



CENTERS FOR MEDICARE & MEDICAID SERVICES

DATE: January 30, 2013

TO: Medicare-Medicaid Plans in States Seeking to Implement Capitated Financial Alignment Demonstrations in 2013

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

Cynthia G. Tudor, Ph.D.
Director, Medicare Drug Benefit and C&D Data Group

SUBJECT: Capitated Financial Alignment Demonstration Medicare-Medicaid Plan Annual Requirements and Timeline for CY 2014

This guidance provides an overview of the contract year (CY) 2014 Medicare requirements and timeframes for Medicare-Medicaid plans (MMPs) in states that anticipate implementing their demonstrations in 2013. The Centers for Medicare & Medicaid Services (CMS) released separate guidance on January 9, 2013, to organizations interested in participating state demonstrations that will begin in 2014.¹ The requirements described in this guidance are in addition to those required at the time of application for CY 2013 and are consistent with the annual renewal requirements for all Medicare health plans.

Starting with the CY 2014 cycle, the MMP annual submission timelines will be 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.
- If applicable based on the initial model of care submission in the CY 2013 cycle, a model of care that meets CMS and any applicable state requirements.
- An integrated formulary that meets Part D and Medicaid requirements;
- 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.

¹ http://cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/2014_PlanGuidance01092013.pdf

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/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 ²	http://cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/2014-Application-Cycle-PastPerformance-Methodology-Final.pdf

A. Health Plan Management System (HPMS)

CMS and state reviewers will continue to use the Health Plan Management System (HPMS) as the system of record for managing MMPs.

B. Network Adequacy Determinations

MMPs will be required to resubmit their network information in 2013 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.

C. Model of Care (MOC)

All MMPs in States implementing capitated financial alignment demonstration in 2013 were granted a two or three-year approval of their Models of Care. Therefore, there will be no MOC resubmission requirements for these plans in the CY 2014 cycle.

² Information on the 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>.

D. 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. We note that the CY 2014 formulary submission process has been streamlined relative to the CY 2013 MMP formulary requirements. For CY 2014 formulary approval, MMPs must submit: (1) an updated base Part D formulary and supplemental Part D formulary files, as applicable; and (2) an updated supplemental non-Part D drug formulary file. MMPs must submit their base formularies no later than **May 31, 2013**. Supplemental formulary files are due in HPMS on **June 7, 2013**.

All MMPs must submit a supplemental formulary file called the Additional Drug Demonstration (ADD) file which can only contain non-Part D drugs. Non-Part D drugs include drugs in Medicare Part D excluded categories, over-the-counter drugs, and other products required by the state to be included on the integrated formulary. Beginning with the CY2014 submissions, Medicare-Medicaid Plans will no longer be required or permitted to submit an Excluded Drug File for drugs in Part D excluded classes of drugs. Instead, all non-Part D drugs must be represented on the ADD file. Non-Part D drugs cannot be submitted to CMS on Prescription Drug Event (PDE) records.

CMS has requested that states provide guidance to interested organizations as early as possible in 2013 regarding drugs required to be included on the ADD file, by 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 has made updates to the formulary review and approval process in HPMS to provide states with a specific reviewer track for the ADD file in HPMS. We will provide more information on this process prior to the formulary submission deadline.

E. 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

³ <http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter7.pdf>

- 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 2014 MTMP submission requirements via an HPMS memorandum. The 2014 MTMP submission module will be launched on April 22, 2013, with a submission deadline of May 6, 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.⁴

F. 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 in mid-April 2013 and MMPs must submit their integrated PBPs to CMS by **June 3, 2013**. CMS has enhanced the PBP software to allow for expanded data entry for non-Medicare benefits. No later than the launch of the PBP module in April, states should issue guidance that clearly defines the state-required Medicaid benefits and supplemental demonstration benefits. CMS will conduct a training on the CY 2014 PBP software for interested organizations in early 2013.

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

⁴ <http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Memo-Contract-Year-2013-Medication-Therapy-Management-MTM-Program-Submission-v041012.pdf>

Appendix 1. Key Dates for MMP Submission of Annually Required Information for CY 2014

Key Date	Entity	Required Action
Early 2013 – Spring 2013	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.
April 2013	CMS	Release of the Plan Benefit Package module in HPMS.
April 22, 2013	CMS	Release of the CY 2014 Medication Therapy Management (MTM) program submission module in HPMS.
May 6, 2013	MMPs	Deadline for submitting MTM programs via HPMS.
May 13, 2013	CMS	Release of HPMS Part D formulary submission module for CY 2014.
May 31, 2013	MMPs	2014 Part D Formulary Submissions due from all sponsors offering Part D including Medicare-Medicaid Plans (11:59 p.m. PDT).
June 3, 2013	MMPs	Deadline for submitting plan benefit packages via HPMS.
June 7, 2013	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.
June - July 2013	CMS and states	CMS and the states review plan benefit packages and drug file submissions.
July 31, 2013	CMS	CMS completes MTM program 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 16-30, 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.
Fall 2013	MMPs	MMPs submit annual network information.
October 1, 2013	MMPs	CY 2014 marketing activity begins.
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.