DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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MEDICARE MEDICAID COORDINATION OFFICE

Date: November 12, 2015

To: All Medicare Medicaid Plans

From: Sharon Donovan, Director, Program Alignment Group

Subject: Contract Year (CY) 2016 Medicare Requirements Readiness Checklist for Medicare-Medicaid Plans (MMPs)

The Centers for Medicare & Medicaid Services (CMS) reminds organizations of critical Medicare requirements for the Annual Election Period (AEP) and coverage beginning January 1, 2016.

The Contract Year (CY) 2016 Readiness Checklist summarizes key operational requirements as established in statutes, regulations, manual chapters, Health Plan Management System (HPMS) memos, applications, and other advisory materials.

Your organization should review this checklist carefully and take the necessary measures to fulfill these key requirements for CY 2016. It is important to note that the checklist is not an exhaustive list of all MMP requirements, however.

If you need additional information regarding requirements listed in the checklist, please refer to the appropriate CMS guidance or contact your Contract Management Team.

CY 2016 Medicare Requirements Readiness Checklist for Medicare-Medicaid Plans

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A. Systems, Data, & Connectivity

I. Health Plan Management System (HPMS)

- Ensure key staff members register for the Plan Connectivity Data (PCD) 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. Prescriber Enrollment

- No later than June 1, 2016, physicians and other eligible professionals who write prescriptions for Part D drugs are required to be enrolled in Medicare in an approved status or to have a valid opt-out affidavit on file for their prescriptions to be covered under Part D, unless the prescriber is an "Other Authorized Prescriber". MMPs should utilize the enrollment file that identifies physicians and eligible professionals who are enrolled in Medicare in an approved status or have a valid opt-out affidavit on file with a Medicare Administrative Contractor (MAC) to determine a prescriber's Medicare enrollment or opt-out status when processing Part D pharmacy claims. MMPs must also cover 3-month provisional supplies when applicable and comply with the written beneficiary and prescriber notice requirements.
- Organizations offering Part D prescription drug coverage in conjunction with other Medicare coverage should confirm their contracting providers are eligible to furnish Part D prescriptions. If an organization anticipates that a contracted physician or eligible professional, including a dentist, may write prescriptions for Part D drugs, the organization should confirm that the contracted physician or eligible professional is enrolled in Medicare in an approved status.
- MMPs and their PBMs are encouraged to begin outreach activities to Medicare Part D prescribers no later than January 1, 2016. (HPMS memo 10/13/2015)

(HPMS memos 12/03/2014, 06/01/2015, 06/09/2015)

III. National Provider Identifier (NPI) Requirements

- Consistent with the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), for plan year 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 memo 06/09/2015)

IV. MARx

- Below are the key steps in establishing data exchanges with CMS MARx enrollment and payment system:
  - 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 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.
- An individual's access to IACS will be partially disabled when 60 days or more lapses between system logins. (*IACS User Guide Document Version 2.0*, November 2013)

V. Electronic Correspondence Reporting System (ECRS)

- MMPs must implement the October 1, 2015 implementation of CMS' International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM),

which replaces the ICD-9 code sets used to report medical diagnoses and inpatient procedures. (http://www.cms.gov/Medicare/Coding/ICD10/CMSImplementationPlanning.html)

- ECRS transactions capture diagnosis codes related to No-Fault, Worker's Compensation, or Liability Medicare Secondary Payer (MSP) cases. Although only Medicare Advantage-Prescription Drug (MA-PD) plans can submit ECRS change requests, all Part D plans may submit inquiries concerning possible MSP coverage and use the diagnosis codes reported on the inquiry response and on the Medicare Advantage Prescription Drug (MARx) COB file to identify prescription drug claims that may be subject to MSP payment rules.
- MMPs should use ECRS to request changes to a prescription drug record reporting coverage that is supplemental or primary to Part D.

(HPMS memos 02/18/2015, 09/03/2015, 09/11/2015, 09/25/2015)

VI. Medicare Plan Finder Data (MPF)

- **Pricing Data and Pharmacy Network Files.** MMPs must ensure timely and accurate submission of CY 2016 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 6/19/2015)
  - MMPs must confirm pricing and pharmacy network data files for MPF are correct and accurate, and that only pharmacies under contract for 2016 are included for display. Incorrect data may result in suppression from MPF and/or applicable compliance actions.

  (CY 2016 Pricing Data Requirements – 06/16/2015)
- **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 2016 pricing and pharmacy data which was previously a known exception in 2015, your organization must re-confirm that the data continue to be accurate. If you do not confirm these data, MMPs may have their pricing data 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' 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 process are posted on the MPF Communication website, https://PartD.ProgramInfo.us/User_Security.

VII. 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.

VIII. 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 04/08/2015)
- **New MMPs for 2016** – Your organization will receive log-on credentials directly from the Patient Safety Analysis Website contractor, and you will begin reviewing these reports in spring of 2016.

IX. Overutilization Monitoring System

- MMPs must ensure 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 memos 04/08/2015; also see Section *H.X. Improving Drug Utilization Controls in Part D*)

X. Prescription Drug Event (PDE) Requirements

- CMS requires that MMPs submit timely PDE records as follows (HPMS memo 05/16/2011):
    - 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 10/24/2013)

- MMPs must establish access to Acumen's PDE Analysis and PDE Reports websites. (HPMS memo 04/21/2015)

- 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 (HPMS memo 04/16/2014), and
  - Payment Reconciliation System 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. For a general overview of the Medicare Health Outcomes Survey program, visit http://www.cms.gov/hos. (HPMS memo 10/09/2015)

- **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 reporting requirements (as applicable); conduct appropriate data validation for the Part C and Part D measures; and submit data to CMS according to the requirements. (HPMS memo 05/07/2015)

- **Reporting and Returning MMP Identified Overpayments**
  - Every organization offering Part D benefits is required to report and return to CMS any overpayment it received no later than 60 days after the date on which the MMP identified the overpayment. (HPMS memos 02/18/2015, 08/28/2015)

- **Encounter Data.**
  - MMPs must submit encounter data consistent with general CMS and State specific guidance and clarifications. (HPMS memo06/02/2015)

- **Fiscal Soundness.**
  - MMPs must use the Fiscal Soundness Module in HPMS to submit annual independently audited financial reports and 2016 quarterly financial statements. (HPMS memo 03/27/2015)

C. Contracting, Subcontractor Provisions, and Oversight

I. Any Willing Pharmacy (AWP)Contracting Requirements

- To comply with the AWP requirement, an MMP must make standard terms and conditions available for the plans it offers. For those terms to be reasonable and relevant, they 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* 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)

* *Offshore subcontractor* is defined as a first tier/downstream/related entity located out of the one of the fifty United States, the District of Columbia, or one of the United States Territories (American Samoa, Guam, Northern Marianas, Puerto Rico, and Virgin Islands).

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

- If making changes to any FDR contracts and/or contractors fulfilling key MMP functions (as identified in HPMS) on behalf of the MMP:
    - Notify your Contract Management Team (CMT) at least 60 days prior to the effective date of the new contract (or sooner per terms of the three-way contract).
    - CMS recommends that MMPs making network changes provide both those providers and/or pharmacies whose network status is changing, and enrollees using those providers and/or pharmacies, with notices of changes specific to their situation.
- If making Pharmacy Benefit Manager (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) and MAC Pricing referenced in Section G below.

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 Speaking 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 seven (7) minutes of reaching the customer service representative (CSR).
- 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 include the Multi-Language Insert with the Summary of Benefits and the ANOC/EOC (Member Handbook).

Medicare Marketing Guidelines, Sections 30.5, 30.5.1, 30.6, 30.7, 80.1, 100.1, and Appendix 3; 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 2016 MTM program annual cost threshold increased to $3,507. (*Medicare Marketing Guidelines*, *Section 100.2.1*, HPMS memo 04/07/15)

IV. Pharmacy Technical Help Desk Call Centers

- MMPs must ensure pharmacy technical support is available at all times 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.

V. Complaints Tracking Module (CTM)

- 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)

E. Marketing

MMPs must market consistent with the CY2016 Medicare Marketing Guidelines and state-specific MMP marketing guidance document (HPMS memos 06/02/2015, 08/13/2015)

I. Individuals with Disabilities - Anti-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)

II. Formulary

- MMPs' formulary must be updated on the website when changes are made, and only approved formularies may be marketed. (Medicare Marketing Guidelines, Section 60.5; state-specific marketing guidance document, Section 60.5)

III. Websites

- The ANOC/EOC, Member Handbook, Summary of Benefits, Provider and/or Pharmacy Directories, Formulary and Utilization Management Documents, and Multi-Language Insert must be posted on the website by September 30 for the upcoming contract year (HPMS Memo 08/13/2015, state-specific marketing guidance, and *Medicare Marketing Guidelines*, Section 100.1).

- Provider and Pharmacy Directories must be updated at least monthly and contain, among other things, a provider's ability to accept new patients. (HPMS memo 08/13/2015, Medicare Marketing Guidelines, Section 100.4)
- 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 05/29/2015)

F. Enrollment/Disenrollment and Premium Billing

I. Retroactive Enrollments – Medicare Advantage Organizations and Part D Sponsors

- 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 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 (RxBIN, RxPCN, RxGRP and RxID), must be submitted by an MMP within 72 hours after the successful enrollment reply on the daily Transaction Reply Report (TRR). 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.

G. Benefits Administration & Beneficiary Protections

- **MMP Benefits and Beneficiary Protections**
  - MMPs must review and implement new guidance and clarifications introduced in the updated Chapter 4 of the Medicare Managed Care Manual, titled "Benefits and Beneficiary Protections." (HPMS memo 11/07/2014)
  - MMPs must ensure that their provider networks meet CMS network adequacy standards.

- **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 memos 01/15/2015, 03/25/15)
  - MMPs must update electronic funds transfer information used for the CGDP via the online form on the third party administrator's web site (http://tpaadministrator.com). These data are collected and maintained outside of the Automated Plan Payment System.
- **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)
  - **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 30 days' supply (as applicable based on cost sharing amounts for the drug) in accordance with 42 C.F.R. § 423.153(b)(4)(i). (Calendar Year 2014 Medicare Advantage and Part D Final Call Letter)

- **MAC Pricing.** Effective January 1, 2016, drug pricing based on maximum allowable cost (MAC) is subject to the regulations governing the disclosure and updating of prescription drug pricing standards at 42 CFR §§423.501; 423.505(b)(21).

  These regulations require MMPs to 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.

(CY 2016 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter)

- **P&T Committee**. MMPs' P & T 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.

- **Auto-Ship Refill Programs in Part D**
  - MMPs must follow the mail-order auto ship guidance, as detailed below:
    - 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. Exceptions to the Auto-Ship Policy:
    - Two exceptions authorizing automatic deliveries without prior beneficiary consent were offered to MMPs agreeing to meet the conditions stated.
    - MMPs interested in offering automatic deliveries of <u>new</u> prescriptions (as described in the 12/12/2013 HPMS 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 in the HPMS memo.

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

- **Quality Improvement (QI) Programs**
  - MMPs' QI program must meet the applicable requirements for the services furnished 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 and report on 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)
- Both the QIP Annual Update and the CCIP Annual Update are due during the CMS-determined submission window in the fall of the first year of implementation following approval of the QIP Plan Section and the CCIP Plan Section, and annually thereafter, until project completion. The 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)

- **Improving Drug Utilization Controls in Part D**
  - MMPs must implement processes and procedures to comply with the drug utilization management requirements of 42 C.F.R § 423.153 *et seq*. to prevent overutilization of prescribed covered Part D drugs. (2013 Call Letter, HPMS memo 9/6/2012, 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.)

H. 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, 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)

II. Low Income Subsidy Deeming

- MMPs should follow the CMS guidance for re-determination of Part D LIS eligibility for 2016. (HPMS memo 09/11/2015)
- 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 6th 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 F28, Loss of Subsidy Data File (http://www.cms.hhs.gov/MMAHelp, HPMS memo 09/11/2015).
- 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.

III. Best Available Evidence (BAE)

- If LIS cost-sharing data is not reflected in the MMP's system for full benefit Medicare/Medicaid dual-eligible individuals when presented with evidence that information showing the beneficiary to be ineligible is not correct, MMP must follow the BAE policy guidance in the Medicare Prescription Drug Manual, Chapter 13, Sections 70.5.1~70.5.10.

I. Coordination of Benefits (COB) and Automatic TrOOP Balance Transfer

I. **Coordination of Benefits (COB) Data Report/File Processing**

- **Automated TrOOP balance transfer (ATBT) Process.** Beginning in January 2016, MMPs must 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 beneficiaries in hospice status, ensure that your organization has 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 entitled "Hospice Information for Medicare Part D Plans" to facilitate communication between MMPs, hospices, prescribers, and pharmacists who serve beneficiaries enrolled in hospice. (HPMS memo 03/24/2015)

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

- MMPs may 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))

J. Claims Processing and Transition Process

- CMS expects each MMP to fully test how its transition policy works in 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 CY 2016. (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 CY2015 to CY2016). 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 2016 formulary prior to January 1, 2016. Sending the ANOC is not sufficient to effectuate the transition. (HPMS memo 03/25/2010, 08/27/2010)
- MMPs must ensure a transition supply has been provided is to closely monitor current enrollees' rejected claims after the beginning of CY 2016, among other monitoring strategies.

K. 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 requirement 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. The physician or other health care professional must have a current and unrestricted license to practice within the scope of his or her profession in a State, Territory, Commonwealth of the United States, or the District of Columbia. (42 C.F.R. §§ 422.562, 423.562, 422.566, and 423.566)

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. Your organization must be able to demonstrate that clinical decision-making involves the consideration of your Member Handbook, 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)

IV. **Online Appeals Training Courses**

- MMPs' compliance officer, staff involved with initial coverage decisions, appeals, and grievances, and CSRs, must be trained in Part C and Part D processes. CMS provides two optional web-based training 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.

L. Compliance and Fraud, Waste, and Abuse (FWA) Compliance Program – Medicare Advantage Organizations and Part D Sponsors

- Starting January 1, 2016, to comply with compliance training requirements, MMPs must accept from FDRs (including the FDR's employees) certificates of completion of CMS' training located on the Medicare Learning Network (MLN). CMS will accept either the MLN system generated certificates of completion, or, an attestation confirming that the organization has completed the appropriate compliance and FWA training. Use of the web-based training via the CMS MLN website is optional for MMP's employees. Updated training modules will be available in November 2015. (HPMS memo 06/17/2015)