DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CENTER FOR MEDICARE

DATE: January 14, 2014

TO: Medicare-Medicaid Plans

FROM: Danielle Moon, J.D., M.P.A
Director, Medicare Drug and Health Plan Contract Administration Group

Tracey McCutcheon, M.H.S.A., M.B.A.
Acting Director, Medicare Drug Benefit and C&D Data Group

SUBJECT: Capitated Financial Alignment Demonstration Medicare-Medicaid Plan Annual Requirements and Timeline for CY 2015

This guidance provides an overview of the contract year (CY) 2015 Medicare requirements and timeframes for Medicare-Medicaid plans (MMPs) in states that have already implemented their demonstrations in 2013 and 2014, as well as those states that will implement their demonstrations later in 2014. The Centers for Medicare & Medicaid Services (CMS) released separate guidance on January 13, 2014, "CY 2015 Capitated Financial Alignment Demonstration Timeline," to organizations interested in participating in state demonstrations that will begin in 2015.[1] The requirements described in this guidance are in addition to those required at the time of application and are consistent with the annual renewal requirements for all Medicare health plans.

The MMP annual submission timelines are aligned with the standard Medicare Advantage and Part D annual schedule. CMS requires that MMPs resubmit the following items on an annual basis:

- A network adequate to provide enrollees with timely and reliable access to providers and pharmacies for Medicare drug and medical benefits based on requirements in the Medicare Parts C and D programs. In addition, states will evaluate networks for Medicaid services, including long-term supports and services.
- If applicable based on the initial model of care submission in the CY 2013 or CY 2014 application cycle, a model of care that meets CMS and any applicable state requirements.
- An integrated formulary that meets Part D and Medicaid requirements;

[1] Refer to http://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Downloads/2015_NewApplicantGuidance.pdf.

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

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

Table 1: Previously Released Guidance

Topic	Link to document
Preferred Demonstration Standards (Appendix 1)	http://cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Downloads/FinalCMSCapitatedFinancialAlignmentModelPlanGuidance.pdf
State-specific Readiness Review Information	http://cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/ReadinessReviews.html
MMP Enrollment and Disenrollment Guidance	http://cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/MMPFinalEnrollGuidance.pdf
Additional State-specific Enrollment Guidance	http://cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/InformationandGuidanceforPlans.html
State-specific Enrollment and Marketing Guidance	http://cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/InformationandGuidanceforPlans.html
Waiver of Part D LIS Cost-Sharing Amounts	http://cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/Part_D_Cost_Sharing_Guidance.pdf
Model of Care Scoring Criteria	January 2014
Model of Care Submission Requirements	January 2014. Applicants and current plans required to resubmit their models of care should refer to the CY 2015 MMP application for additional information.

Past Performance Review Methodology Updates for CY 2015 [2]	January 2014

A. Network Adequacy Determinations

MMPs will be required to resubmit their network information in 2014 to ensure that each MMP continues to maintain a network of providers that is sufficient in number, variety, and geographic distribution to meet the needs of the enrollees in its service area. CMS will release guidance on this resubmission process later this year.

B. Model of Care (MOC)

Only those plans that received one-year approvals of their MOCs at the time of application will be required to resubmit their MOCs during the CY 2015 cycle. MOCs must be submitted no later than February 25, 2014. Please note that, effective CY 2015, all newly submitted MOCs must conform to the revised MOC, which has been reorganized to reflect four elements. Please note, however, that the revised MOC continues to capture all of the information previously collected as part of the original MOC structure. Additional information about these requirements will be released concurrent with the release of the CY 2015 applications.

MMPs will receive an automated HPMS notification during the application cycle that their MOCs are due for resubmission . For example, an MMP with a MOC that is approved through CY 2016 would receive an HPMS notification at the beginning of the CY 2016 application cycle in January 2015. MMPs that need to resubmit MOCs after their initial application has been approved will not be required to complete a new application.

C. Formulary and Supplemental Drug Files

Each year, MMPs must submit and be approved to offer an integrated formulary for that contract year that meets both Medicare Part D and Medicaid requirements. CMS will require all MMPs to submit a demonstration-specific formulary. For CY 2015 formulary approval, MMPs must submit: (1) an updated base Part D formulary and supplemental Part D formulary files, as applicable, consistent with CY 2015 Part D formulary application guidance; and (2) an updated supplemental non-Part D drug formulary file, the Additional Demonstration Drug (ADD) file. MMPs must submit their base formularies no later than **June 2, 2014**. Supplemental formulary files are due in HPMS on **June 6, 2014**.

All MMPs must submit an ADD file which can only contain non-Part D drugs. Non-Part D drugs include drugs in Medicare Part D excluded categories, over-the-counter drugs, and other

---

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

products required by the state to be included on the integrated formulary. Non-Part D drugs cannot be submitted to CMS on Prescription Drug Event (PDE) records.

CMS will work with states to provide guidance to interested organizations by April 2014 regarding drugs required to be included on the ADD file, by National Drug Code (NDC) and/or Universal Product Code (UPC), to ensure that MMPs 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 are solely responsible for reviewing and approving the ADD file. CMS will approve all other submitted formulary files. Reviews will begin immediately after the submission deadlines and will continue until all deficiencies have been resolved. CMS will work with states to establish deadlines for finalizing state reviews of the ADD files.

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

D. Medication Therapy Management (MTM) Program

As provided under 42 CFR §423.153(d) and in Chapter 7 of the Prescription Drug Benefit Manual,[3] all Part D sponsors, including MMPs, are required to annually submit Medication Therapy Management (MTM) programs. Although state reviewers will be able to view MTM program submissions in HPMS, CMS is fully responsible for reviewing and approving interested organizations' MTM program submissions. Each interested organization must establish an MTM program 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 MTM program, including interventions for both beneficiaries and prescribers, an annual comprehensive medication review (CMR) with written summaries in CMS standardized format (the CMR must include an interactive person-to-person, or telehealth consultation), and quarterly targeted medication reviews with follow-up interventions when necessary.

CMS expects to release guidance on the 2015 MTMP submission requirements via an HPMS memorandum after finalization of the 2015 Call Letter and Final Rule. The 2015 MTMP

---

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

submission module will be launched on May 19, 2014, with a submission deadline of June 2, 2014.

Prior to the release of the CY 2015 guidance memorandum, states may obtain MTMP information from the guidance memorandum provided to Part D sponsors regarding CY 2014 MTMP submissions.[4] Also, states should be aware of proposed revisions through the annual Call Letter process for 2015. Other proposed revisions to Part D MTM requirements, with a proposed effective date of January 1, 2015, have been published as a notice of proposed rulemaking in the Federal Register (CMS-4159-P, Medicare Program: Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs). Revisions include proposed changes to the MTM eligibility criteria to target more beneficiaries (including lowering the MTM program annual cost threshold) and requirements for sponsors to have an outreach strategy designed to effectively engage all at-risk beneficiaries enrolled in the plan.

E. Plan Benefit Package (PBP)

Medicare-Medicaid plans must also submit their plan benefit packages (PBPs) annually to ensure that MMPs accurately describe the coverage details and cost-sharing for all Medicare, Medicaid, and demonstration-specific benefits.

CMS will launch the HPMS PBP module on April 11, 2014 and MMPs must submit their integrated PBPs to CMS by **June 2, 2014.** CMS is further enhancing the PBP software for CY 2015 to allow for expanded data entry for non-Medicare benefits. CMS will work with states to issue PBP guidance that clearly defines the state-required Medicaid benefits and supplemental demonstration benefits by the time the PBP module is launched in April 2014. CMS will release an online training module on the CY 2015 PBP software for plans on April 11, 2014.

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

F. Past Performance

It is a priority for both CMS and states to assess MMPs' capacity and experience in serving Medicare-Medicaid beneficiaries, both prior to and following the plan selection process. Previous performance in the Medicare program will continue to be used to determine organizations' eligibility for receiving passively enrolled beneficiaries. Among the mechanisms CMS will use to assess an organization's Medicare performance are sanctions, the past

---

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

performance review methodology, and the Medicare Plan Finder "consistently low performing" icon (LPI).

1. Sanctions

In our March 29, 2012, guidance (refer to http://cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/MarchGuidanceDocumentforFinancialAlignmentDemo.pdf), CMS explained that organizations currently under Medicare enrollment and/or marketing sanction are ineligible to participate in the demonstration. Organizations will be ineligible to participate if they are under sanction, as described in 42 CFR §422.750 and 42 CFR §423.750, at the time CMS and the state seek to execute the three-way contract. As such, CMS accepted 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' January 17, 2013, HPMS memorandum entitled "2014 Application Cycle Past Performance Review Methodology Update" available at the following link: http://cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/2014-Application-Cycle-PastPerformance-Methodology-Final.pdf. CMS recently released draft past performance review methodology guidance for CY 2015 for comment via an HPMS memorandum entitled, "2015 Application Cycle Past Performance Review Methodology Update – REQUEST FOR COMMENTS."CMS plans to release final past performance review methodology guidance for CY 2015 in January 2014.

- LPI designation is given to entities with poor or below average Medicare plan ratings (also called "star ratings" or "quality ratings") – i.e., less than three stars for three or more consecutive years.

An organization that is an outlier in CMS' past performance analysis and/or has an LPI on the Medicare Plan Finder website may qualify to offer an MMP, provided that the organization meets all plan selection requirements in the CMS-state joint plan selection process and passes its

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

An organization that is ineligible to receive passive enrollment will only be able to enroll: 1) individuals who are currently enrolled in another Medicare or Medicaid managed care plan sponsored by the same organization; and 2) individuals who opt into the organization's MMP. When an organization is no longer considered by CMS to be a past performance outlier and/or no longer has an LPI on Medicare Plan Finder, it may be eligible to receive passive enrollment.

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

Some interested organizations that have no experience in the Medicare program may have a parent or sibling organization with previous Medicare experience. For these entities, CMS' past performance and LPI methodologies consider information about the parent and sibling organizations' previous Medicare past performance.

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

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

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

b. Treatment of New Legal Entities under the LPI Analysis

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

Appendix 1: Key Dates for MMP Resubmission of Annually Required Information for CY 2015

Key Date	Entity	Required Action
Early 2014 – Spring 2014	States	States develop specifications for representing Medicaid and demonstration-specific benefits and covered drugs in HPMS: **<u>Plan Benefit Package</u>:** States inform MMPs how to represent Medicaid and demonstration-specific benefits in the updated PBP module. **<u>Drug Files</u>:** States develop a list of the drugs the MMPs are required to include on the ADD file (by NDC and/or UPC). States should provide this list to CMS and interested organizations as early as possible. It is at the states' discretion whether to require their plan applicants to include one proxy NDC or multiple NDCs on the ADD file for each covered product.
February 25, 2014	MMPs	If applicable based on the approval period for the initial model of care submission in the CY 2013 or CY 2014 application cycle, a model of care that meets CMS and any applicable state requirements.
April 5, 2014	CMS	Release of the Plan Benefit Package module in HPMS.
May 19, 2014	CMS	Release of the CY 2015 Medication Therapy Management (MTM) program submission module in HPMS.
May 9, 2014	CMS	Release of HPMS Part D formulary submission module for CY 2015.
June 2, 2014	MMPs	2015 Part D Formulary Submissions due from all sponsors offering Part D including Medicare-Medicaid Plans (11:59 p.m. PDT).
June 2, 2014	MMPs	Deadline for submitting plan benefit packages via HPMS.
June 2, 2014	MMPs	2015 MTM program submissions due from all sponsors offering Part D including Medicare-Medicaid Plans (11:59 p.m. PDT).

Key Date	Entity	Required Action
June 6, 2014	MMPs	Deadline for submitting Additional Demonstration Drug file and any applicable Part D supplemental formulary files (Free First Fill File, Over-the-Counter Drug File, and Home Infusion File) via HPMS (11:59 p.m. PT).
June - July 2014	CMS and states	CMS and the states review plan benefit packages and drug file submissions.
August 31, 2014	CMS	CMS completes MTM program reviews.
September 2014	CMS	Roll-out of MA and Part D plan landscape documents, which include details (including high-level information about benefits and cost-sharing) about all available Medicare health and prescription drug plans for CY 2015.
September 16-30, 2014	CMS	CMS mails the CY 2015 Medicare & You handbook. The handbook includes high-level information – including basic cost-sharing and premium information – about available health plan options in a beneficiary's specific geographic location.
September 30, 2014		Annual Notice of Change (ANOC) must be received by current members by September 30 consistent with each state's MMP marketing guidance
Fall 2014	MMPs	MMPs submit annual network information.
October 1, 2014	MMPs	CY 2015 marketing activity begins.
October 1, 2014	CMS	Medicare Plan Finder on www.medicare.gov goes live for CY 2015.
October 15, 2014 – December 7, 2014	Beneficiaries	Annual Coordinated Election Period.