.

Q20. How do you define a beneficiary that our organization would enroll? Is this a beneficiary seen within the last year, 2 years, or 3 years etc.?

A20. Your participating practitioners should enroll eligible beneficiaries as they are seen during regularly scheduled face-to-face visits after Go-Live. For more information on beneficiary eligibility, please refer to page 9 of your onboarding packet.

Q21. Can we only send a notification letter after a visit or can we send it once we identify a beneficiary as meeting eligibility criteria? Does anything have to happen face-to-face with the beneficiary?

A21. Beneficiaries should receive their enrollment notification letters at the point of provisional enrollment (i.e. their face-to-face visit with a participating practitioner at your organization). At this time, your participating or practitioners or care team can review the letter with the beneficiary and direct him/her to contact the MH Model Team or Medicare with any further questions about the model.

Q22. What is the expected number of enrolled beneficiaries per organization and is there a penalty for missing any goals?

A22. Your organization is expected to document or update clinical indicators in the MH Data Registry for at least 90% of eligible beneficiaries seen by participating providers at your organization during each model performance year. The MH Data Registry will track enrollment, and through the alignment process described on pages 9-10 of your onboarding packet will identify eligible beneficiaries who were seen by your organization during the reporting period and not enrolled. If your organization does not reach these goals, it may be placed on a Corrective Action Plan (CAP). In addition, your organization is expected to submit updated clinical indicators and demographic data for at least 95% of previously reported on beneficiaries in subsequent years.

Q23. Are we risk stratifying enrolled beneficiaries? Do we notify them of their ASCVD risk?

A23. No. Your practitioners will not be risk stratifying enrolled beneficiaries, and therefore will not notify enrolled beneficiaries of their ASCVD risk through the MH Model. We apologize for any confusion caused by page 12 of your onboarding packet which states “Beneficiaries enrolled in the MH Model by your practitioners must receive a notification letter after their enrollment and initial ASCVD risk stratification.” **CORRECTION Control group practices will NOT be risk stratifying beneficiaries as part of the MH Model, but must provide them with the notification letter at the point of enrollment.**

Q24. What if a beneficiary doesn't have cholesterol data on file? Given that these are Control group beneficiaries, do we have to order cholesterol tests?

A24. Cholesterol data for each beneficiary may be no older than 5 years to meet the reporting requirements for the MH Model. If this data is not on file or was collected more than 5 years ago, a cholesterol test is appropriate for enrolled beneficiaries.

Q25. What if we have missing or incomplete data for our beneficiaries at the time of enrollment?

A25. CMS encourages your participating practitioners to document as much data as available at the time of enrollment, and follow up with your enrolled beneficiary as needed to collect any necessary additional clinical data for submission. Your organization can submit data as often as daily or monthly, but is required to submit data annually. CMS encourages your organization to submit data every six months, as payment will be dispersed twice annually, about three-four months after the end of each six-month reporting period.

Q26. Is enrollment limited to beneficiaries whose practitioner is one of the 20 practitioners we had submitted to POST portal?

A26. This applies only to Control Group organizations which employ more than 20 practitioners. If your organization is employs more than 20 practitioners, you were required to upload a list of 20 practitioners to POST portal during onboarding. Only these 20 practitioners may participate and enroll beneficiaries into the MH Model.

Q27. If a beneficiary is seen for a Medicare Wellness visit, is that visit type considered eligible for enrollment?

A27. Yes, any face-to-face visit is appropriate for enrolling eligible beneficiaries into the model.

MH DATA REGISTRY AND REPORTING

Q28. Will the data that we need to upload from our enrolled beneficiaries work with our EHR systems?

A28. Your organization will be able to submit beneficiary data to the MH Data Registry in three ways:

- 1) Manual entry of individual beneficiary data
- 2) Bulk upload of beneficiary data using a template downloaded from the MH Data Registry
- 3) Bulk upload of beneficiary data from certain EHR vendors that have not yet been determined.

Further information regarding data entry will be provided to you during training prior to Go-Live.

Q29. When can our organization see the specifications for the data file that we need to submit to the MH Data Registry?

A29. Please see the answer above for details on your organization's options for how to submit data to the MH Data Registry. The clinical and demographic data fields required on each enrolled beneficiary for upload are detailed in the MH Model MPA on page 8 and copied below:

- 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

Q30. Are data on beneficiaries we are submitting into the MH Data Registry de-identified?

A30. No, data on enrolled beneficiaries stored in the MH Data Registry will include an individual's Health Insurance Claim Number (HICN), date of birth, first and last name, and other clinical data. The MH Data Registry is being hosted at a CMS data center and is built to comply with CMS Security standards, which includes meeting all FISMA and CMS security requirements for all PHI and PII administered within the database. These robust security standards ensure that your beneficiary data is kept confidential for the duration of the MH model and beyond.

Q31. If we report annually on clinical data – is this at the end of the year, or can it be as we enroll beneficiaries and only once that year? Do we need to report data every time an enrollee is seen?

A31. Manually enter or bulk upload the clinical data required for each beneficiary into the MH Data Registry as often as you would like (daily, monthly), but at minimum every six months. Any care team member, from administrative to clinical staff can input this data into the MH Data Registry. **You will only receive payment for uploading data on each enrolled beneficiary annually, so do not submit data on the same beneficiary twice in the same year of the model.**

PARTICIPANT ORGANIZATION RELATED QUESTIONS

Q32. We are an FQHC - do our Prospective Payment System Medicare beneficiaries count as eligible for enrollment or just our traditional Medicare B HCFA 1500 billed beneficiaries count?

A32. Yes, CMS is accepting the enrollment of Prospective Payment System Medicare beneficiaries from Federally Qualified Health Centers (FQHC) into the model.

Q33. Can Rural Health Clinics enroll beneficiaries whose care is covered by the AIR (all inclusive rate)?

A33. Yes, CMS is accepting the enrollment of these Rural Health Clinic beneficiaries into the model.

Q34. Would participation in CPC+/ Healthy Hearts/ a heart and stroke collaborative prohibit us from being a control group in the MH Model since we may be making practice or protocol transformations that could affect our data?

A34. No, participation in any other CMMI model demonstrations, or any other programs including cardiovascular health related initiatives such as Healthy Hearts does not prohibit your

organization from participating in the MH Model as a member of the control group. CMS encourages your organization to continue delivering your current standard of care and participate in any other care improvement opportunities that your organization would normally apply to including, but not limited to, any cardiovascular health related programs or care transformation initiatives.

Q35. Do Control group participant organization members have to attend any in-person meetings?

A35. No. All training events for Control Group organizations will be held virtually.

Q36. Are there regulatory requirements for this protocol? In other words, do we have to submit the protocol and other documents to our IRB for review and approval?

A36. Centers for Medicare & Medicaid Innovation (CMMI) evaluation research is in all but very rare cases exempt from the IRB process. The statutory language has been included below for your reference. CMMI cannot give guidance on any local rules that may be imposed by hospitals or other health practitioner systems; however, CMMI requires no IRB process for this model test. Section 45 CFR 46.101(b)(5) states: (b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy: (5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs (45 CFR 46.101(b)(5)).Q13.

Q37. Will beneficiaries enrolled by Control group practices have access to fewer resources to promote their cardiovascular health than the Intervention group? Will this be the case for the full five years or will best practice and resources that prove effective be shared with the control group within the duration of the program?

A37. As a Control Group member, members of your organization are encouraged to visit the Million Hearts® Initiative website (<http://millionhearts.hhs.gov/>) and utilize publically available resources for practitioners and other care practitioners found on the 'Tools & Protocols' page. The Initiative website can also be shared with your beneficiaries, as it also includes many cardiovascular health improvement tips and tools for beneficiary use. Any best practices identified by this model demonstration will be shared after the 5 year model has ended.

Q39. Will our organization receive credits toward CMS's new requirement for "Clinical Practice Improvement Activities" by participating in the MH Model?

A39. No, as a Control Group member your organization cannot claim credit for the Clinical Practice Improvement Activities (CPIM) requirement by participating in the MH Model.

Q40. Would you say that this "orientation webinar is an appropriate webinar for my staff (medical assistants and receptionists, etc.) to watch to give them the most info about the layout of the program?

A40. Yes! Please distribute the orientation webinar slides and these resulting FAQs to your organization's appropriate staff members. The MH Model Team also encourages your designated POCs to forward all email invites for training events and training materials to the applicable staff that will be assisting in all MH model activities.

Q41. Three of our practitioners were not on our original application because they are still participating in CPCI. Can they be added to our list of participating practitioners once they complete CPCI participation in Jan 2017?

A41. If your organization employs **less than 20 practitioners** (and therefore did not submit a 20 practitioner list to POST portal during onboarding), these practitioners may be added to your participating practitioner list. Refer to pages 6 and 7 of your onboarding packet for more information on how to update your practitioner list after Go-Live.