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TO: Organizations Interested in Participating as Medicare-Medicaid Plans in States Seeking to Implement Capitated Financial Alignment Demonstrations in 2015

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SUBJECT: CY 2015 Capitated Financial Alignment Demonstration Timeline

This guidance provides an overview of the requirements and timeframes for the Medicare portion of the joint CMS and state plan selection process for the Capitated Financial Alignment Demonstrations. These instructions apply only to organizations seeking to offer Medicare-Medicaid Plans (MMPs) in states that anticipate implementing demonstrations in 2015 and that have not already applied. Interested organizations that applied during the CY 2014 cycle in states that deferred their demonstration start dates to 2015 will not be required to resubmit an application but will be subject to the annual renewal requirements for all MMPs, including submission of a model of care, as applicable, a formulary (including Part D transition attestations and policy), a plan benefit package, and a medication therapy management program for CY 2015. CMS will issue separate guidance on the annual resubmission requirements for MMPs in states that have already implemented or will implement demonstrations in 2013 and 2014.

The Medicare plan selection requirements described in this document are in addition to any that may be required for the state selection process. It is important to note that many critical aspects of the demonstrations—such as self-directed care, community integration, and recovery-oriented behavioral health services—are addressed in the state requirements and are not addressed in the minimum Medicare requirements that are the focus of this guidance. The Medicare and state review processes are complementary and do not conflict with, supersede, or undermine one another's requirements. In addition, some information submitted to CMS during the Medicare plan selection process will be subject to approval by both the state and CMS. Materials that do not require state approval will also be shared with the state and may be considered in the state selection process.

CMS has aligned its plan selection timeframes with the standard Medicare Advantage and Part D review and approval schedule. Interested organizations should familiarize themselves with the Medicare process and timeframes.

CMS requires that interested organizations submit and obtain approval of, among other items, the following elements:

- A demonstration-specific application, which includes, among other items, demonstrating a network adequate to provide enrollees with timely and reliable access to providers and pharmacies for Medicare drug and medical benefits based on requirements in the Parts C and D programs;
- A model of care that meets Medicare, Medicaid, and demonstration-specific requirements;
- A formulary that meets Part D and Medicaid requirements;
- A medication therapy management program (MTMP) that meets Part D requirements; and
- A plan benefit package (PBP) that integrates Medicare, Medicaid, and demonstration-specific benefits.

Table 1 below catalogues previously released guidance on the Medicare-required materials. CMS will release updated or new guidance as necessary; where more recent guidance exists or is released for topics that appear in previously released documents, interested organizations should use the most recent document.

Table 1. Previously Released Guidance

Topic	Link to document
Preferred Demonstration Standards (Appendix 1)	http://cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Downloads/FinalCMSCapitatedFinancialAlignmentModelPlanGuidance.pdf
State-specific Readiness Review Information	http://cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/ReadinessReviews.html
MMP Enrollment and Disenrollment Guidance	http://cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/MMPFinalEnrollGuidance.pdf
Additional State-specific Enrollment Guidance	http://cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/InformationandGuidanceforPlans.html
State-specific and Enrollment Marketing Guidance	http://cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/InformationandGuidanceforPlans.html
Waiver of Part D LIS Cost-Sharing Amounts	http://cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/Part_D_Cost_Sharing_Guidance.pdf
CY 2015 Notice of Intent to Apply	http://cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/2015_NOIA_Part_C_PartD_MMP-FINAL.pdf
CY 2015 MMP Application	TBD

Topic	Link to document
CY 2015 Model of Care Scoring Criteria	January 2014
CY 2015 Model of Care Submission Requirements	January 2014. Applicants should refer to the CY 2015 MMP application for additional information.
Past Performance Review Methodology Updates for CY 2015 ¹	January 2014

A. Past Performance

It is a priority for both CMS and states to assess MMPs' capacity and experience serving Medicare-Medicaid beneficiaries, both prior to and following the plan selection process. The joint plan selection process will therefore take into account interested organizations' previous performance in Medicare and Medicaid, as applicable. Previous performance in the Medicare program will also be used to determine organizations' eligibility for receiving passively enrolled beneficiaries. The CMS policies described in this guidance are the minimum demonstration standards and in no way prevent a state from establishing higher standards for plan selection or stricter eligibility requirements for receiving passive enrollment. Among the mechanisms CMS will use to assess an organization's Medicare performance are sanctions, the past performance review methodology, and the Medicare Plan Finder "consistently low performing" icon (LPI).

1. Sanctions

In our March 29, 2012, guidance (refer to <http://cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/MarchGuidanceDocumentforFinancialAlignmentDemo.pdf>), CMS explained that organizations currently under Medicare enrollment and/or marketing sanction are ineligible to participate in the demonstration. Organizations will be ineligible to participate if they are under sanction, as described in 42 CFR §422.750 and 42 CFR §423.750, at the time CMS and the state seek to execute the three-way contract. As such, CMS will accept applications from all organizations, regardless of their sanction status, and will consider all organizations potentially eligible to participate as MMPs prior to the execution of the contracts. If, however, an organization is under sanction and that sanction is not removed at the time CMS and the state seek to execute the three-way contract, the organization will not be permitted to offer an MMP for the duration of the demonstration. An organization that is sanctioned after the execution of a contract will be unable to enroll any new members – either through passive or opt-in enrollment – until the sanction is lifted.

¹ Refer to November 15, 2013 HPMS memorandum entitled, "2015 Application Cycle Past Performance Review Methodology Update – REQUEST FOR COMMENTS." Final guidance will be released in January 2014.

2. Past Performance Review and “Consistently Low Performing” Icon (LPI)

CMS’ additional mechanisms for assessing an organization’s overall Medicare performance, past performance outlier status and the “consistently low performing” icon (LPI), are separate designations:

- Past performance outlier status is based on an entity’s performance in 11 categories – compliance letters, performance metrics, multiple ad hoc corrective action plans (CAPs), ad hoc CAPs with beneficiary impact, failure to maintain fiscally sound operation, one-third financial audits, performance audits, exclusions, enforcement actions, terminations and non-renewals, and outstanding compliance concerns not otherwise captured. An overview of the current CMS past performance methodology is included in CMS’ January 17, 2013, HPMS memorandum entitled “2014 Application Cycle Past Performance Review Methodology Update” available at the following link: <http://cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/2014-Application-Cycle-PastPerformance-Methodology-Final.pdf>. CMS recently released draft past performance review methodology guidance for CY 2015 for comment via an HPMS memorandum entitled, “2015 Application Cycle Past Performance Review Methodology Update – REQUEST FOR COMMENTS.” CMS plans to release final past performance review methodology guidance for CY 2015 in January 2014.
- LPI designation is given to entities with poor or below average Medicare plan ratings (also called “star ratings” or “quality ratings”) – i.e., less than three stars for three or more consecutive years.

An organization that is an outlier in CMS’ past performance analysis and/or has an LPI on the Medicare Plan Finder website may qualify to offer an MMP, provided that the organization meets all plan selection requirements in the CMS-state joint plan selection process and passes its readiness review. However, any such organization will be ineligible to receive passive enrollment until it is no longer considered by CMS to be a past performance outlier and/or it no longer has an LPI on Medicare Plan Finder. Past performance analyses are conducted twice per year – once in the fall in and once in the spring – and star ratings are updated annually in October and are the basis for determining whether an organization has an LPI designation. The results of the past performance review for the CY 2015 Medicare Advantage and Part D application and contracting cycle will be finalized in April 2014. In addition, CMS provided plans with the results of an interim past performance analysis on November 12, 2013.

An organization that is ineligible to receive passive enrollment will only be able to enroll: 1) individuals who are currently enrolled in another Medicare or Medicaid managed care plan sponsored by the same organization; and 2) individuals who opt into the organization’s MMP. When an organization is no longer considered by CMS to be a past performance outlier and/or no longer has an LPI on Medicare Plan Finder, it may be eligible to receive passive enrollment. Some interested organizations that have no experience in the Medicare program may have a parent or sibling organization with previous Medicare experience. For these entities, CMS’ past performance and LPI methodologies consider information about the parent and sibling organizations’ previous Medicare past performance.

a. Treatment of New Legal Entities under the Past Performance Review Methodology

Under the Medicare past performance methodology, CMS identifies applying contracting organizations with no prior contracting history with CMS (i.e., a legal entity brand new to the Medicare program). We determine whether that entity is held by a parent of other Part C or D contracting organizations. In these instances, it is reasonable, in the absence of any actual contract performance by the subsidiary applicant, to impute to the applicant the performance of its sibling organizations as part of CMS' application evaluation. This approach prevents parent organizations whose subsidiaries are poor Part C or D performers from evading CMS' past performance review authority by creating new legal entities to submit Part C or D applications. It also forces parent organizations to direct their attention away from acquiring new Medicare business when their focus should be on bringing their current Medicare contract performance up to an acceptable level. Should one or more of the sibling organizations be past performance outliers, the application from the new legal entity will be denied.

We will apply this same methodology for purposes of determining whether a new legal entity applying as an MMP will be eligible to receive passive enrollment.

b. Treatment of New Legal Entities under the LPI Analysis

To determine whether a new legal entity applying to be an MMP will be eligible to receive passive enrollment, CMS will impute an LPI to a new legal entity – one with no prior contracting history with CMS as a Medicare Advantage organization (MAO) or a Prescription Drug Plan (PDP) sponsor – if any of the sibling organizations held by that organization's parent company has an LPI prior to the effectuation of a wave of passive enrollment into the MMP.

B. Passive Enrollment Policies

Although each state's enrollment strategy will be outlined in its Memorandum of Understanding (MOU), the following policies will serve as the minimum standards for any state requesting to use passive enrollment in its demonstration. These policies are a framework upon which states may build more stringent passive enrollment requirements.

1. Minimum Standards for Plans to be Eligible for Passive Enrollment

In addition to the CMS and state requirements for an interested organization to participate in the demonstration, MMPs must meet additional criteria to be eligible to receive passive enrollment:

- The MMP must have been selected to operate in a demonstration service area in which CMS and the state have agreed to implement passive enrollment;
- The MMP must have successfully completed the readiness review; and
- The MMP must not be a past performance outlier or have an LPI designation, consistent with Section B of this memorandum.

CMS and the state may also establish additional prerequisites for receiving passive enrollment at any time prior to or during the demonstration. Prior to implementation, MMPs will be required to demonstrate sufficient capacity for their projected enrollment during their readiness review.

After receipt of passively enrolled beneficiaries, CMS will conduct implementation monitoring requiring MMPs to demonstrate that they can fully address the needs of those enrollees before receiving additional cohorts of passively enrolled beneficiaries.

2. Maintaining Beneficiary Choice in the Context of Passive Enrollment

Capitated Financial Alignment Demonstrations will be subject to the requirement that beneficiaries have a choice of at least two plans in a region when the state mandates Medicaid managed care enrollment for all eligible individuals, as provided in Section 4701 of the Balanced Budget Act of 1997 (BBA, P.L. 105-33) and implemented in 42 CFR 438.52. The requirement does not apply in states that do not mandate Medicaid managed care enrollment, in areas that have obtained rural or other exceptions under Medicaid rules, or to California's County Organized Health Systems (COHS). CMS will only allow passive enrollment in an area with one MMP if that service area is exempt from the aforementioned BBA requirements.

We note that, regardless of the number of plans in a service area, disenrollment from MMPs and any transfers between MMPs must be allowed on a month-to-month basis anytime during the year throughout the entire duration of the demonstration.

For those demonstrations that are required to offer a choice of at least two plans, and for which CMS has approved the use of passive enrollment, each demonstration service area must meet both of the following requirements in order to implement passive enrollment:

- The service area must have at least two MMPs that successfully pass the required readiness review; and
- At least one of the MMPs that successfully passes the readiness review in a given service area must be eligible to receive passive enrollment.

a. If at least two MMPs pass readiness review but only 1 MMP in a given service area is eligible for passive enrollment

In areas where a choice of at least two MMPs is required, and at least two MMPs pass readiness review but only one of the MMPs is eligible for passive enrollment, CMS and the state will implement strategies to ensure that the MMP eligible to accept passive enrollment also has the capacity to serve the anticipated number of new enrollees. Such strategies may include, but are not limited to, multiple periods of passive enrollment, enrollment caps, and readiness review and implementation monitoring processes that assess the MMP's capacity to accommodate the anticipated number of plan enrollees. CMS will work with states to design and implement appropriate risk mitigation strategies. As outlined more fully in Section A of this memorandum, an MMP that is not eligible to receive passive enrollment at the beginning of a demonstration may become eligible to receive passive enrollment once it is no longer identified as a past performance outlier and/or is no longer associated with an LPI in Medicare Plan Finder.

b. If only 1 MMP in a service area passes readiness review

In a service area where a choice of at least two MMPs is required but only one MMP passes the readiness review, the service area does not meet the Medicaid standard for offering beneficiaries a choice of at least two plans. As such, CMS will not permit passive enrollment in that service area even if the plan that passed the readiness review is also eligible to receive passive enrollment. In such a circumstance, CMS and the state will develop alternate strategies for

enrollment, such as allowing enrollment only on an opt-in basis into the plan that passed the readiness review, or delaying enrollment for the entire service area until at least two plans have passed the readiness review.

3. Passive Enrollment Phasing

CMS strongly encourages states to phase in passive enrollment during the first year of the demonstration. We also strongly encourage states to begin their implementation with a period of opt-in only enrollment. Phasing enrollment will enable CMS and a state to assess a plan's ability to serve its currently enrolled beneficiaries before allowing it to enroll new beneficiaries. The process will also spread MMPs' intensive intake and assessment efforts over a several periods of passive enrollment. The details of each state's proposed enrollment strategy will be addressed during the MOU development, at which time CMS and the state will ensure that the enrollment strategy provides robust protections to enrollees.

In order to provide states with additional CMS support that is dedicated specifically to monitoring and mitigating any operational or beneficiary access issues during MMPs' implementation of passive enrollment, CMS is offering states a choice of two timeframes in which each MMP may conduct its first phase of passive enrollment: January 1 and April 1, 2015. These options apply only to the initial round of passive enrollment for a particular MMP within a particular state; an MMP's subsequent phases of passive enrollment may occur outside these timeframes. For example, a state may choose to effectuate its initial phase of passive enrollment for all MMPs in April 2015, with a second phase of passive enrollment in June 2015 if the first wave is successfully implemented, as determined by the implementation monitoring conducted by CMS and the state.

The timeframes for initial passive enrollment phases will not affect the start dates for opt-in enrollment, which can occur at any time between January and September 2015. CMS may update this policy if there are significant challenges with rolling start dates for opt-in enrollees during the 2014 demonstration year.

4. Passive Enrollment of Individuals Included in Medicare Part D Reassignment Effective January 1, 2015

Medicare-Medicaid enrollees who are included in the Medicare Part D reassignment effective January 1, 2015, or are moved from their current (2014) Medicare Prescription Drug Plan (PDP) or terminating Medicare Advantage Prescription Drug Plan (MA-PD) to another PDP, will be eligible for passive enrollment into a state's MMP, with an opportunity to opt-out, effective January 1, 2016.

C. Notice of Intent to Apply (NOIA)

CMS' October 31, 2013, guidance² provided plans with an overview of the NOIA submission process. CMS advised interested organizations to complete the CY 2015 NOIA by November 14, 2013 to guarantee that applicants will have access to the online application tool in January 2014. Though CMS cannot guarantee timely application tool access for organizations submitting NOIAs after November 14, 2013, CMS will continue to process NOIAs through January 31,

² Memo available at: http://cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/2015_NOIA_PartC_PartD_MMP-FINAL.pdf

2014. Timely completion of the NOIA, as well as the CMS User ID connectivity form, is necessary for interested organizations to obtain HPMS access and meet key program deadlines. Submitting a NOIA does not bind an organization to submit a formulary, application, MTMP, plan benefit package, or any other information to CMS.

D. Health Plan Management System (HPMS)

CMS uses the Health Plan Management System (HPMS) as the system of record for managing Medicare health plans and prescription drug plans. Current and prospective Medicare plans submit their applications, provider networks, plan benefit packages, formularies, and other information via HPMS. The system tracks and records CMS' review and approval of submitted materials. State reviewers will also use HPMS to review and, in some cases, approve the information submitted by plans in their respective states.

Since it may take up to two weeks to obtain HPMS access, organizations are strongly encouraged to submit HPMS access applications as soon as possible.

- If there are no individuals in your organization with HPMS access, please download a copy of the Application for Access to CMS Computer Systems form at:
<http://www.cms.hhs.gov/InformationSecurity/Downloads/EUAaccessform.pdf>
- Complete the form as follows:
 - Section 1 – Check “New” as the type of request.
 - Section 2 – Check “Medicare Advantage / Medicare Advantage with Prescription Drug / Prescription Drug Plan / Cost Contracts – Using HPMS Only”. Complete the other data entry fields, as appropriate.
 - Section 3 – Enter the contract number(s) for which you need access.
 - Section 4 – Check the first row beneath the "Default Non-CMS Employee" row (i.e., place a check in the Connect box of the third row). On the blank line beside your check mark, write "HPMS_P_CommUser".
 - Section 5 – State briefly that you require HPMS.
 - Section 6 – Leave blank.
 - Sign and date the Privacy Act Statement on page 3 of the form. Also enter your name and Social Security Number at the top of page 3. This step is critical to ensuring the successful processing of your request.
- Send the completed form to the attention of Lori Robinson via an expedited mail service as soon as possible:

ATTENTION: Lori Robinson
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Mail Stop: C4-18-13
Baltimore, MD 21244

- On each individual's form, please ensure that it includes an original signature/date, social security number, and the contract number(s) for which the user needs HPMS access. Your request will not be processed without completing these steps.

E. Demonstration Plan Application

CMS will release the HPMS Capitated Financial Alignment Demonstration Application module on January 14, 2014. Interested organizations will be required to submit their applications via HPMS by **February 25, 2014**. States will have access to interested organizations' application submissions and may use any of the submitted documentation to support the state components of the plan selection process.

Interested organizations' applications must satisfy CMS' requirements for participation in the demonstration, including:

- Part D requirements under 42 CFR §423;
- Part D and Medicare medical service network adequacy standards under 42 CFR §422.112, §422.114, and §423.120;
- A model of care for the targeted population consistent with requirements under 42 CFR §422.152(g);
- Documentation to demonstrate state licensure and solvency requirements, as well as CMS standards for fiscal soundness, consistent with 42 CFR §422.2 and §422.400; and
- Administrative and management requirements consistent with 42 CFR §422.503(b) and 42 CFR §423.504(b).

CMS will host two application training calls for all plan types, including MMPs. These trainings will take place on January 15, 2014, from 3:30 to 5 p.m. ET, and on January 22, 2014, from 3:30 to 5:00 p.m. ET.

F. Network Adequacy Determinations

Network adequacy standards will help ensure that each plan has a network of providers that is sufficient in number, variety, and geographic distribution to meet the needs of the anticipated number of enrollees in the service area. As detailed in our January 25, 2012, guidance,³ CMS' minimum standard for demonstrating network adequacy under the Capitated Financial Alignment Demonstration is to use Medicare standards for medical services and prescription drugs.^{4,5} For long-term care supports and services (LTSS), MMPs will use state Medicaid network adequacy standards.⁶ For services that are covered under both Medicaid and Medicare, such as home health, the appropriate (and more beneficiary-friendly) network adequacy standard will be determined via the CMS-state MOU development process and included in the three-way

³ Guidance available at: <http://cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/FINALCMSCapitatedFinancialAlignmentModelplanguidance.pdf>.

⁴ Medicare Advantage requires that plans maintain and monitor a network of appropriate providers that is supported by written agreements and is sufficient to provide adequate access to covered services to meet the needs of the population served. These providers are typically used in the network as primary care providers (PCPs), specialists, hospitals, skilled nursing facilities, home health agencies, ambulatory clinics, and other providers. Also, plans must provide or arrange for necessary specialty care. The MA organization arranges for specialty care outside of the plan provider network when network providers are unavailable or inadequate to meet an enrollee's medical needs. 42 CFR 422.112

⁵ Part D plans must have a contracted pharmacy network that assures convenient access to network pharmacies, including retail, home infusion, long-term care, and I/T/U pharmacies. 42 CFR 423.120

⁶ Medicaid managed care contracts must require the plan give assurances to the state and provide supporting documentation that demonstrates that it has the capacity to serve the expected enrollment in its service area in accordance with the state's standards for access to care. Among other requirements, plans must maintain a network of providers that is sufficient in number, mix, and geographic distribution to meet the needs of the anticipated number of enrollees in the service area. 42 CFR 438.207

contract. In addition to meeting minimum network standards, all selected MMPs should have processes for continuously building their networks to respond to the needs and preferences of beneficiaries. Continuous network improvement efforts should include options for beneficiaries to direct their own services, as appropriate.

Interested organizations will work directly with states during the plan selection process to satisfy state-specific network adequacy requirements for LTSS, behavioral health, and any Medicare/Medicaid overlapping services for which the Medicaid standard has been agreed to by CMS and the state in the MOU. In addition, interested organizations will work with CMS to submit the necessary documentation to be evaluated against Medicare network standards for Part D and medical services. CMS understands that interested organizations and providers will require payment rate information prior to executing signed contracts. If rate information is not available prior to the February 25, 2015 application deadline, interested organizations may submit their anticipated networks based on those medical providers from whom the organization has secured letters of intent (LOIs). CMS and the state will verify MMPs' provider network adequacy, including executed contracts, during readiness reviews. As such, interested organizations do not need to submit their LOIs during the initial network review, though CMS may request copies of an interested organization's LOIs if necessary.

During the readiness review stage, MMPs will be able to utilize an exceptions process in areas where Medicare's medical service network adequacy standards may not reflect the number or needs of Medicare-Medicaid beneficiaries. This means that exception requests will not be considered during the application process. Note that the exception request process pertains only to the medical service networks and does not apply to pharmacy networks. As part of the selection and/or readiness review process, CMS and states will establish a joint exceptions review team to evaluate MMPs' requests for exceptions for portions of service areas where the Medicare medical service standard cannot be met or where an alternate standard has been established in the MOU. The CMS-state exceptions review teams will review all submitted exceptions requests to determine the adequacy of plans' networks in areas where exceptions have been requested. Exception requests are designed to accommodate areas in which existing standards are not applicable due to limited numbers of providers or facilities or because of the specific needs of the area's Medicare-Medicaid enrollee population. The review team will not consider exceptions based solely on an interested organization's inability to contract with a sufficient number of providers and facilities in a timely manner.

G. Model of Care (MOC)

All interested organizations must submit a model of care (MOC) that meets CMS and state requirements for providing high quality care to the targeted population. MOCs are submitted as part of the Medicare application and are due no later than **February 25, 2014**. Organizations that have an approved MOC for a non-demonstration Medicare Advantage (MA) special needs plan (SNP) will be required to submit a demonstration-specific MOC.

The National Committee for Quality Assurance (NCQA) will review and approve MOC submissions on CMS' behalf based on the same elements and scoring standards CMS has established for approval of MA SNP MOCs. CMS approves MOCs for one, two, or three years based on the score assigned to a MOC during its review. NCQA will score the MOCs strictly based on CMS' current scoring criteria for the required SNP elements.

NCQA will evaluate MOCs submitted in HPMS beginning in February 2014. Interested organizations will have two opportunities to correct any deficiencies identified during the review process. Interested organizations will only be allowed to resubmit their MOCs if they score below a passing score of 70 percent. Regardless of the score earned on the subsequent resubmission, or – if necessary – an additional resubmission based on the second and final cure opportunity, organizations that receive a score below 70 percent based on their initial MOC submissions will only be granted a one-year approval and will be required to reapply for approval of their MOCs for CY 2016. Interested organizations that score above 70 percent on their initial submission will receive a 1- or multi-year approval based on that initial score; they will not be permitted to resubmit their MOCs to further improve their scores and obtain longer approval periods for their MOCs.

CMS expects that the information contained in demonstration plan MOCs will be made public. The information will be provided in a format that is easily understandable to the public, and without compromising any proprietary data that may be contained in plans' MOCs. We expect to provide further guidance on this issue in the near future.

CMS will offer two trainings on the standard MOC elements. Note that these trainings will not cover any MMP-specific requirements that states may add for their interested organizations. In addition, CMS will offer a general MOC technical assistance call and two MOC technical assistance calls for plans scoring below a 70 percent. More information for the trainings and the technical assistance calls is provided below.

Topic: MOC elements 1 and 2 Webinar
Date: January 21, 2014
Time: 2:00 p.m. – 4:00 p.m. ET
Conference Line: 1-877 -229-1823
Confirmation ID: 28818541
WebEx URL: <https://ncqaevents.webex.com/ncqaevents/onstage/g.php?t=a&d=662834320>
WebEx Password: Approval2014

Topic: MOC elements 3 and 4 Webinar
Date: January 23, 2014
Time: 2:00 p.m. – 4:00 p.m. ET
Conference Line: 1-877 -229-1823
Confirmation ID: 28824756
WebEx URL: <https://ncqaevents.webex.com/ncqaevents/onstage/g.php?t=a&d=662239392>
WebEx Password: Approval2014

Topic: MOC Technical Assistance Call
Date: February 11, 2014
Time: 2:00 p.m. – 3:30 p.m. ET
Conference Line: 1-877 -229-1823
Confirmation ID: 28825914

Topic: MOC Technical Assistance Call for MMPs Scoring <70 Percent
Date: March 18, 2014
Time: 2:00 p.m. – 3:30 p.m. ET
Conference Line: 1-877 -229-1823
Confirmation ID: 28827167

Topic: MOC Technical Assistance Call for MA/SNPs and MMPs Scoring <70 Percent
Date: April 30, 2014
Time: 2:00 p.m. – 3:30 p.m. ET
Conference Line: 1-877 -229-1823
Confirmation ID: 28828428

H. Formulary and Supplemental Drug Files

MMPs must submit and be approved to offer an integrated formulary that meets both Medicare Part D and Medicaid requirements. The formulary approval process requires interested organizations to submit: (1) a base Part D formulary and supplemental Part D formulary files; and (2) a supplemental non-Part D drug formulary file, the Additional Demonstration (ADD) file. Interested organizations must submit their base formularies no later than **June 2, 2014**.

In addition to submitting a base formulary, interested organizations must submit supplemental formulary files in HPMS by **June 6, 2014**.

All MMPs must submit an ADD file which can only contain non-Part D drugs. Non-Part D drugs include drugs in Medicare Part D excluded categories, over-the-counter drugs, and other products required by the state to be included on the integrated formulary.

CMS will work with states to provide guidance to interested organizations by April 2014 regarding drugs required to be included on the ADD file, by NDC and/or UPC, to ensure that interested organizations indicate coverage for all state-required products, and that this guidance indicate whether interested organizations should submit a single proxy NDC or multiple NDCs on the ADD file.

State reviewers will have state-specific review tracks in HPMS that will enable them to view the base formulary submission and to review and approve the ADD file submitted by each prospective MMP in that state. The states are solely responsible for reviewing and approving the ADD file; however, CMS will approve all other submitted formulary files. Reviews will begin immediately after the submission deadline and will continue until all deficiencies have been resolved.

CMS will release a CY 2015 formulary training video for plans in mid-to-late March 2014.

I. Medication Therapy Management Program (MTMP)

As provided under 42 CFR §423.153(d) and in Chapter 7 of the Prescription Drug Benefit Manual,⁷ interested organizations are required to submit a Medication Therapy Management Program (MTMP). Although state reviewers will be able to view MTMP submissions in HPMS, CMS is fully responsible for reviewing and approving interested organizations' MTMPs. Each interested organization must establish an MTMP that:

- Is designed to ensure that covered Part D drugs prescribed to targeted beneficiaries (those that have multiple chronic conditions, are taking multiple Part D drugs, and are

⁷ <http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter7.pdf>

- likely to incur annual Part D drug costs above a certain threshold) are appropriately used to optimize therapeutic outcomes through improved medication use;
- Is designed to reduce the risk of adverse events, including adverse drug interactions, for targeted beneficiaries;
 - May be furnished by a pharmacist or other qualified provider; and
 - Offers a minimum level of MTM services for each beneficiary enrolled in the MTMP, including interventions for both beneficiaries and prescribers, an annual comprehensive medication review (CMR) with written summaries in CMS standardized format (the CMR must include an interactive person-to-person, or telehealth consultation), and quarterly targeted medication reviews with follow-up interventions when necessary.

CMS expects to release guidance on the 2015 MTMP submission requirements via an HPMS memorandum after finalization of the 2015 Call Letter and Final Rule. The 2015 MTMP submission module will be launched on May 19, 2014, with a submission deadline on **June 2, 2014**.

Prior to the release of the CY2015 guidance memorandum, states may obtain MTMP information from the guidance memorandum provided to Part D sponsors regarding CY 2014 MTMP submissions.⁸ Also, states should be aware of proposed revisions through the annual Call Letter process for 2015. Other proposed revisions to Part D MTM requirements, with a proposed effective date of January 1, 2015, have been published as a notice of proposed rulemaking in the Federal Register (CMS-4159-P, Medicare Program: Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs). Revisions include proposed changes to the MTM eligibility criteria to target more beneficiaries (including lowering the MTM program annual cost threshold) and requirements for sponsors to have an outreach strategy designed to effectively engage all at-risk beneficiaries enrolled in the plan.

J. Plan Benefit Package (PBP)

1. Plan Benefit Package Submission and Review

Interested organizations must submit a plan benefit package that accurately describes the coverage details and cost-sharing for all Medicare, Medicaid, and demonstration-specific benefits. CMS will launch the HPMS PBP module on April 11, 2014; interested organizations must submit their integrated PBPs to CMS by **June 2, 2014**. No later than the launch of the PBP module in April, states should issue guidance that clearly defines the state-required Medicaid benefits and supplemental demonstration benefits. CMS will release an online training module on the PBP software for interested organizations on April 11, 2014.

The PBP review will be conducted jointly between CMS and states. CMS and states will review PBPs to ensure the data entry is consistent with minimum coverage and cost sharing requirements under Medicaid, Medicare Parts A, B, and D, and the state's demonstration. CMS and the states will also verify that the PBP includes, as necessary, any demonstration-specific supplemental benefits, which are benefits not currently covered under Medicaid or Medicare.

⁸ <http://cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Memo-Contract-Year-2014-Medication-Therapy-Management-MTM-Program-Submission-v040513.pdf>

2. Premium and Cost Sharing Requirements

MMPs are prohibited from charging Part C or Part D premiums under the Capitated Financial Alignment Demonstration. In addition, Medicare Parts A and B services must be offered at zero cost-sharing in-network, which must be reflected in provider contracting templates collected as part of the application process.

Interested organizations will be permitted to charge copays for Part D drugs consistent with current Medicare policy. However, states may also encourage or require plans to further reduce Part D drug cost-sharing for all enrollees as a way of testing whether reducing enrollee cost sharing for pharmacy products improves health outcomes and reduces overall health care expenditures through improved medication adherence under the demonstration. This cost sharing reduction can be offered by plans consistent with a waiver of certain Medicare rules described in a recent HPMS guidance memorandum entitled “Waiver of Part D Low-Income Subsidy Cost-Sharing Amounts by Medicare-Medicaid Plans and Operational Implications for Prescription Drug Event Data and Plan Benefit Package Submissions,” available at the following link: http://cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/Part_D_Cost_Sharing_Guidance.pdf.

Appendix 1: Key CY 2015 Dates for Medicare Requirements Portion of the Demonstration Plan Selection Process

Summarized below are the key dates for demonstration plan approval for the 2015 contract year. Our primary focus in this section is on the Medicare-specific requirements that interested organizations will need to satisfy to operate as MMPs. These activities and their timeframes are in addition to any state selection activities. Additional information about key operational timeframes as well as additional criteria established by states will be issued as necessary in CMS sub-regulatory vehicles.

Key Date	Entity	Required Action
November 14, 2013	Interested organizations	Recommended timeframe for interested organizations to submit NOIAs to ensure sufficient time to obtain a CMS User ID and HPMS access. CMS will continue to process NOIAs through January 31, 2014, though CMS cannot guarantee access to the application tool by the application release date for organizations submitting NOIAs after November 14, 2013.
December 5, 2013	Interested organizations	Interested organizations must have submitted CMS User ID connectivity forms to ensure applicants have access to the CMS Health Plan Management System (HPMS).
Early 2014 – Spring 2014	States	States develop specifications for representing Medicaid and demonstration-specific benefits and covered drugs in HPMS: <u>Plan Benefit Package:</u> States inform MMPs how to represent Medicaid and demonstration-specific benefits in the updated PBP module. <u>Drug Files:</u> States develop a list of the drugs the MMPs are required to include on the ADD file (by NDC and/or UPC). States should provide this list to CMS and interested organizations as early as possible. It is at the states' discretion whether to require their plan applicants to include one proxy NDC or multiple NDCs on the ADD file for each covered product.
January 14, 2014	CMS	Release of the CY 2015 MMP Application.

Key Date	Entity	Required Action
January 21, 2014	CMS and interested organizations	MOC elements 1 and 2 Webinar 2:00 p.m. – 4:00 p.m. ET Conference Line: 1-877 -229-1823 Confirmation ID: 28818541 WebEx URL: https://ncqaevents.webex.com/ncqaevents/onstage/g.php?t=a&d=662834320 WebEx Password: Approval2014
January 15 and 22, 2014	CMS and interested organizations	Application training for all plan types, including MMPs.
January 23, 2014	CMS and interested organizations	MOC elements 3 and 4 Webinar 2:00 p.m. – 4:00 p.m. ET Conference Line: 1-877 -229-1823 Confirmation ID: 28824756 WebEx URL: https://ncqaevents.webex.com/ncqaevents/onstage/g.php?t=a&d=662239392 WebEx Password: Approval2014
February 11, 2014	CMS and interested organizations	MOC Technical Assistance Call 2:00 p.m. – 3:30 p.m. ET Conference Line: 1-877 -229-1823 Confirmation ID: 28825914
February 25, 2014	Interested organizations	MMP application due in HPMS. Note that as a part of the MMP application, interested organizations must submit a Model of Care and preliminary network information. Plan Benefit Packages and formularies are not submitted as a part of the application.
Late February – April 2014	CMS and states	CMS, via its contract with the National Committee for Quality Assurance, will evaluate the Models of Care (MOCs) submitted as part of the MMP application.
March 18, 2014	CMS and interested organizations	MOC Technical Assistance Call for MMPs Scoring <70 Percent 2:00 p.m. – 3:30 p.m. ET Conference Line: 1-877 -229-1823 Confirmation ID: 28827167
April 11, 2014	CMS	Release of the Plan Benefit Package module in HPMS.

Key Date	Entity	Required Action
April 30, 2014	CMS and interested organizations	MOC Technical Assistance Call for MA/SNPs and MMPs Scoring <70% 2:00 p.m. – 3:30 p.m. ET Conference Line: 1-877 -229-1823 Confirmation ID: 28828428
May 9, 2014	CMS	Release of HPMS Part D formulary submission module for CY 2015.
May 19, 2014	CMS	Release of the CY 2015 Medication Therapy Management Program (MTMP) submission module in HPMS.
June 2, 2014	Interested organizations	Part D formulary submissions due to CMS. Note that CMS will require all MMPs to submit a demonstration-specific formulary.
June 2, 2014	Interested organizations	Deadline for submitting proposed plan benefit packages.
June 2, 2014	Interested organizations	2015 MTM program submissions due from all sponsors offering Part D including Medicare-Medicaid Plans (11:59 p.m. PDT).
June 6, 2014	Interested organizations	Deadline for submitting Additional Demonstration Drug file and Part D supplemental formulary files (Free First Fill File, Over-the-Counter Drug File, and Home Infusion File) through HPMS (11:59 p.m. PDT).
June - July 2014	CMS and states	CMS and the states review plan benefit packages and drug file submissions.
August 2014	CMS	CMS completes MTM reviews.
September 2014	CMS	Roll-out of MA and Part D plan landscape documents, which include details (including high-level information about benefits and cost-sharing) about all Medicare health and prescription drug plans available on January 1, 2015.
September 16-30, 2014	CMS	CMS mails the CY 2015 Medicare & You handbook. The handbook includes high-level information – including basic cost-sharing and premium information – about available health plan options in a beneficiary’s specific geographic location.

Key Date	Entity	Required Action
October 1, 2014	Selected organizations	CY 2015 marketing activity begins. Demonstration plans must have met all demonstration requirements, including successful completion of the readiness review, to begin marketing.
October 1, 2014	CMS	Medicare Plan Finder on www.medicare.gov goes live for CY 2015.
October 15, 2014 – December 7, 2014	Beneficiaries	Annual Coordinated Election Period.
60 days prior to an individual's passive enrollment effective date	States	The state must provide written notification to individuals passively enrolled into an MMP no fewer than 60 days prior to the effective date of any such enrollment.
January 1, 2015	Selected organizations, beneficiaries	Earliest possible enrollment effective date (for plans that have met all plan selection and readiness review requirements).