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

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TO: Medicare-Medicaid Plans

FROM: Kathryn A. Coleman
Acting Director, Medicare Drug and Health Plan Contract Administration Group, Center for Medicare

Sharon Donovan
Director, Program Alignment Group, Medicare-Medicaid Coordination Office

Amy K. Larrick
Acting Director, Medicare Drug Benefit and C&D Data Group, Center for Medicare

SUBJECT: Medicare-Medicaid Plan Annual Requirements and Timeline for CY 2016

This guidance provides an overview of the contract year (CY) 2016 Medicare requirements and timeframes for Medicare-Medicaid plans (MMPs) whose contracts are already effective, or will become effective at any point in CY 2015. 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. This memorandum also provides additional clarification regarding the use of past performance information for determining eligibility for receipt of passive enrollment.

CMS will provide additional guidance regarding the applicability of CY 2016 Final Call Letter guidance to MMPs following the release of the Final Call Letter.

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:

- Information to ensure the plan has 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 service providers, including long-term supports and services.
- If applicable based on the approval period given to the most recent model of care (MOC) submission, a MOC that meets CMS and any applicable state requirements.
- An integrated formulary that meets Part D and each state's Medicaid and demonstration requirements;

- A medication therapy management (MTM) program that meets Part D requirements; and
- A plan benefit package (PBP) that integrates all 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 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
Past Performance Review Methodology Updates for CY 2016	http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/index.html

A. Network Adequacy Determinations

MMPs will be required to resubmit their network information in September 2015 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. Prior to the September submission, MMCO will provide active MMPs with opportunities to assess the Medicare portion of their medical networks in the HPMS Network Management Module (NMM). The reference file that provides the MMP standards is available at: http://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/InformationandGuidanceforPlans.html as well as on the reference page within the NMM. CMS will release additional guidance on the submission process, including how MMPs will be able to submit exception requests using the new standards for the September submission later this year.

B. Model of Care (MOC)

1. Reapproval of MOCs

No currently operating MMPs are required to resubmit a MOC during the CY 2016 cycle. We do, however, anticipate that some MMPs will be required to submit during next year's (CY 2017) submission cycle in February 2016. 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 2017 would receive an HPMS notification at the beginning of the CY 2017 application cycle in January 2016.

2. Guidance for Off-cycle Submission of Summaries of MOC Changes

CMS continues to emphasize the importance of the MOC as a fundamental component of the MMPs' quality improvement framework. In order to more effectively address the specific needs of its enrollees, an MMP may need to modify its processes and strategies for providing care during the course of its MOC approval timeframe.

We have received some inquiries from MMPs about changes to their originally submitted and approved MOCs since the time of application. We anticipate that only certain circumstances require MMPs to make changes to their MOCs that are so significant that notification of CMS is warranted. In this guidance, we describe MOC changes requiring CMS notification and how MMPs should submit their MOC changes to CMS.

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MMPs should notify CMS of modifications, including fundamental organizational changes and changes that are essential to MOC processes and functions. Examples of changes that need to be submitted include, but are not limited to:

- Changes in legal entity, parent organization, and oversight (novation/mergers, changes to corporate structure);

- Target population changes;
- New benefit inclusion or benefit exclusions;
- Changes in level of authority/oversight (medical provider to non-medical provider/clinical vs. non-clinical personnel conducting care coordination activities);
- Changes to delegated providers and agreements; and
- Changes in policies and/or procedures pertinent to the health risk assessment process, development and ongoing updates to the individualized care plan, changes to risk stratification methodology, care transitions protocols, communication and frequency of meetings with ICT members, beneficiaries, and caregivers.

Changes that do **not** need to be submitted include:

- Changes in administrative staff, types/level of staff;
- Updates on demographic data about the target population;
- Updates to quality improvement metric results;
- Additions/deletions of specific named providers;
- Grammatical and/or language changes; and
- Changes to improve a low scoring MOC.

We refer MMPs to the CY 2016 Draft and Final Call Letters, as well as any subsequent guidance, for additional information about the new HPMS module that will be made available later in 2015. We anticipate that MMPs will be able to use the same functionality to submit MOC changes that must be submitted per the guidance above. In the meantime, however, MMPs that make significant changes to their MOCs must submit a summary of the pertinent modifications to the approved MOC to the Medicare-Medicaid Coordination Office at MMCOCapsModel@cms.hhs.gov. MMPs do not need to submit a redlined version of the approved MOC with the revisions highlighted but should keep one on record in the event that CMS requests it or the MMP is selected to participate in an audit.

C. Formulary and Supplemental Drug Files

Each contract year, each MMP must submit and be approved to offer a demonstration-specific, integrated formulary that meets both Medicare Part D and Medicaid requirements. For CY 2016 formulary approval, MMPs must submit: (1) an updated base Part D formulary and supplemental Part D formulary files, as applicable, consistent with CY 2016 Part D formulary application guidance; and (2) an updated Additional Demonstration Drug (ADD) file containing non-Part D drugs. MMPs must submit their base formularies no later than **June 1, 2015**. Supplemental formulary files are due in HPMS on **June 5, 2015**.

All MMPs must submit an ADD file which can only contain non-Part D drugs. Non-Part D drugs include drugs in Medicare Part D excluded categories, over-the-counter drugs, and other products required by the state to be included on the integrated formulary. Non-Part D drugs cannot be submitted to CMS on Prescription Drug Event (PDE) records.

CMS will work with states to provide ADD file guidance to MMPs by April 2015. As in previous years, state guidance will address what products MMPs are required to cover. 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.

We have recently made changes in HPMS that allow states to approve mid-year ADD file changes. We clarify that mid-year ADD file change submissions are at the discretion of each state. CMS will work with states to open HPMS gates for ad hoc and/or regular ADD file resubmissions as necessary.

CMS will release a CY 2016 formulary training video for plans on or around March 18, 2015.

D. Medication Therapy Management (MTM) Program

As provided under 42 CFR §423.153(d) and in Chapter 7 of the Prescription Drug Benefit Manual,[1] 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. All MMPs must implement 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 2016 MTM program submission requirements via an HPMS memorandum after finalization of the 2016 Final Call Letter. The 2016 MTMP submission module will be launched on April 20, 2015, with a submission deadline of May 4, 2015.

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

E. Plan Benefit Package (PBP)

1. Annual Resubmission of the PBP

MMPs must 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 10, 2015 and MMPs must submit their integrated PBPs to CMS by **June 1, 2015.** CMS is further enhancing the PBP software for CY 2016 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 2015. CMS will release an online training module on the CY 2016 PBP software for plans on April 10, 2015.

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.

2. PBP Corrections for MMPs

As part of our demonstration implementation activities, the Medicare-Medicaid Coordination Office, in partnership with the Center for Medicare, has provided additional flexibility to MMPs with respect to PBP corrections after the time of final PBP approval. This flexibility has been necessary to accommodate mid-year legislative changes to Medicaid benefits, as well as the timing of payment rate finalization.

In this guidance, we clarify that:

1. For currently operating MMPs, CMS will approve MMPs' requests to make PBP revisions to add or remove plan-offered supplemental benefits between the time of the release of the National Average Monthly Bid Amount in early August and sign-off of PBPs in HPMS in late August. This will allow plans to accommodate any benefit changes in their required documents (including the Annual Notice of Change, Evidence of Coverage/Member Handbook, and Summary of Benefits) during the Annual Election Period.

2. For currently operating MMPs, we will allow rate-related PBP corrections to supplemental benefits during the Center for Medicare's annual correction window in September (see CY 2016 Final Call Letter for the exact dates of this window), but only for purposes of adding supplemental benefits to PBPs. MMPs that elect to correct their PBPs must work with their contract management team on an appropriate member communication strategy (e.g., addenda or errata sheets for materials that have already been mailed to members; updates to other materials for current and prospective members). In addition, there will be no compliance penalty for a PBP correction provided an MMP meets these conditions.

3. For all MMPs, any PBP corrections after the Center for Medicare's annual correction window in September (or, for MMPs with mid-year contract effective dates, the start date of marketing stipulated in the plan's final readiness report) will be considered on a case-by-case basis. PBP corrections due to plan error will be subject to compliance action.

F. Past Performance

It is a priority for both CMS and states to assess MMPs' capacity and experience in serving Medicare-Medicaid beneficiaries, both before and after the plan selection process. Previous and current 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 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 effectuate the three-way contract. As such, CMS accepted applications from all organizations, regardless of their sanction status, and considers all organizations potentially eligible to participate as MMPs prior to the effectuation of the three-way contracts. If, however, an organization is under sanction and that sanction is not removed at the time CMS and the state seek to effectuate 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 effectuation 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. CMS recently released final past performance review methodology guidance for CY 2016 via a February 11, 2015, HPMS memorandum entitled, "2016 Application Cycle Past Performance Review Methodology Final."

- 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 2016 Medicare Advantage and Part D application and contracting cycle will be finalized in April 2015. In addition, CMS will provide plans with the results of an interim past performance analysis in the fall of 2015.

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.

Below, we clarify how CMS will assess a new legal entity's eligibility for passive enrollment after its three-way contract is effectuated.

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

Some MMPs 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 prior to the effectuation of the three-way contract.

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 apply this same methodology for purposes of determining whether a new legal entity offering an MMP will be eligible to receive passive enrollment at the time of the three-way contract's effectuation. However, once the new legal entity begins to acquire contracting experience (that is, after the three-way contract's effectuation), CMS begins to calculate a past performance score for the new legal entity, independent of it siblings' past performance scores. However, as noted below in section F.4, this will not be the only factor considered in determining an organization's eligibility for passive enrollment if a sibling entity's past performance prevented an MMP from participating in passive enrollment at the time of the three-way contract's effectuation.

b. Treatment of New Legal Entities under the LPI Analysis

To determine whether a new legal entity offering an MMP will be eligible to receive passive enrollment at the time of the three-way contract's effectuation, CMS imputes 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 three-way contract's effectuation.

However, given that star ratings are calculated at the contract level and that each contract begins to accumulate its own data related to star ratings after the three-way contract's effectuation, CMS does not impute sibling entity's star ratings or LPI status to a new legal entity once it begins to operate as an MMP contractor. This is similar to our treatment of past performance information for new legal entities as clarified in section F.3.a above. As noted below in section F.4, MMCO will consider certain factors in determining an organization's eligibility for passive enrollment if a sibling entity's LPI status prevented an MMP from participating in passive enrollment at the time of the three-way contract's effectuation.

4. Eligibility for Passive Enrollment after Effectuation of the Three-Way Contract

We clarify that MMP contracts whose past performance outlier or LPI status is attributable to a sibling legal entity's Medicare performance may be eligible for passive enrollment if the MMP's legal entity has demonstrated both sufficient MMP contracting experience and satisfactory operational performance. We will consider sufficient MMP contracting experience to be a period of no less than 90 calendar days following the effective date of the first wave of passive enrollment that would have been applicable to the MMP contract in a particular state had the contract not been prohibited from receiving passive enrollment. In addition, the MMP in question would need to not otherwise be a past performance outlier (based on the most current analysis of the new legal entity's performance), and would need to have demonstrated satisfactory operational performance and capacity since effectuation of the three-way contract. Satisfactory operational performance could be determined through, but would not be limited to, the following:

1. Satisfactory updated staffing estimates based on the projected new volume of enrollees. This information is initially collected as part of each MMP's readiness review process but would be re-reviewed based on the new enrollment assumptions.

2. Analysis of any MMP monthly reported data.

3. Review of any potential compliance actions either already issued, or in process of issuance; issues identified by contract management team; and complaints data in the complaints tracking module in HPMS.

If an MMP does not demonstrate satisfactory operational performance and capacity, MMCO and the state would delay receipt of passive enrollment for one or more additional cycles.

Appendix 1: Key Dates for MMP Resubmission of Annually Required Information for Contract Year 2016

Key Date	Entity	Required Action
Early 2015 – Spring 2015	States	States develop specifications for representing Medicaid and demonstration-specific benefits and covered drugs in HPMS: **Plan Benefit Package:** States inform MMPs how to represent Medicaid and demonstration-specific benefits in the updated PBP module. **Drug Files:** 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.
On or about March 18, 2015	CMS	Release of HPMS Part D formulary submission module for CY 2016.
May 4, 2015	MMPs	2016 MTM program submissions due from all sponsors offering Part D including MMPs (11:59 p.m. PDT).
April 10, 2015	CMS	Release of the Plan Benefit Package (PBP) module in HPMS.
April 20, 2015	CMS	Release of the CY 2016 Medication Therapy Management (MTM) program submission module in HPMS.
June 1, 2015	MMPs	2016 Part D Formulary Submissions due from all sponsors offering Part D including MMPs (11:59 p.m. PDT).
June 1, 2015	MMPs	Deadline for submitting PBPs via HPMS.
June 5, 2015	MMPs	Deadline for submitting Additional Demonstration Drug (ADD) 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 2015	CMS and states	CMS and the states review PBPs and drug file submissions.
August 31, 2015	CMS	CMS completes MTM program reviews.

Key Date	Entity	Required Action
September 2015	CMS	Roll-out of plan landscape documents on all available Medicare health and prescription drug plans for CY 2016.
September 16-30, 2015	CMS	CMS mails the CY 2016 Medicare & You handbook. The handbook includes high-level information about available health plan options in a beneficiary's specific geographic location.
September 30, 2015		Annual Notice of Change (ANOC) must be received by current members by September 30 consistent with each state's MMP marketing guidance
Fall 2015	MMPs	MMPs submit annual network information.
October 1, 2015	MMPs	CY 2016 marketing activity begins.
October 1, 2015	CMS	Medicare Plan Finder on www.medicare.gov goes live for CY 2016.
October 15, 2015 – December 7, 2015	Beneficiaries	Annual Coordinated Election Period.