



**CENTERS FOR MEDICARE & MEDICAID SERVICES**

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DATE: January 9, 2013

TO: Organizations Interested in Participating as Medicare-Medicaid Plans in States Seeking to Implement Capitated Financial Alignment Demonstrations in 2014

FROM: Melanie Bella  
Director, Medicare-Medicaid Coordination Office

Jonathan Blum  
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SUBJECT: 2014 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 2014. CMS will issue separate guidance on the annual resubmission requirements for organizations seeking to offer MMPs in states implementing Capitated Financial Alignment Demonstrations in 2013.

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;
- A model of care that meets Medicare, Medicaid, and demonstration-specific requirements;
- A formulary that meets Part D 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
CY 2014 Notice of Intent to Apply	<a href="http://cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/NOIA_Memo.pdf">http://cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/NOIA_Memo.pdf</a>
Preferred Demonstration Standards (Appendix 1)	<a href="http://cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/FINALCMSCapitatedFinancialAlignmentModelplanguidance.pdf">http://cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/FINALCMSCapitatedFinancialAlignmentModelplanguidance.pdf</a>
Readiness Review	<a href="https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/Mass_RR_memo.pdf">https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/Mass_RR_memo.pdf</a>
Waiver of Part D LIS Cost-Sharing Amounts	<a href="http://cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/Part_D_Cost_Sharing_Guidance.pdf">http://cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/Part_D_Cost_Sharing_Guidance.pdf</a>
Model of Care Scoring Criteria (Appendix 2)	<a href="http://cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/MarchGuidanceDocumentforFinancialAlignmentDemo.pdf">http://cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/MarchGuidanceDocumentforFinancialAlignmentDemo.pdf</a>
Model of Care Submission Requirements	<a href="http://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/MOCGuidance.pdf">http://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/MOCGuidance.pdf</a>
Past Performance Review Methodology Updates for CY 2014 <sup>1</sup>	<a href="http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Fall2012PastPerformanceMethodology.pdf">http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Fall2012PastPerformanceMethodology.pdf</a>

### A. Past Performance

It is a priority for both CMS and states to assess MMPs’ capacity and experience in order to promote access to those plans that are best equipped to serve 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).

<sup>1</sup> As indicated in the 2014 Application Cycle Past Performance Review Methodology Update – REQUEST FOR COMMENTS, CMS expects to issue guidance on the final methodology in January 2014. Information on the current 2013 Application Cycle Past Performance Review Methodology is available at the following link: <http://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Part-C-HPMS-Guidance-History-Items/CMS1255618.html>.

## 1. Sanctions

In our March 29, 2012, guidance, CMS explained that organizations currently under Medicare enrollment and/or marketing sanction are ineligible to participate in the demonstration. CMS clarifies that 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.

## 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’ December 2, 2011, HPMS memorandum entitled “2013 Application Cycle Past Performance Review Methodology Update” available at the following link: <http://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Part-C-HPMS-Guidance-History-Items/CMS1255618.html>. CMS recently released draft past performance review methodology guidance for CY 2014 for comment; this guidance is available at the following link: <http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Fall2012PastPerformanceMethodology.pdf>. CMS plans to release final past performance review methodology guidance for CY 2014 in January 2013.
- 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 interested organization that is an outlier in CMS’ past performance analysis for the upcoming Contract Year (CY) 2014 and/or has an LPI on the Medicare Plan Finder website for CY 2014 may qualify to offer an MMP, provided that the organization meets all plan selection requirements in the CMS-state joint plan selection process. 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.

CMS and/or the state will determine whether an MMP is eligible to accept passive enrollment prior to the scheduled date of execution of the three-way contract. 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. As discussed in Section B.1 of this guidance, CMS and the state may establish

additional requirements for MMPs' receipt of passive enrollment, such as demonstrating sufficient capacity during readiness review and meeting implementation milestones for those beneficiaries who are already enrolled.

The results of the past performance review for the CY 2014 Medicare Advantage and Part D application and contracting cycle will be finalized in early April 2013. In addition, CMS will provide states with the results of its interim past performance analysis in early 2013. CMS releases plan ratings each fall, and these plan ratings are the basis for determining whether an organization has an LPI designation. States should consider all this information, along with any applicable previous performance in the Medicaid program, in their plan selection processes.

### **3. Treatment of New Legal Entities in CMS' Past Performance Methodologies**

Some interested organizations that have little or 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 have a high negative performance score, 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 that does not currently operate as a Medicare Advantage organization (MAO) or a Prescription Drug Plan (PDP) sponsor, or one that is too new to the Medicare program to have a plan rating calculation – if any of the sibling organizations held by that organization's parent company has an LPI prior to the execution of the three-way contract.

### **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.

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;<sup>2</sup> 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

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<sup>2</sup> For additional information on readiness reviews and implementation monitoring, states should review the Massachusetts readiness review materials available at the following link: [https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/Mass\\_RR\\_memo.pdf](https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/Mass_RR_memo.pdf).

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 four timeframes in which each MMP may conduct its first phase of passive enrollment: January 1, April 1, July 1, or September 1, 2014. 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 2014, with a second phase of passive enrollment in June 2014 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 2014. CMS may update this policy if there are significant challenges with rolling start dates for opt-in enrollees during the 2013 demonstration year.

**4. Passive Enrollment of Individuals Included in Medicare Part D Reassignment Effective January 1, 2014**

Medicare-Medicaid enrollees who are included in the Medicare Part D reassignment effective January 1, 2014, or are moved from their current (2013) 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, 2015.

### C. Notice of Intent to Apply (NOIA)

CMS' October 19, 2012, guidance<sup>3</sup> provided plans with an overview of the NOIA submission process. CMS advised interested organizations to complete the CY 2014 NOIA by November 14, 2012, to guarantee that applicants will have access to the online application tool in January 2013. Though CMS cannot guarantee timely application tool access for organizations submitting NOIAs after November 14, 2012, CMS will continue to process NOIAs through January 31, 2013. 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.

### E. Demonstration Plan Application

CMS will release the HPMS Capitated Financial Alignment Demonstration Application module on January 10, 2013. Interested organizations will be required to submit their applications via HPMS by **February 21, 2013**. 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 a webinar training on the Capitated Financial Alignment Demonstration application. More information on this training is provided below.

**Topic: 2014 MMP Application**

Date: January 17, 2013

Time: 1:00 p.m. – 4:00 p.m. ET

Conference Line: 877-267-1577

Meeting ID: 6865

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<sup>3</sup> Memo available at: [http://cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/NOIA\\_Memo.pdf](http://cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/NOIA_Memo.pdf).

## 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,<sup>4</sup> CMS' minimum standard for demonstrating network adequacy under the Capitated Financial Alignment Demonstration is to use Medicare standards for medical services and prescription drugs.<sup>5,6</sup> For long-term care supports and services (LTSS), MMPs will use state Medicaid network adequacy standards.<sup>7</sup> 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 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 21, 2013, 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. 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

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<sup>4</sup> Guidance available at: <http://cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/FINALCMSCapitatedFinancialAlignmentModelplanguidance.pdf>.

<sup>5</sup> 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

<sup>6</sup> 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

<sup>7</sup> 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

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 21, 2013**. 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.

As outlined in MMCO's March 29, 2012 and May 25, 2012, guidance memoranda,<sup>8</sup> the National Committee for Quality Assurance (NCQA) will review and approve MOC submissions on CMS' behalf based on the same 11 elements and scoring standards CMS has established for approval of MA SNP MOCs.<sup>9</sup> 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 11 required elements, though states may require interested organizations to include additional elements in their MOCs. For example, a state may require that interested organizations include a twelfth element that addresses demonstration-specific requirements not otherwise captured in CMS' 11 existing elements. Alternatively, states may require organizations to address state-specific requirements within the 11 elements required by CMS.

CMS has requested that states provide guidance to interested organizations on any state-specific MOC requirements by **January 25, 2013**. Interested organizations must receive sufficient guidance in advance of the February application deadline to ensure that they are able to develop and submit comprehensive, integrated MOCs by **February 21, 2013**. We have recommended that states instruct interested organizations to address state-specific requirements in separate and easily distinguishable sections and sub-sections.

NCQA will evaluate MOCs submitted in HPMS beginning in February 2013. States that elect to review MOCs will review MOCs concurrently with the NCQA review. Interested organizations will have two opportunities to correct any deficiencies identified during the review process; however, we note that the process for correcting those deficiencies is being revised for both SNPs and MMPs. Per the Announcement of Calendar Year (CY) 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter,<sup>10</sup> starting in the CY 2014 application cycle, interested organizations will only be allowed to resubmit their MOCs if they score below 70 percent. Regardless of the score earned on the subsequent resubmission, organizations receiving an initial score below 70% will only be granted a one-year approval and will be required to reapply for approval of their MOCs for CY 2015. Interested organizations that score above 70 percent on their initial submission will not be permitted to resubmit their MOCs to further improve their scores and obtain longer approval

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<sup>8</sup>Guidance available at: <http://cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/MarchGuidanceDocumentforFinancialAlignmentDemo.pdf> and <http://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/MOCGuidance.pdf>.

<sup>9</sup> Refer to section 90 and Appendix 1 of Chapter 16b of the Medicare Managed Care Manual for more information about CMS' model of care requirements for SNPs: <http://www.cms.gov/manuals/downloads/mc86c16b.pdf>.

<sup>10</sup> Call letter available at <http://www.cms.gov/Medicare/Health-Plans/MedicareAdvgtgSpecRateStats/Downloads/Announcement2013.pdf>

periods for their MOCs. States may elect to allow additional MOC resubmissions to allow interested organizations to address deficiencies relative to the state-specific requirements.

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 issue further guidance on this issue.

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. More information for the trainings and the technical assistance call is provided below.

**Topic: MOC elements 1 through 5**

Date: January 16, 2013

Time: 2:00 p.m. – 3:30 p.m. EST

Conference Line: 877-474-1132

Meeting ID: 83870664

Webinar: <https://ncqaevents.webex.com/ncqaevents/onstage/g.php?t=a&d=662714982>

Event Password: Approval2013

**Topic: MOC elements 6 through 11**

Date: January 22, 2013

Time: 2:00 p.m. – 3:30 p.m. EST

Conference Line: 877-474-1132

Meeting ID: 83878792

Webinar: <https://ncqaevents.webex.com/ncqaevents/onstage/g.php?t=a&d=661681594>

Event Password: Approval2013

**Topic: MOC Technical Assistance**

Date: February 5, 2013

Time: 2:00 p.m. – 3:30 p.m. EST

Conference Line: 877-474-1132

Meeting ID: 84021331

## **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. Interested organizations must submit their base formularies no later than **May 31, 2013**.

In addition to submitting a base formulary, interested organizations must submit supplemental formulary files in HPMS by **June 7, 2013**.

All MMPs must submit a supplemental formulary file called the Additional Drug Demonstration (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 has requested that states provide guidance to interested organizations as early as possible in 2013 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.

### **I. Medication Therapy Management Program (MTMP)**

As provided under 42 CFR §423.153(d) and in Chapter 7 of the Prescription Drug Benefit Manual,<sup>11</sup> 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 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 2014 MTMP submission requirements via an HPMS memorandum. The 2014 MTMP submission module will be launched in April 2013, with a submission deadline in May 2013. Prior to the release of the CY2014 guidance memorandum, states may obtain MTMP information from the guidance memorandum provided to Part D sponsors regarding CY 2013 MTMP submissions.<sup>12</sup>

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<sup>11</sup> <http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter7.pdf>

<sup>12</sup> <http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Memo-Contract-Year-2013-Medication-Therapy-Management-MTM-Program-Submission-v041012.pdf>

## **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 in mid-April 2013; interested organizations must submit their integrated PBPs to CMS by **June 3, 2013**. 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 hold a training on the PBP software for interested organizations in early 2013.

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.

### **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.

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](http://cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/Part_D_Cost_Sharing_Guidance.pdf).

## Appendix 1. Key Dates for Medicare Requirements Portion of the Demonstration Plan Selection Process

Summarized below are the key dates for demonstration plan approval for the 2014 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
Late 2012 – Early 2013	CMS and states	CMS and states continue MOU development and approval.
November 14, 2012	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, 2013, though CMS cannot guarantee access to the application tool by the application release date for organizations submitting NOIAs after November 14, 2012.
December 6, 2012	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).
January 16, 2013	CMS and interested organizations	Training on MOC Elements 1 through 5 Time: 2:00 p.m. – 3:30 p.m. EST Conference Line: 877-474-1132 Meeting ID: 83870664 Webinar: <a href="https://ncqaevents.webex.com/ncqaevents/onstage/g.php?t=a&amp;d=662714982">https://ncqaevents.webex.com/ncqaevents/onstage/g.php?t=a&amp;d=662714982</a> Event Password: Approval2013
January 17, 2013	CMS and interested organizations	Training on the Capitated Financial Alignment Demonstration application Time: 1:00 p.m. – 4:00 p.m. ET Conference Line: 877-267-1577 Meeting ID: 6865 Webinar: <a href="https://webinar.cms.hhs.gov/MMPApplicationtraining2014/">https://webinar.cms.hhs.gov/MMPApplicationtraining2014/</a>
January 22, 2013	CMS and interested organizations	Training on MOC elements 6 through 11 Time: 2:00 p.m. – 3:30 p.m. EST Conference Line: 877-474-1132 Meeting ID: 83878792 Webinar: <a href="https://ncqaevents.webex.com/ncqaevents/onstage/g.php?t=a&amp;d=661681594">https://ncqaevents.webex.com/ncqaevents/onstage/g.php?t=a&amp;d=661681594</a> Event Password: Approval2013
January 25, 2012	States	States provide interested organizations with guidance on their MOC submissions.
February 5, 2013	CMS and interested organizations	MOC Technical Assistance Call Time: 2:00 p.m. – 3:30 p.m. EST Conference Line: 877-474-1132 Meeting ID: 84021331

**Appendix 1. Key Dates for Medicare Requirements Portion of the Demonstration Plan Selection Process**

Key Date	Entity	Required Action
February 21, 2013	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 2013	CMS and states	CMS, via its contract with the National Committee for Quality Assurance, and state reviewers will evaluate the Models of Care (MOCs) submitted as part of the MMP application. State participation in the MOC review process is at the state’s discretion.
April 2013	CMS	Release of the Plan Benefit Package module in HPMS.
April 2013	CMS	Release of the CY 2014 Medication Therapy Management Program (MTMP) submission module in HPMS.
May 2013	Interested organizations	Deadline for submitting MTMPs.
May 13, 2013	CMS	Release of HPMS Part D formulary submission module for CY 2014.
May 31, 2013	Interested organizations	Part D formulary submissions due to CMS. Note that CMS will require all MMPs to submit a demonstration-specific formulary.
June 3, 2013	Interested organizations	Deadline for submitting proposed plan benefit packages.
June 7, 2013	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.
June - July 2013	CMS and states	CMS and the states review plan benefit packages and drug file submissions.
June - August 2013	CMS and states	CMS and states conduct readiness reviews for selected plans. CMS and states make final preparations for implementation, test operational systems, and review adherence to contract requirements prior to implementation. CMS and states jointly confirm MMPs have met readiness requirements.
August 2013	CMS	CMS completes MTMP reviews.
September 2013	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 available Medicare health and prescription drug plans for CY 2014.
September 2013	CMS, states, and selected organizations	Three-way contracts between selected plans, states, and CMS should be finalized and signed. State-specific timeframes may vary.

**Appendix 1. Key Dates for Medicare Requirements Portion of the Demonstration Plan Selection Process**

Key Date	Entity	Required Action
Mid- to late September 2013	CMS	CMS mails the CY 2014 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.
October 1, 2013	Selected organizations	CY 2014 marketing activity begins. Demonstration plans must have met all demonstration requirements, including successful completion of the readiness review, to begin marketing.
October 1, 2013	CMS	Medicare Plan Finder on <a href="http://www.medicare.gov">www.medicare.gov</a> goes live for CY 2014.
October 15, 2013 – December 7, 2013	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, 2014	Selected organizations, beneficiaries	Earliest possible enrollment effective date (for plans that have met all plan selection and readiness review requirements).