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

MEDICARE-MEDICAID COORDINATION OFFICE

Date: November 17, 2016

To: All Medicare Medicaid Plans

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Subject: Contract Year (CY) 2017 Medicare Requirements Readiness Checklist for Medicare-Medicaid Plans (MMPs)

The purpose of this memorandum is to remind Medicare-Medicaid Plans (MMPs) of critical Medicare Parts C and D requirements for the Annual Election Period (AEP) and coverage beginning January 1, 2017.

The Contract Year (CY) 2017 Readiness Checklist is a non-exhaustive summarization of key operational requirements as established in statutes, regulations, manual chapters, Health Plan Management System (HPMS) memos, applications, and other advisory materials. This checklist is meant to serve as technical assistance to MMPs for those Medicare requirements that should be in place for CY 2017.

Your organization should review this checklist carefully and take the necessary measures to fulfill these key requirements for CY 2017. Please note that the Readiness Checklist is not an exhaustive list of all requirements. In addition to Medicare Advantage and Part D references cited throughout the readiness checklist, your organization should refer to its three-way contract; Appendix 5: Additional State Specific Enrollment Guidance; State Specific Marketing Guidance; State Specific MMP Reporting Requirements; and other guidance documents for MMPs that can be found at http://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/InformationandGuidanceforPlans.html.

Should you identify areas where your organization needs assistance or is not/will not be in compliance, your organization must report those problems to your Contract Management Team (CMT). If you need additional information regarding requirements listed in the checklist, please refer to the appropriate CMS guidance, contact your CMT, or email the Medicare-Medicaid Coordinate Office at MMCOCapsReporting@cms.hhs.gov.

CY 2017 Medicare-Medicaid Plan Readiness Checklist

Table of Contents

A. Systems, Data, & Connectivity

I. Health Plan Management System (HPMS)

- Ensure key staff members register for the Plan Connectivity Data Module within HPMS by e-mailing hpms_access@cms.hhs.gov.
- Update your organization's contact contract information in HPMS, ensuring all information is current. Changes to any HPMS contacts or MMP data are expected to be made immediately upon the effective date of the responsibility transfer.
- All MMPs are required to keep the data on the HPMS contact and data information pages up-to-date throughout the year. It is critical to enter and maintain contract-level contact information as it is used for other purposes within HPMS and other CMS systems, as well as in support of information displayed publicly.
- Refer to the HPMS contact definitions to assist you with completing the contact and information sections.

(HPMS Basic Contract Management Manual and Contact Definitions)

II. National Provider Identifier (NPI) Requirements

- Consistent with the Medicare Access and CHIP Reauthorization Act of 2015, for CY 2016 and thereafter, claims for covered Part D drugs must include a valid prescriber NPI.
- MMPs must submit to CMS only prescription drug event (PDE) records containing an active and valid individual prescriber NPI. 42 C.F.R. 423.102(c)(5) and (6).

(HPMS memos 10/1/2012, 04/23/2013, and 04/7/2016)

III. MARx

- Review and implement guidance regarding software improvements to the enrollment and payment systems that occur on a quarterly basis (February, May, August, and November)
- Below are the key steps in establishing data exchanges with CMS MARx enrollment and payment systems:
- MMPs must complete a Plan Connectivity Data (PCD) Module form available in HPMS under the Contract Management Tab with a dropdown option of "Plan Connectivity." This is an online form which requires the enrollment connectivity information for how data will be transmitted or received between MMP and CMS.

    Enrollment Submission Method Connectivity Type:
    - TIBCO MFT Internet Server [IS] (SFTP),
    - TIBCO MFT IS (HTTPS),

  - TIBCO MFT Platform Server (PS),
  - T1 Connect: Direct,
  - Gentran, or
  - 3rd Party.

- MMPs must designate External Point of Contact (EPOC), an approving official (responsible IT security manager or supervisor) who acts as the authorizer for approving end users and CMS enrollment vendor requesting access via the CMS Enterprise Identity Data Management (EIDM) system. (https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/mapdhelpdesk/IACS.html)
- MMPs must appoint an EPOC in their organization and submit a designation letter with name, title, address and contact information of the EPOC with company official wet signature to:

  The Centers for Medicare & Medicaid Services
  CM/MPPG/DPO
  7500 Security Boulevard, Mail Stop C1-05-17
  Baltimore, MD 21244

- EPOC assumes an important role in controlling end user access to CMS MARx system within the MMP organization as well as outside entities per the three-way contract (State Medicaid Agencies and their enrollment brokers). Therefore, EPOC must be notified of any staffing changes whether a new staff comes on board or the staff leaves the MMP organization or moves to another duties within the organization. This includes staffing changes that occur in State Medicaid Agency or enrollment broker organization.
- EPOC must approve CMS enrollment vendor's access as a submitter and ensure their access stays uninterrupted to the EIDM system. Their role is to submit any MMP enrollment and disenrollment transactions to CMS MARx system on behalf of capitated financial alignment model demonstration states as well as transmit any enrollment changes or informational updates that are communicated through the daily and monthly MARx reports to capitated financial alignment model demonstration states and to respective MMP.
- Ensure your External Point of Contact (EPOC) is notified of the changes regarding the Enterprise Identity Manager (EIDM) users.
  - An individual's access to EIDM will be partially disabled when 60 days or more lapses between system logins. (EIDM-IACS Migration Users Guide)
  - Submit beneficiary-level opioid point of sale (POS) edit notifications within seven (7) business days of the date on the beneficiary's written advance notice and submit implementations, terminations, and modifications of opioid POS edits into MARx within seven (7) business days of the event. (2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter)

IV. Medicare Plan Finder Data (MPF)

- **Pricing Data and Pharmacy Network Files.** MMPs must ensure timely and accurate submission of CY 2017 pricing data for posting on the Medicare Plan Finder (MPF). MMPs are required to submit MPF data during each regular submission window, which occurs every two weeks. MMPs may not auto-certify their pharmacy cost files. (HPMS memo 06/29/2016)
- MMPs must confirm pricing and pharmacy network data files for MPF are correct and accurate, and that only pharmacies under contract for 2017 are included for display. Incorrect data may result in suppression from the Medicare Plan Finder, and/or applicable compliance actions.

  (CY 2017 Pricing Data Requirements – 05/19/2016)
- **MPF File Pre-Submission Quality Assurance Testing.** MMPs must perform quality assurance activities prior to submitting MPF files to CMS. MMPs may be subject to Part D program compliance and enforcement actions as a result of MPF suppressions or inaccurate data submissions.
  - If your organization receives an outlier notification for your 2017 pricing and pharmacy data which was previously a known exception in 2016, your organization must re-confirm that the data continue to be accurate. If you do not confirm these data, your organization's pricing data may be suppressed on the MPF.
  - MPF submissions must be complete and accurate in all respects, and MMPs are solely accountable for any errors in their MPF data, regardless of how they come to CMS's attention. Because of the critical role the MPF plays in providing beneficiaries with reliable information about their drug plan options, CMS will suppress the display of an MMP's plan information as the result of any identified inaccuracy or failure to respond to a CMS inquiry about a data submission.
- **MPF Communications Website.** MMPs must ensure they have access to the MPF Communications website and have authorized new users. Updates and announcements relating to the quality assurance (QA) process are posted on the MPF Communication website, https://PartD.ProgramInfo.us/User_Security.

V. User Group Calls

- MMPs must ensure key staff registers for the CMS Part C & D User Calls at https://www.mscginc.com/registration/. Participants should call fifteen minutes before start time to ensure timely access to the call.

VI. Patient Safety Analysis Website

- MMPs must access the monthly Patient Safety Reports via the Patient Safety Analysis Website to compare their performance to overall averages and monitor their progress in improving Part D patient safety measures over time.

- These actionable reports include contract-level patient safety reports for expanded analyses and information and detailed beneficiary-claim level and outlier reports. Be advised that MMPs are required to use the website to view and download the reports and should be engaged in performance monitoring. (HPMS memo 04/06/2016)
- MMPs must ensure the Medicare Compliance Officer authorizes users to access the Overutilization Monitoring System (OMS), available via the Patient Safety Analysis Website. At least one user from each contract must have access to Summary and Confidential Beneficiary Reports to view and respond to beneficiary-level overutilization issues.
- MMPs must ensure the OMS quarterly reports are reviewed and acted upon and CMS receives a response within 30 days of the report. For additional information, the OMS User Guide is available on the Patient Safety Analysis Website under Help Documents. (HPMS memo 04/06/2016; also see *Improving Drug Utilization Controls in Part D*)

VII. Risk Adjustment Data Submissions[1]

- In order to receive proper payment, MMPs must be certified to submit data through both the EDS and RAPS. Information about becoming certified to submit data, guidance regarding data submission to CMS, and other resources can be found on the Customer Service Support Center (CSSC) website, www.csscoperations.com. Assistance with data submission can be obtained by csscoperations@palmettogba.com, or by calling 1-877-534-2772.
- MMPs shall submit encounter data consistent with MMP guidelines that can be found in HPMS Memos (dated October 24, 2013, April 29, 2014, May 23, 2014, and August 10, 2016) and in the applicable Medicare-Medicaid Capitated Financial Alignment Model Quality Withhold Technical Notes. The technical notes for Demonstration Year 1 are available at: https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Downloads/DY1QualityWithholdGuidance060614.pdf. The technical notes for Demonstration Years 2 and 3 are available at: https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Downloads/DY2and3QualityWithholdGuidance042916.pdf.
- Checklist items for EDS and RAPS submission are as follows:
    - Enroll to submit data through CSSC,
    - Subscribe to receive email updates,

[1] Risk adjustment data includes Risk Adjustment Processing System (RAPs) data and Encounter Data System (EDS) data.

- Perform certification requirements,
- Be familiar with guidance contained on the CSSC website, and
- Begin submission of production data within 4 months of contract effective date and within 180 days of date of service.

VIII. Prescription Drug Event (PDE) Requirements

- CMS requires that MMPs submit timely PDE records as follows: Submit original PDEs within 30 days following Date Claim Received or Date of Service (whichever is later),
    - Resolve rejected records and re-submit within 90 days following receipt of rejected record status from CMS, and
    - Submit adjustments and deletions within 90 days following discovery of issue requiring change.
- CMS expects MMPs to promptly resolve rejected PDE records and take corrective action to prevent a recurrence of the issue.
- MMPs must establish access to Acumen's Part D Payment Process Support Website. (HPMS memo 02/16/2016)
- MMPs must establish access to Acumen's PDE Analysis and PDE Reports websites. (HPMS memo 04/12/2016)
- MMP must ensure procedures are in place for analysis of recurring reports so that PDE data maintained by CMS (which are the basis for Part D Payment Reconciliation) and the organization's internal records correspond. CMS reports include:
    - Drug Data Processing System (DDPS) Cumulative Beneficiary Summary,
    - PDE Accounting Report,
    - P2P (Plan to Plan) files,
    - Coverage Gap Invoice Report,
    - Part D Potential Exclusion Warning Report and Part D Exclusion from Reconciliation Report, and
    - Payment Reconciliation System (PRS) reports.

B. Reporting

I. Healthcare Effectiveness and Data and Information Set (HEDIS®), Health Outcomes Survey (HOS), and Consumer Assessment of Healthcare Providers and Systems (CAHPS®)

- MMPs must be prepared to submit HEDIS, HOS, and CAHPS measures to the appropriate entity by the specified due date. (HPMS memo 08/19/2016)

II. Part C and Part D Reporting Requirements

- In addition to the MMP Core Reporting Requirements and applicable State-specific reporting measures, MMPs must be prepared to collect data on all Part C and Part D (as applicable) reporting requirements; conduct appropriate data validation for the Part C and Part D measures; and submit data to CMS according to the requirements. (HPMS memo 05/06/2016)

III. Reporting and Returning MMP Identified Overpayments

- Every organization offering an MMP is required to report and return to CMS any overpayment it received no later than 60 days after the date on which the organization or sponsor identified the overpayment. (HPMS memos 02/18/2015, 8/28/2015, 12/29/2015, 06/07/2016)

IV. Fiscal Soundness

- MMPs must use the Fiscal Soundness Module in HPMS to submit annual independently audited annual financial statements and 2017 quarterly financial statements. (HPMS memos 11/17/2015, 03/25/2016)

C. Contracting, Subcontractor Provisions, and Oversight

I. Any Willing Pharmacy (AWP) Contracting Requirements

- To comply with the Any Willing Pharmacy requirement, MMPs must make standard terms and conditions available for all Part D plans they offer. For those terms to be reasonable and relevant, MMPs must identify for the pharmacy the plan(s) to which they apply, and the offer must include language that obligates the MMP to include the pharmacy in the identified plan(s) upon the pharmacy's acceptance of the terms and conditions. (HPMS memo 08/13/2015)
- CMS expects MMPs to provide the applicable standard terms and conditions document to the requesting pharmacy within two business days of receipt of the request. (HPMS memo 08/13/2015)

II. Offshore Subcontracting

- MMPs with offshore subcontractor*[2] arrangements must ensure the HPMS Offshore Subcontracting module is up to date regarding the functions offshore subcontractors perform within 30 calendar days of signing an offshore contract. (HPMS memos 07/23/2007, 09/20/2007, and 08/26/2008) Changes

[2] *Offshore subcontractor* is defined as a first tier/downstream/related entity located outside of the one of the fifty U.S. states, the District of Columbia, or one of the U.S. Territories (American Samoa, Guam, Northern Marianas, Puerto Rico, and Virgin Islands).

to First Tier/Downstream/Related Party (FDR) Contracts for Key MMP Functions

- Notify your CMT at least 60 days prior to the effective date of the new contract (or sooner per terms of the three-way contract).

III. Changes to First Tier/Downstream/Related Party (FDR) Contracts for Key MMP Functions

- CMS recommends that MMPs making pharmacy network changes provide those pharmacies whose network status is changing, and enrollees using those pharmacies, with notices of changes specific to their situation.
- If making PBM/ Processor changes:
    - MMPs must take all steps per the *Medicare Prescription Drug Manual Chapter 5, Section 50*, if making changes to the PBM contracted to maintain your organization's pharmacy networks.
    - MMPs must update all members' 4Rx data prior to the effective date of the PBM change to reflect the new BIN and PCN. (Medicare Managed Care Manual Chapter 2 and Medicare Prescription Drug Plan Chapter 3 *Eligibility, Enrollment, and Disenrollment*, Section IV.D.a)
- Effective January 1, 2016, drug pricing based on maximum allowable cost (MAC) is subject to the prescription drug pricing standard regulations governing the contract between the MMP and all FDRs, which must contain a provision: (A) Establishing regular updates of any prescription drug pricing standard used by the MMP consistent with 42 C.F.R. § §423.505(b)(21); and (B) Indicating the source used by the MMP for making any such pricing updates. See 42 C.F.R. 423.505(i)(3)(vii).

D. Customer Service

I. Customer Service Call Centers

- MMPs must ensure that toll-free beneficiary call centers will be staffed appropriately to handle increased call volume during the AEP and any passive enrollment dates. MMPs must operate a toll-free call center for both current and prospective enrollees per the three-way contract, the Medicare Marketing Guidelines, and the state-specific MMP marketing guidance document. Call centers must be able to provide free interpreter services for Limited-English Proficient (LEP) beneficiaries. (*Marketing Guidelines, Section 80*)
- MMPs must have telephone-to-telephone typewriter (TTY) services available for callers with hearing impairment.

II. Limited English Proficient (LEP) Beneficiaries

- All MMPs' call centers must have interpreter services available to call center personnel to answer questions from non-English speaking beneficiaries. This requirement is in place regardless of the percentage of non-English speaking beneficiaries in a service area.
- MMPs must inform beneficiaries that interpreter services are "free." Interpreters should be available within a prescribed time after reaching the Customer Service Representative (CSR). Please refer to the annual call center monitoring memo released each Fall for more detail.
- MMPs must make the marketing materials identified in the state-specific MMP marketing guidance document, section 30.5, available in any language that meets the more stringent of either the Medicare standard (the primary language of five (5) percent or more of an MMP's plan benefit package service area) or the state's standard. Additionally, MMPs must place translated versions of these materials on the plan's website.
- MMPs must create a Multi-Language Insert that includes the alternate language tagline translated in at least the top 15 languages spoken by individuals with LEP in the relevant State. (https://www.hhs.gov/sites/default/files/resources-for-covered-entities-top-15-languages-list.pdf) MMPs must include the Multi-Language Insert with the Summary of Benefits (SB) and the Annual Notice of Changes (ANOC)/Evidence of Coverage (EOC) (Member Handbook).

(*Medicare Marketing Guidelines,* Sections 30.5, 30.5.1, and 100.1; State-specific marketing guidance document, Section 30.5, 30.5.1, 30.7, 80.1, 100.1; 42 C.F.R. §§ 422.2264(e), 423.2264(e)); HPMS memo 09/17/2015.)

III. Customer Service Staff Knowledge

MMPs must ensure that CSRs are familiar with the plan's Medication Therapy Management (MTM) program, including eligibility criteria and additional information required to be available on a dedicated MTM Program page linked from the MMP's website, and how to direct beneficiaries to the plans' MTM program page. The 2017 MTM program annual cost threshold increased to $3,919. (*Medicare Marketing Guidelines*, *Section 100.2.1,* HPMS memo 04/08/2016, 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letters)

IV. Pharmacy Technical Help Desk Call Centers

MMPs must ensure pharmacy technical support is available at all times when any network pharmacy is open. MMPs that have pharmacy networks with 24-hour pharmacies in their networks must operate their pharmacy technical help call centers 24 hours a day, including Thanksgiving and Christmas. (Medicare Marketing Guidelines, Appendix 3)

V. Complaints Tracking Module

MMPs should be prepared to resolve at least 95% of CTM Module complaints designated as "immediate need" within two calendar days, complaints designated as "urgent" within seven days, and resolve at least 95% of all CTM complaints designated without an issue level within 30 days. MMPs are urged to make interim contact with beneficiaries if their complaints will take more than seven days to resolve. (HPMS memo 02/06/2015, 12/30/2015)

E. Marketing

MMPs must market consistent with the CY2017 Medicare Marketing Guidelines and state-specific MMP marketing guidance document (HPMS memo 06/10/2016)

I. Individuals with Disabilities and Non-Discrimination

- MMPs must provide basic services and information to individuals with disabilities, upon request, per the provisions of the three-way contract.
- MMPs must make available all plan materials and information, including those produced or distributed by contracted providers, in alternate formats (e.g., braille, large print, and audio) to individuals with disabilities upon request per the provisions of the three-way contract.

  (HPMS memo 09/09/2014, Medicare Marketing Guidelines, Section 30.4).
- MMPs must ensure implementation of the procedural requirements under the regulation implementing Section 1557 of the Affordable Care Act of 2010—Nondiscrimination Communication Requirements and Grievance Procedures. Compliance with Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age, or disability**.** (HPMS memo 8/8/16, 09/09/2014; HPMS email 8/25/16; *Medicare Marketing Guidelines*, Section 30.4)

II. Formulary

MMPs' formulary must be updated on the website when changes are made, and MMPs must ensure that only approved formularies are marketed. (*Medicare Marketing Guidelin*es, Section 60.4; and state-specific marketing guidance, section 60.4)

III. Websites

- The ANOC/EOC (Member Handbook), Summary of Benefits, Provider and Pharmacy Directory, Formulary and Utilization Management Documents, and Multi-Language Insert must be posted on the website by September 30 for the upcoming contract year. The only exception to this requirement is for MMPs that mail the ANOC and EOC (Member Handbook) separately; such MMPs must post the ANOC by September 30 and the EOC by December 31.

All other documents noted above must be posted by September 30. (State-specific marketing guidance, Section 60.7, and Medicare Marketing Guidelines, Section 100.2.2)

- MMPs are expected to update Provider and Pharmacy Directory information any time they become aware of changes. All updates to the online provider directories are expected to be completed within 30 days of receiving information. Updates to hard copy provider directories must be completed within 30 days; however, hardcopy directories that include separate updates via addenda are considered up-to-date. MMPs should contact their network/contracted providers on a quarterly basis to update the following information in provider directories. (HPMS memos 08/13/2015, 11/13/2015, *Medicare Managed Care Manual, Chapter 4, Section 110.2.2*)
- Third-party websites that market MMPs' products are expected to meet applicable CMS marketing requirements. Entities that market MMPs' products are expected to meet applicable CMS and state-specific marketing requirements. (*Medicare Marketing Guidelines*, Section 100.3)

IV. Agents and Brokers

MMPs must implement agent/broker compensation rates, submissions, and training and testing requirements (as applicable in the three-way contract and state-specific marketing guidance). (HPMS memo 05/27/2016)

F. Enrollment/Disenrollment and Premium Billing

I. Retroactive Enrollments

- MMPs delegated to perform enrollment functions per the terms of the three-way contract) must submit enrollments and disenrollments directly to MARx following the "current calendar month" cycle. MMPs delegated to perform enrollment functions per the terms of the three-way contract can submit enrollments and disenrollments for the current calendar month and for the calendar month prior to the current calendar month, using the User Interface (UI) or in batch submissions.
- MMPs delegated to perform enrollment functions per the terms of the three-way contract should prepare systems and processes to support the submission of retroactive enrollment and disenrollment corrections that cannot be accomplished within the Current Calendar Month cycle to the retroactive processing contractor (Reed & Associates). These requests must be made appropriately and timely. For more information, please visit www.reedassociates.org.

II. Deadline for Submitting 4Rx data to CMS MARx System

- MMPs must submit 4Rx data to CMS in accordance with existing Medicare Part D requirements in "Chapter 14- Coordination of Benefits" (please see:

http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.html).

- The 4Rx data, also known as Part D pharmacy billing codes (Rx BIN, Rx PCN, Rx GRP and Rx ID), must be submitted by an MMP within 72 hours after the successful enrollment reply on the daily Transaction Reply Report (DTRR). This requirement applies to both opt-in enrollments, as well as passive enrollments, including those submitted by states in early October for a January 1 effective date. MMCO will monitor MMPs' compliance with this requirement.
- If state data are not yet available, MMPs can obtain mailing and residence address information from MARx via Batch Eligibility Query process to generate their 4Rx data and should be able to timely submit 4Rx data to MARx system within 72 hours.

H. Benefits Administration & Beneficiary Protections

I. MMP Benefits and Beneficiary Protections

- MMPs must review and implement new guidance issued for the updated Chapter 4 *Medicare Managed Care Manual*, titled "Benefits and Beneficiary Protections." (HPMS memo 04/28/2016)
- MMPs must ensure that their provider networks meet CMS network adequacy standards.
- Insure your organization and its contracted hospitals and critical access hospitals (CAHs) implement the provisions of the NOTICE Act. Under the NOTICE Act, hospitals and CAHs must deliver the Medicare Outpatient Observation Notice (MOON) to any beneficiary (including an MA enrollee) who receives observation services as an outpatient for more than 24 hours. See the final rule that was published on August 22, 2016) at: https://www.federalregister.gov/articles/2016/08/22/2016-18476/medicare-program-hospital-inpatient-prospective-payment-systems-for-acute-care-hospitals-etc

II. Cost-Sharing and Billing Rules Applicable Medicare-Medicaid Plan (MMP) Enrollees

- MMPs cannot assess any cost-sharing for covered Medicare Parts A and B services and items. (See the three-way contract.) Additionally, under 42 C.F.R. § 504(g) MMPs must adopt measures to protect MMP enrollees from improper billing and inform network providers about applicable billing prohibitions. Note that Low Income Subsidy copayments may still apply for Part D benefits provided by MMPs.

III. Coverage Gap Discount Program (CGDP)

- MMPs should be prepared to repay manufacturers for negative invoice amounts caused by PDE adjustments. Such amounts are included in quarterly invoices and must be paid to manufacturers via the CGDP portal within 38 days of invoice receipt. (HPMS memo 01/22/2014)
- MMPs must update electronic funds information and reflects the correct personnel listed for the following fields:
    - HPMS field "Third Party Administrator (TPA) Liaison" for the TPA Primary Contact role
    - HPMS field "Coverage Gap Discount Program (CGDP) Payment Contact" for the TPA Payment Initiator role (if different from the Primary Contact)
- MMPs must update the appropriate Bank Account Change Form on the TPA Website if there have been any changes to the accounts used for sending or receiving payments. MMPs must also validate any debit blocks and velocity filters which may be in place. These data are collected and maintained outside of the Automated Plan Payment System (APPS). The Bank Account Change Form can be found under the EFT Information line on the TPA web site (http://tpadministrator.com).

IV. Formulary

- **Monitor Rejected Claims.** MMPs must routinely monitor rejected claims so that any potential errors are identified and corrected timely. Review the August 27, 2014 HPMS memo entitled "Common Conditions, Improvement Strategies and Best Practices based on 2013 Program Audit Reviews," which includes common findings, best practices, and CMS recommendations relating to formulary administration. (HPMS memo 08/27/2014)
- **Transition Policy.** MMPs must ensure they properly administer CMS' transition policy as outlined in 42 CFR § 423.120 (b)(3) and applicable three-way contracts. (HPMS memos 08/27/2014, 12/30/2015, 08/19/2016)
- **Biosimilars.** Biosimilars may be added to plan formularies at any time as a formulary enhancement. Formulary changes involving the addition of the biosimilar and removal of the reference biological product will generally be considered a non-maintenance change. These formulary changes will be evaluated, as are all non-maintenance changes, on a case-by-case basis, and allowed if the formulary continues to meet the formulary review standards with the corresponding addition of the biosimilar. Because biosimilars are not interchangeable with the reference biological product, CMS expects that MMPs Pharmacy and Therapeutics (P&T) committees will review newly approved biosimilars in accordance with section 30.1.5 of Chapter 6 of the *Medicare Prescription Drug Benefit Manual*. (HPMS memo 3/30/2015)
- **Daily Cost Sharing Requirements.** MMPs must apply a daily cost sharing rate whenever certain prescriptions (depending on the drug dispensed) are

dispensed by a network pharmacy for less than a month's supply in accordance with 42 C.F.R. § 423.153(b)(4)(i).

- **MAC Pricing.** MMPs must update MAC drug prices at least every seven days and to disclose all individual MAC drug prices to be updated to the applicable pharmacies in advance of their use. In addition, the disclosure must be made in a manner that enables the pharmacies to validate prices. (42 CFR §§423.501; 423.505(b)(21))
- **Pharmacy & Therapeutics (P&T) Committee**. MMPs' committee must clearly articulate and document processes to determine that the requirements under paragraphs 42 C.F.R. § 423.120(b)(1)(i) through (iii) have been met, including the determination by an objective party of whether the disclosed financial interests are conflicts of interest and the management of any recusals due to any conflicts.

V. Mail-Order and Auto-Ship Refill Programs in Part D

- MMPs must work with their mail order pharmacies to develop and implement protocols for providing access to urgently needed medications. Further, beneficiaries should be informed of their options when requesting a rush order, with clear steps detailed in all applicable beneficiary materials. (Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter)
- MMPs must ensure they follow the mail-order auto ship guidance.
    - If a beneficiary has experience using mail-order or other automatic delivery programs under the plan, MMPs do not need to establish an additional opt-in procedure to acquire explicit consent to fill initial scripts.
    - If a beneficiary has had no previous mail-order, home delivery, or other automatic shipment experience under the plan, then a new prescription for that beneficiary is not eligible for the exception, and MMPs should receive consent from the beneficiary before that prescription is filled.
- Such confirmation is unnecessary when the beneficiary personally initiates the prescription request.
- Two exceptions authorizing automatic deliveries without prior beneficiary consent were offered to MMPs agreeing to meet the conditions stated Exceptions to the Auto-Ship Policy
- MMPs interested in offering automatic deliveries of <u>new</u> prescriptions (as described in the HPMS 12/12/2013 memo) will no longer need to request an exception to the auto ship policy by emailing CMS. Instead, the exception will remain available to all MMPs, without the need to specifically submit a request. MMPs are permitted to start or continue automatic shipments, provided they meet the conditions listed.

(HPMS memos dated 10/28/2013, 12/12/2013, 03/21/2014, 09/22/2014 and Calendar Year 2014 & 2016 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letters)

VI. Quality Improvement (QI) Programs

- MMPs' QI program must meet the applicable requirements for the services that it furnishes to their enrollees, as specified at 42 C.F.R. §422.152 and detailed in Chapter 5 of the Medicare Managed Care Manual.
- Under the QI program, MMPs are required to conduct at least two improvement projects: (1) a quality improvement project (QIP) that addresses specified clinical and non-clinical areas of health care that would improve the health outcomes for enrollees; and (2) a chronic care improvement program (CCIP) that targets MMP enrollees with multiple or sufficiently severe chronic conditions. (HPMS memo 09/08/2015). The number of QIPs and CCIPs and the topic areas for each improvement project that an MMP will be required to complete are determined by each respective state, in consultation with CMS. (HPMS memo 09/08/2015)
- In addition, MMPs are required to report on the QIP to CMS. The reporting requirements include both QIP Plan Section and QIP Annual Update submissions. The reporting requirement for the CCIP has been discontinued for CY 2016 and beyond. Although MMPs will no longer report on CCIPs, they should continue with their current CCIP efforts to comply with the Medicare Advantage Q Program regulations as outlined in 42 CFR §422.152. (HPMS memo 04/06/2016)
- The QIP Annual Update is due during the CMS-determined submission window in January after the first year of implementation following approval of the QIP Plan Section, and annually thereafter, until project completion. The QIP Annual Update should include the results or findings to date based on the intervention(s); any barriers encountered during the update period; risk mitigation activities implemented to address barriers encountered; the impact on the established goal or benchmark; and next steps for the project. (*Medicare Managed Care Manual*, Chapter 5)
- Effective August 1, 2014, MMPs will work with one of two new Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC-QIOs), replacing the pre-August 1 QIO contractors. (HPMS memo 8/1/2014)

VII. Improving Drug Utilization Controls in Part D

- MMPs must implement processes and procedures to comply with the drug utilization management (DUM) requirements of 42 C.F.R §423.153 *et seq*. to prevent overutilization of prescribed covered Part D drugs. (CY 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter and http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html

- MMPs must ensure processes are in place to submit beneficiary-level POS drug edit information for Identified Drug Overutilizers of opioids to MARx. (Plan Communications Users Guide, Section 11, Reporting Identified Drug Overutilizers, available on the CMS website at: https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/mapdhelpdesk/Plan_Communications_User_Guide.html.
- MMPs must ensure their Pharmacy and Therapeutics (P&T) committees develop the specifications to implement a soft and/or hard formulary-level cumulative morphine equivalent dose (MED) POS edit(s) based on any opioid overutilization in your plan(s), and reasonable numbers of targeted beneficiaries for plan oversight. (Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter)

I. Best Available Evidence (BAE) and Low Income Subsidy (LIS)

I. Low Income Subsidy Benefit Administration

- MMPs must apply the correct CMS LIS levels to enrollees by immediately applying any updates received via the daily TRR to establish the correct premium, cost sharing, and deductible levels with the correct effective dates for prior, current, and prospective enrollees. (Medicare Prescription Drug Benefit Manual Chapter 13, Section 70.1)
- MMPs must reimburse LIS eligible individuals, or others who have paid or are holding receivables on behalf of the beneficiary, any excess premiums or cost-sharing paid by the individual, including refunding of cost-sharing amounts that were paid during the period of LIS retroactive coverage.
- Whenever an MMP receives information that necessitates a retroactive claims adjustment, the MMP must process the adjustment and issue refunds or recovery notices within 45 days of the MMP's receipt of complete information regarding claims adjustment. (*Medicare Prescription Drug Benefit Manual* Chapter 13, Section 70.3.1 and 42 C.F.R. §§ 423.466, 423.800)
- MMPs must meet CMS requirements for accepting specific forms of BAE to establish a more favorable low income copayment status of a full benefit dual eligible beneficiary and beneficiaries who applied to the SSA for the LIS. (HPMS memo 08/04/2008 and 10/16/2008)
- MMPs must meet CMS requirements for accepting specific forms of BAE to establish a beneficiary is institutionalized or enrolled in a home community based waiver program and qualifies for zero cost-sharing.
- MMPs must provide beneficiaries access to covered Part D drugs at the reduced cost-sharing level as soon as one of the specific forms of BAE is presented.

- MMPs must implement procedures to accept BAE at point-of-sale, update systems within 48-72 hours of receipt of the documentation, and ensure correct charges of premium, deductible, and cost sharing to low-income subsidy beneficiaries. MMPs must request manual updates to CMS within 60 days if routine reporting doesn't correct for deemed beneficiaries. (*Medicare Prescription Drug Benefit Manual Chapter 13, Section 70.5*)
- MMPs must follow CMS' process for assisting individuals without BAE documentation. MMPs must develop appropriate member services and pharmacy help desk scripting to identify cases involving a situation in which the BAE policy applies, and to allow callers either to submit BAE, or request assistance with securing BAE, pursuant to CMS requirements. When assisting beneficiaries with securing BAE, MMPs are required to use the process outlined in *Medicare Prescription Drug Benefit Manual Chapter 13, Section 70.5.3*.

II. Loss of Low Income Subsidy Data File

- In response to the Loss of Subsidy Data File (released in December of each year), MMPs must set their organization's systems to charge the correct premium, deductible, and copayments as well as send the appropriate notification to affected beneficiaries. The only exception to this requirement is for those beneficiaries whom the organization confirms are awaiting a Social Security Administration determination on an LIS application and have been granted a grace period by the organization, if applicable. In these situations, organizations should wait until they receive the result of the SSA determination to update their systems.
- MMPs must make reasonable attempts to notify affected members to advise them of their retroactive liability for higher premiums and cost sharing when LIS status or eligibility is removed. (*Medicare Prescription Drug Benefit Manual Chapter* 13, 70.3.1)

(HPMS memos 11/30/2009, 08/12/2014, 09/10/2015, and 07/20/2016)

III. Low Income Subsidy Deeming

- MMPs must follow the CMS guidance for re-determination of Part D LIS eligibility for 2016. (HPMS memo 07/20/2016)
- MMPs must take appropriate actions in response to files concerning deeming from CMS: Twice a year, in September and December, CMS issues Loss of Subsidy files related to Part D sponsors' LIS members. The September 7 file identifies the beneficiaries receiving the CMS "undeemed" letter, and is to be used by sponsors for outreach to those individuals. The December file is the definitive file of those losing LIS status, and sponsors must use that file to update their systems and send affected beneficiaries the LIS termination notice. Additional information is available in the Plan Communication Guide (PCUG) Section, Loss of Subsidy Data File (HPMS memo 07/20/2016).

- MMPs must ensure procedures are in place to submit corrections to beneficiaries' LIS deemed status to the CMS contractor, Reed & Associates, following the instructions in the *Medicare Prescription Drug Manual*, Chapter 13, Section 70.5.6.

J. Coordination of Benefits (COB) and Automatic True Out-of-Pocket Cost (TrOOP) Balance Transfer

I. Coordination of Benefits (COB) Data Report/File Processing/Automated TrOOP balance transfer (ATBT) Process

- MMPs must be able to accept and respond to financial information reporting (FIR) transactions triggered under the enhanced ATBT process for years in the extended time period. Therefore, MMPs must ensure that their FIR processors are contracted to handle transactions for the current as well as all prior years covered under the enhanced ATBT process. For some MMPs, this may entail re-contracting with a former processor to process prior year FIR transactions. (HPMS memo 07/02/2015)

II. Hospice (applicable if this population is eligible for continued enrollment under your demonstration)

- For hospice beneficiaries, MMPs must have in place beneficiary-level Prior Authorization (PA) requirements on four categories of prescription drugs: analgesics, antinauseants (antiemetics), laxatives, and antianxiety drugs (anxiolytics). The updated FAQ document can be found at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/index.html. (HPMS memo 07/18/2015)
- MMPs must use the approved form for collection of Hospice Information for Medicare Part D Plans to facilitate communication between MMPs, hospices, prescribers, and pharmacists who serve beneficiaries enrolled in hospice: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Downloads/Hospice-Info-PartD.zip. (HPMS memo 03/24/2015)

III. End-Stage Renal Disease (ESRD) (applicable if this population is eligible for enrollment under your demonstration)

- MMPs do not pay for drugs and biologics that are included in the Medicare Part B bundled payment to an ESRD dialysis facility (as specified in section 1881(b)(14) of the Social Security Act and in Federal regulations at Part 413). When an MMP receives a daily TRR showing an ESRD beneficiary is receiving renal dialysis services, the MMP must have controls in place to comply with this requirement.
- We strongly encourage MMPs to place beneficiary-level PA requirements on the four categories of drugs that are always used for ESRD treatment; CMS removed anti-infectives from the always ESRD-related categories of drugs in

the 2015 ESRD prospective payment system final rule which appeared in the Federal Register on November 6, 2014. (HPMS memo 5/12/15)

- In addition, we strongly encourage MMPs to remove the beneficiary-level PA edits on the seven categories of prescription drugs that may be used for ESRD treatment. MMPs are not expected to place ESRD PA requirements on these seven categories of drugs or take special measures beyond their normal compliance and utilization review activities. However, if it is determined through routine utilization review or otherwise that a renal dialysis service drug has been inappropriately billed to Part D, the MMP and the ESRD facility should negotiate repayment. (HPMS memos 05/12/2015 and 11/14/2014)

IV. Drugs Available under Part A or Part B

- MMPs must coordinate all benefits administered by the plan with respect to drugs for which payment may be available under Part A or Part B. (42 C.F.R. § 422.112(b)(7))

K. Claims Processing and Transition Process

- CMS expects each MMP to fully test how their transition policy works within its claims adjudication system, including pharmacy notification, in order to ensure that the transition policy has been programmed correctly into systems prior to the start of 2017. (HPMS memo 03/25/2010)
- MMPs must implement a transition process for current enrollees who will experience negative changes as a result of revisions to their plan's formulary across contract years (i.e., from CY2016 to CY2017). MMPs should work aggressively to prospectively transition current enrollees to therapeutically equivalent formulary drugs or work to complete requests for formulary and tiering exceptions to the new CY 2017 formulary prior to January 1, 2017. Sending the ANOC is not sufficient to effectuate the transition. (HPMS memos 03/25/2010 and 08/27/2010)
- MMPs must ensure a transition supply has been provided by closely monitor enrollees' rejected claims, among other monitoring strategies.

L. Grievances, Initial Coverage Decisions, and Appeals

I. Staffing Requirements Related to Initial Coverage Decisions and Appeals

- MMPs must employ a medical director who is responsible for the clinical accuracy of all initial coverage decisions and appeals that involve medical necessity. The medical director must be a physician with a current and unrestricted license to practice medicine in a State, Territory, Commonwealth of the United States, or the District of Columbia. (42 C.F.R. §§ 422.562, 423.562) In addition, your organization must be staffed to satisfy the following requirements: (1) that a physician or other appropriate health care

professional with sufficient medical and other expertise, including knowledge of Medicare coverage criteria, review the initial coverage decision if your organization expects to issue a partially or fully adverse decision based on medical necessity (42 C.F.R. §§ 422.562, 423.562, 422.566, and 423.566), and (2) that a physician who was not involved in the initial denial make the redetermination/reconsideration when the initial decision involved a determination of medical necessity (42 C.F.R. §§ 422.590(h) and 423.590(f)).

II. Appropriateness of Clinical Decision Making

- MMPs must ensure that clinical and administrative staff and delegated entities involved in processing initial coverage decisions and appeals comply with all CMS and plan coverage rules. You must be able to demonstrate that clinical decision-making involves the consideration of your CMS-approved Explanation of Benefits, drug formulary, appropriate CMS regulations and guidance, required drug compendia, previous claims history, and all submitted clinical information. You must also be able to demonstrate procedures for making and documenting requests for necessary clinical documentation from providers and prescribers when documentation is needed to properly adjudicate coverage requests and appeals.

III. Proper Use of Adjudication Timeframe Extensions

- Under limited circumstances, MMPs may extend the adjudication timeframe for organization determinations and reconsiderations. Ensure that your organization is in compliance with the use of extensions per the regulatory requirements at §422.568, §422.572 and §422.590 (February 12, 2015 Federal Register, Vol. 80, p. 7912) and any applicable provisions in the three-way contract.

IV. Online Appeals Training Courses

- MMPs' compliance officer, staff involved with initial coverage decisions, appeals, and grievances, and customer service representatives, are trained in Part C and Part D processes. CMS provides two optional web-based training (WBT) courses below to supplement in-house training. http://go.cms.gov/MLNProducts. CMS strongly suggests that compliance officers incorporate these courses into their existing in-house training and use the certificate to track course completion within the organization. (HPMS memo 04/28/2014)

V. Rights of Medicare C & D Enrollees

- MMPs must ensure that their organization provides immediate access to the coverage determination and redetermination processes via a toll-free telephone number and website and provides access to model forms for making coverage and appeal requests.

M. Compliance and Fraud, Waste, and Abuse (FWA) Compliance Program

- MMPs must ensure and be able to demonstrate they have implemented an effective compliance program which includes measures to prevent, detect and correct program non-compliance and fraud, waste and abuse. 42 C.F.R. §§422.503 and 423.504. CMS strongly recommends all Compliance Officers and personnel routinely review and share throughout your organization information from the CMS Compliance and Audit webpage. The webpage provides useful resources to assist your organization in understanding and implementing compliance program requirements; provides materials CMS uses to conduct program audits; annual Program Audit and Enforcement Reports; and, information pertaining to compliance and enforcement actions. https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/index.html.
- MMPs are strongly encouraged to use discretion when developing the criteria for determining whether an entity is a first tier, downstream and related entity (FDR) for purposes of the compliance training requirement. Section 40 of the Compliance Program Guidelines, located in Pub. 100-18, Chapter 9 of the *Medicare Prescription Drug Manual* and Chapter 21 of Pub. 100-16, the *Medicare Managed Care Manual* has an enumerated list of factors to consider in determining whether an entity is an FDR. MMPs should consult the three-way contract for further definition of an FDR. Also, we strongly encourage MMPs and FDRs to be reasonable and cooperative in identifying the compliance training vehicle.
- As a reminder CMS, is suspending review of the FDR compliance training certification requirement pending additional guidance. MMPs will not be required to provide documentation of FDR compliance program training certification.