DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services

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TO: States Planning to Implement Capitated Financial Alignment Demonstrations in 2014

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SUBJECT: 2014 Capitated Financial Alignment Demonstration Timeline

This guidance provides states implementing Capitated Financial Alignment Demonstrations in 2014 with an overview of the requirements and timeframes for the Medicare portion of the joint CMS and state Medicare-Medicaid Plan (MMP) selection process. CMS has aligned its plan selection timeframes with the standard Medicare Advantage and Part D review and approval schedule. It is important for states to understand these timeframes so that they can be prepared to review materials that require both state and CMS approval. CMS requires that interested organizations submit and obtain approval of, among other items, the following elements:

- A formulary that meets Part D requirements;
- A medication therapy management program (MTMP) that meets Part D requirements;
- A plan benefit package (PBP) that integrates Medicare, Medicaid, and demonstration-specific benefits;
- 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; and
- A model of care that meets Medicare, Medicaid, and demonstration-specific requirements.

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 thoroughly 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.

For states' reference, 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, states should use the most recent document.

Table 1. Previously Released Guidance

Topic	Link to document
CY 2014 Notice of Intent to Apply	http://cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/NOIA_Memo.pdf
Preferred Demonstration Standards (Appendix 1)	http://cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/FINALCMSCapitatedFinancialAlignmentModelplanguidance.pdf
Readiness Review	https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/Mass_RR_memo.pdf
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
Model of Care Scoring Criteria (Appendix 2)	http://cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/MarchGuidanceDocumentforFinancialAlignmentDemo.pdf
Model of Care Submission Requirements	http://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/MOCGuidance.pdf
Past Performance Review Methodology Updates for CY 2014 [1]	http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Fall2012PastPerformance Methodology.pdf.

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).

[1] As indicated in the 2014 Application Cycle Past Performance Review Methodology Update – REQUEST FOR COMMENTS, CMS intends to publish the final methodology in December 2012. 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 C.F.R. 422.750 and 42 C.F.R. 423.750, at the time CMS and the state seek to execute the MMP 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 three-way MMP 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 either an outlier in CMS' past performance analysis for 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 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 past performance methodology in the Medicare program, 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 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 as 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 passively enrolled beneficiaries:

- 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.

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; [2] 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.

[2] 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.

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 areas where a choice of at least two MMPs is required but only one MMP in a given service area 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 or contingency strategies for enrollment, including 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 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 Medicare reassignment effective January 1, 2014, or 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. 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 approve the information submitted by plans in their respective states. To ensure that state users will be able to review the materials submitted by interested organizations, state reviewers must submit applications for CMS User ID forms no later than **mid-January 2013**. Specific instructions for state users are provided in Appendix 2. In early 2013, CMS will provide state reviewers with training and guidance for using HPMS during the review process.

State reviewers may recall that interested organizations were advised to submit their CMS User ID forms by December 6, 2012, in order to obtain HPMS access by the January 2013 release of the application module in HPMS. The timeframe for state reviewers to obtain CMS User IDs and HPMS access is later than for interested organizations because state reviewers will not need access to HPMS prior to the late February launch of the application module.

D. Notice of Intent to Apply (NOIA)

Organizations interested in participating in the Capitated Financial Alignment Demonstration have, or will soon, submit a demonstration-specific Notice of Intent to Apply (NOIA) via CMS' web tool. Submitting a NOIA does not bind an organization to submit a formulary, application, MTMP, plan benefit package, or other required information. CMS' October 19, 2012, guidance[3] 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 access to the application tool 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.

[3] Memo available at: http://cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/NOIA_Memo.pdf.

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).

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

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[4] Guidance available at: http://cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/FINALCMSCapitatedFinancialAlignmentModelplanguidance.pdf.

[5] 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

[6] 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

[7] 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

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 numbers 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 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 in an area due to limited numbers of providers or facilities in that area 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 organizations' 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. 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,[8] 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.[9] 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 wish to require that interested organizations include a twelfth element

[8] 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.

[9] 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.

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.

To facilitate the state review, CMS recommends that states instruct interested organizations to address state-specific requirements in separate and easily distinguishable sub-sections. If a state opts to capture its requirements in a twelfth element, for example, it could instruct plans to organize the new element into subsections (such as self-directed care, person-centered planning, support in transitioning from institutions to the community, and integration in the delivery of primary care and behavioral health services). If a state chooses to incorporate its requirements into the existing elements, it can direct plans to add these sub-sections to existing elements as appropriate. For example, a state could require that interested organizations add a sub-section to Element 7 of CMS' MOC standards to address the state's requirements for the health risk assessment process and tool.

States should provide guidance on state-specific MOC requirements as early as possible. 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**.

CMS and state reviewers will evaluate MOCs submitted in HPMS beginning in February 2013. 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,[10] starting in the CY 2014 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 MOC for CY 2015. Interested organizations that score above 70 percent on their initial submission will not be permitted to resubmit their MOC to further improve their score and obtain a longer approval period for their MOC. States may elect to allow additional MOC resubmissions to allow interested organizations to revise only the state-specific subsections.

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.

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 on **June 7, 2013**, plan benefit package submission deadline.

[10] Call letter available at: http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2013.pdf

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 will provide technical guidance on the format and requirements for this file in early 2013.

States should issue guidance 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. States should provide the list to CMS and interested organizations as early as possible in 2013. 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. We encourage 2014 demonstration states to issue clear guidance on whether the state expects submission of 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,[11] interested organizations are required to submit Medication Therapy Management Programs (MTMPs). 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.[12]

[11] http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter7.pdf

[12] 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. To assist states as they develop their guidance and benefit specifications, CMS will provide states with training on the PBP software in early 2013. CMS will hold a training for interested organizations shortly after the state training.

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 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 Parts A and B.

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.

K. Promoting Health Information Technology

Recognizing the important role health information technology plays in coordinating care and improving beneficiary health outcomes, state demonstrations should support the efforts of MMPs and providers to leverage existing programs and opportunities to support the care of demonstration beneficiaries. CMS and the Office of the National Coordinator for Health Information Technology have launched numerous initiatives designed to promote meaningful and innovative use of health IT and encourage exchange of health information. The details of ONC programs and HHS adopted standards and specifications can be found on the Department's website: http://healthit.hhs.gov. CMS will work with interested states to outline the details of coordinating or incentivizing provider and MMP participation in these initiatives in their plan selection processes.

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 demonstration plans. These activities and their timeframes are in addition to, and independent of, 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 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 11, 2013	States	State reviewers must submit CMS User ID connectivity forms for access to HPMS.
Early 2013	States	States issue guidance to interested organizations if the state will require the Model of Care (MOC) to incorporate additional information beyond the 11 required elements of the Medicare Advantage Special Needs Plan MOC. State participation in the MOC review and approval process is at each state's discretion. If a state would like to add criteria and review the MOCs submitted for its demonstration, states should release such guidance on their additional criteria in early 2013. Note that interested organizations are required to submit their MOCs between the January 10, 2013, launch of the HPMS application module, and the February 21, 2013, application deadline.
Early 2013	States	States develop specifications for Medicaid and demonstration-specific benefits and covered drugs: **Plan Benefit Package:** States should identify their required Medicaid and demonstration-specific benefits, to include specific covered services, maximum benefit coverage amounts, maximum benefit periodicity, copayments/coinsurance amounts, and prior authorization requirements. **Drug Files:** States should develop a list of the drugs required to be included 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.

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

Key Date	Entity	Required Action
Early 2013 – Spring 2013	CMS	CMS will provide states with training on the use of HPMS to review materials submitted by interested organizations via HPMS. CMS will provide states with technical guidance on representing Medicaid and demonstration-specific benefits in HPMS, use of HPMS during the review process, and the joint review process in general.
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.
March - April 2013	States	States release guidance to interested organizations on the minimum Medicaid and demonstration-specific benefits to be included in MMPs' plan benefit package submissions.
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	MTMP submission deadline.
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	Submission of proposed plan benefit packages to CMS.
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 perform reviews to assure adherence to contract requirements prior to implementation. CMS and states jointly confirm readiness requirements have been met.

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

Key Date	Entity	Required Action
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.
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 www.medicare.gov 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).

Appendix 2. Instructions for State Users to Obtain a CMS User ID

How to Request a CMS User ID with HPMS Access for a State User Needing Access for the Capitated Financial Alignment Program

To obtain a CMS user ID with access to HPMS, the state user should follow these steps:

- Download the *Application for Access to CMS Computer Systems* form from http://www.cms.hhs.gov/InformationSecurity/Downloads/EUAaccessform.pdf.

- Complete the form as follows for each individual that will need HPMS access:

  - Section 1 – Check "New" as the type of request.

APPLICATION FOR ACCESS TO CMS COMPUTER SYSTEMS

1. TYPE OF REQUEST *(Check only one)*:

☑ NEW *(Issue a CMS UserID)*

☐ CONNECT/DISCONNECT *(Add/remove access authorities)*

☐ CERTIFY *(Due date: ___/_____)* *mo* *yr*

☐ CHANGE USER INFORMATION *(Note new info)*

☐ DELETE *(Remove CMS UserID from all CMS systems)*

USERID *(Capital Letters)*

  - Section 2 – Check "State Agency" and enter your state name followed by "FA Demo" (e.g., Maryland FA Demo). Complete the Section 2 data entry fields, where applicable.

2. USER INFORMATION

☐ CMS Employee
☐ Medicare Advantage / Medicare Advantage with Prescription Drug / Prescription Drug Plan / Cost Contracts – Using HPMS Only
☐ Medicare Advantage / Medicare Advantage with Prescription Drug / Prescription Drug Plan / Cost Contracts – Using Other Systems
☐ CITIC Contractor
☐ Program Safeguard Contractor
☐ Medicare Contractor/Intermediary/Carrier
☐ Contractor (non-Medicare contract with CMS)
☐ Researcher
☐ Quality Improvement Organization
☐ End-Stage Renal Disease Network
☑ State Agency (State of Maryland FA Demo)
☐ Federal Govt – Baltimore HR Center

  - Section 3 – Leave blank.

Appendix 2. Instructions for State Users to Obtain a CMS User ID

- 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_CommlUser".

4. REQUIRED ACCESSES *(See http://www.cms.hhs.gov/mdcn/bmcjcreport.asp for list of available jobcodes)*

☐ Connect	☐ Disconnect	☐ Keep	Default CMS Employee (standard desktop & network with CMS e-mail acct)	☐ Connect	☐ Disconnect	☐ Keep
				☐ Connect	☐ Disconnect	☐ Keep
				☐ Connect	☐ Disconnect	☐ Keep
☐ Connect	☐ Disconnect	☐ Keep	Default Non-CMS Employee (standard network access)	☐ Connect	☐ Disconnect	☐ Keep
				☐ Connect	☐ Disconnect	☐ Keep
				☐ Connect	☐ Disconnect	☐ Keep
☑ Connect	☐ Disconnect	☐ Keep	HPMS_P_CommlUser	☐ Connect	☐ Disconnect	☐ Keep

- Section 5 – State briefly that you are a state user who needs to access HPMS for the Capitated Financial Alignment program.

5. JUSTIFICATION *(If name change, show Old Name =, New Name =)*

State user who needs access to HPMS for the Capitated Financial Alignment program.

- 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. <u>This step is critical to ensuring the successful processing of your request</u>.

- Submit the original form (not a copy) user ID form via traceable carrier to:

  Marla Rothouse
  Re: HPMS Access
  7500 Security Blvd.
  Location: S3-12-07 / Mailstop: S3-13-23
  Baltimore, MD 21244-1850

For questions regarding these instructions, please contact Marla Rothouse at either 410-786-8063 or marla.rothouse@cms.hhs.gov. For questions regarding the status of a request, state reviewers should contact hpms_access@cms.hhs.gov.

- Please note that User IDs are unique and states should submit completed forms for each individual who will need access to HPMS.

<u>Common Mistakes on the *Application for Access to CMS Computer Systems* Form</u>

Please be aware of the following common mistakes when preparing your request for HPMS access:

- You must always provide a Social Security Number. CMS will **<u>not</u>** process a request without this piece of information.
- You must complete the form in ink, not pencil.
- You must submit the original hardcopy form with an original signature and date. **<u>Photocopies and faxes are unacceptable</u>**.