DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard

Baltimore, Maryland 21244-1850

CENTERS FOR MEDICARE & MEDICAID SERVICES

Date: November 18, 2014

To: Medicare-Medicaid Plans

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

             Kathryn A. Coleman, Acting Director, Medicare Drug & Health Plan Contract Administration Group

             Tim Engelhardt, Director, Medicare Medicaid Coordination Office, Models, Demonstrations and Analysis Group

Subject: 2015 Readiness Checklist for Medicare-Medicaid Plans

The Centers for Medicare & Medicaid Services (CMS) is reminding organizations of the requirements critical to ensuring a plan's enrollees receive effective coverage beginning January 1, 2015. The Contract Year (CY) 2015 Readiness Checklist summarizes 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 of those Medicare requirements that should be in place for contract year 2015. While many of these items were reviewed during the readiness review process, CMS wants to ensure that your organization is prepared for the start of the new contract year.

Your organization should review this checklist carefully and take the necessary measures to ensure that these key requirements are in place for contract year 2015. 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.

Similar to the readiness checklist process used in Medicare Advantage and Part D, CMS expects your organization to perform your own audit of these requirements. At a later date, CMS will provide a timeline to report these results to us through a secure information collection website. The purpose of this process is to identify any areas where technical assistance may be required from CMS. Should you identify areas where your organization needs assistance or is not/will not

be in compliance, your organization must report these problems to your Contract Management Team directly in writing, and in a timely manner. Please do not wait for the formal Readiness Checklist response request.

We appreciate your cooperation and remain committed to working with organizations to ensure that beneficiaries have continued access to health care services and prescription drugs during the upcoming contract year.

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 2015 Medicare-Medicaid Plan Readiness Checklist

Table of Contents

A. Systems, Data, & Connectivity

I.   Health Plan Management System (HPMS)

   A.   Ensure key staff members register for the Plan Connectivity Data (PCD) Module within HPMS by e-mailing hpms_access@cms.hhs.gov.

   B.   Update your organization's contact and contract information in HPMS, ensuring all information is current. Changes to any HPMS contacts or Part C and Part D Information are expected to be made immediately upon the effective date of the responsibility transfer.

      i.   All sponsors 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.

      ii. 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. MARx

  A. Review and implement guidance regarding software improvements to the enrollment and payment systems for Medicare Advantage and Prescription Drug (MA-PD) programs, which are applicable to MMPs as well. (Ongoing HPMS memos)

  B. Ensure your External Point of Contact (EPOC) is notified of the changes regarding the Individuals Authorized Access to the CMS Computer Services (IACS) users. (http://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/IACS/index.html?redirect=/IACS/)

    NOTE: 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)

  C. Ensure your organization is prepared to implement modifications and updates to the Transaction Reply Codes and the Daily Transaction Reply Report made throughout the year.

III. Electronic Correspondence Reporting System (ECRS)

- Prepare for the October 1, 2015 implementation of CMS' International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), which will replace the ICD-9 code sets used to report medical diagnoses and inpatient procedures.

  (HPMS email dated 2/27/2014)

IV. Medicare Plan Finder Data (MPF)

  A. Ensure timely and accurate submission of CY 2015 pricing data for posting on the Medicare Plan Finder. Sponsors are required to submit MPF data during each regular submission window, which occurs every two weeks. Sponsors may not auto-certify their pharmacy cost files. (HPMS memo 10/03/2014)

      i. Confirm pricing and pharmacy network data files for MPF are correct and accurate, and that only pharmacies under contract for 2015 are included for display. Incorrect data may result in suppression from the MPF, and/or compliance actions. (HPMS memo 07/03/2014)

      ii. The initial CY 2015 data submission period for live/public pricing data for currently operating plans was September 8 through September 9, 2014. The data was published on www.Medicare.gov on October 1, 2014. (Updated CY 2015 Pricing Data Requirements – 9/22/2014)

      iii. The initial CY 2015 data submission period for live/public pricing data for plans starting enrollment in early 2015 is November 10, 2014. The data will be

published on www.Medicare.gov on December 8, 2014. (HPMS memo 09/22/2014)

B. Ensure your organization performs quality assurance activities prior to submitting MPF files to CMS.

i. If your organization receives an outlier notification for your 2015 pricing and pharmacy data which was previously a known exception in 2014, your organization must re-confirm that the data continue to be accurate. If you do not confirm these data, sponsors may have their pricing data suppressed on the MPF.

ii. MPF submissions must be complete and accurate in all respects, and sponsors 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 a sponsor's plan information as the result of any identified inaccuracy or failure to respond to a CMS inquiry about a data submission.

NOTE: Sponsors may be subject to Part D program compliance and enforcement actions as a result of MPF suppressions or inaccurate data submissions.

C. Ensure your organization has access to the MPF Communications website and has 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

Ensure key staff registers for the CMS biweekly 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. National Provider Identifier (NPI) Requirements

A. Be advised, CMS guidance specifies that the NPI is intended to uniquely identify a health care provider in standard transactions, such as health care claims. The Health Insurance Portability and Accountability Act (HIPAA) required covered entities to use NPIs in standard transactions by May 23, 2008. This guidance is in a FAQ available on the CMS Web site at: http://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/NationalProvIdentStand/index.html?redirect=/nationalprovidentstand/

B. Part D sponsors must submit to CMS only prescription drug event (PDE) records containing an active and valid individual prescriber NPI. 42 CFR 423.102(c)(5)

VII. Patient Safety Analysis Website

A. Ensure your organization accesses 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, sponsors are required to use the website to view and download the reports and should be engaged in performance monitoring. (Ongoing HPMS memos)

<u>New sponsors for 2015</u> – 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 2015.

VIII. Overutilization Monitoring System

A. 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.

B. 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. (Ongoing HPMS memos; also see Section *H.X. Improving Drug Utilization Controls in Part D*)

Sponsors may begin receiving these reports as early as January 31, 2015 for beneficiaries who enroll in your contract's plans.

IX. Prescription Drug Event (PDE) Requirements

A. CMS requires that sponsors submit timely PDE records (*2011 Regional Prescription Drug Event Data Technical Assistance Participant Guide*)

    i. Submit original PDEs within 30 days following Date Claim Received or Date of Service (whichever is later),

    ii. Resolve rejected records and re-submit within 90 days following receipt of rejected record status from CMS, and

    iii. Submit adjustments and deletions within 90 days following discovery of issue requiring change.

CMS expects sponsors to promptly resolve rejected PDE records and take corrective action to prevent a recurrence of the issue.

B. Ensure your organization meets PDE testing and certification requirements outlined at http://csscoperations.com/ (follow link, "Enroll to Submit PDE"). After completing certification, sponsors must submit PDEs at least once monthly. (*PDE Welcome Letter*)

C. Ensure your organization establishes access to Acumen's PDE Analysis and PDE Reports websites as described in the May 6, 2013 HPMS memo.

D. Ensure procedures are in place for analysis of recurring reports to ensure 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:

   i. Drug Data Processing System (DDPS) Cumulative Beneficiary Summary,

   ii. PDE Accounting Report,

   iii. P2P (Plan to Plan) files, and

   iv. Coverage Gap Invoice Report.

E. Practice due diligence in determining if a drug is a Part D covered drug and is currently marketed using the FDA's Comprehensive NDC Structured Product Labeling (SPL) Data Elements file (NSDE) to edit PDEs.

   The presence or absence of an NDC on the NSDE and the accuracy of the listing information is NOT a coverage determination. CMS expects Part D sponsors to reach out to manufacturers regarding missing or inaccurate information on the NSDE. (HPMS memos 05/14/2012 and 08/16/2012, 10/25/2012)

X. Risk Adjustment Data Submissions

Risk Adjustment data includes Risk Adjustment Processing System (RAPS) data and Encounter Data System (EDS) data.

- Be advised that Medicare Advantage Organization payment is primarily based on data submitted to CMS. In order to receive proper payment, MAOs and other entities 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.

   Checklist items for EDS and RAPS submission are as follows:

   i. Enroll to submit data through CSSC,

   ii. Subscribe to receive email updates,

   iii. Perform certification requirements,

   iv. Be familiar with guidance contained on the CSSC website,

   v. Begin submission of production data within 4 months of contract effective date, and

   vi. Register to attend all User Groups.

Assistance with data submission can be obtained by csscoperations@palmettogba.com, or by calling 1-877-534-2772.

XI. **CMS Standards of Electronically Transmitted Personal Health Information (PHI)**

- If applicable, organizations developing and offering electronic enrollment mechanisms made available via a plan owned electronic device or secure internet website must ensure that CMS' guidelines are applied to electronic enrollment mechanisms, including, but not limited to:

  o Submit all materials, web pages, and images (e.g. screen shots) related to the electronic enrollment process for CMS approval per established processes for the review and approval of marketing materials and other enrollment request mechanisms.
  o Comply with CMS' data security policies, at a minimum. https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/InformationSecurity/Information-Security-Library.html

  (Medicare Managed Care Manual Chapter 2 and Medicare Prescription Drug Benefit Manual Chapter 3, Section 40.1.2 – Electronic Enrollment)

B. Reporting

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

Ensure your organization is prepared to submit HEDIS, HOS, and CAHPS measures to the appropriate entity by the specified due date. The HPMS memo dated 8/1/2014 provides the type of reporting required for MMPs and other contract types and the deadlines for data submission. For a general overview of the Medicare Health Outcomes Survey program, visit http://www.cms.gov/hos.

(HPMS memo 8/1/2014)

II. **Part C and Part D Reporting Requirements**

A. Ensure your organization is prepared to collect data on all Part C and Part D (as applicable) reporting requirements, conduct appropriate data validation, and submit data to CMS according to the requirements, deadlines, and technical specifications. (HPMS memo 06/04/2014, HPMS email 09/17/2014, and the Plan Reporting Sites: http://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/ReportingRequirements.html and http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_ReportingOversight.html)

B. Ensure your organization is prepared to collect data on all applicable MMP Core Reporting Requirements and State-specific reporting measures.

C. Contracting, Subcontractor Provisions, and Oversight

I. **Contracting Requirements**

Ensure all contracts for Medicare services meet all the requirements according to CMS' application, contract, guidance, regulations, and other advisory materials. Also, recall that the requirements included in the 2015 Medicare-Medicaid Plan applications/solicitations are binding for organizations that applied using earlier application/solicitation versions. (*Annual Contract with CMS*)

II. Offshore Subcontracting

For organizations with offshore subcontractor* arrangements, 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 Part C and Part D Functions

If making changes to any FDR contracts and or contractors fulfilling key Part C and/or Part D functions on behalf of the sponsor/plan sponsor:

A. Notify your Contract Management Team at least <u>60 days prior</u> to the effective date of the new contract.

B. Ensure all systems involved are fully tested, have an executable implementation timeline with milestones and deliverables, and critical systems are run in parallel until assurances that any new system is fully functional.

C. Part D Sponsors – If making Pharmacy Benefit Manager (PBM)/ Processor changes:

   i. Ensure all steps have been followed per the *Medicare Prescription Drug Manual Chapter 5, Section 50*, if making changes to the PBM contracted to maintain your organization's pharmacy networks.

   ii. Update all members' 4Rx data prior to the effective date of the PBM change to reflect the new BIN and PCN. Additional 4Rx information is available in Medicare Managed Care Manual Chapter 2 and Medicare Prescription Drug Plan Chapter 3 Eligibility, [Enrollment and Disenrollment, Section IV.D.a](#)

   iii. CMS recommends referencing the February 2014 NCPDP white paper, *Part D Plans Moving Processors V.4.0*, available on the NCPDP website in the section "Recommendations and Guidance Documents": http://www.ncpdp.org/Resources/Medicare-Part-D

D. Customer Service

I. Customer Service Call Centers

A. Ensure that toll-free beneficiary call centers will be staffed appropriately to handle increased call volume, which includes the AEP and opt-in and passive enrollment start dates. MMPs must meet CMS standards as well as those requirements in the three-way contract. MMPs must operate a toll-free call center for both current and prospective enrollees open during usual business hours, which CMS considers to be seven (7) days a week, at least from 8:00 A.M. to 8:00 P.M. (according to the time zones for the regions in which your organization operates). Alternative technologies may be used as described in MMPs' state-specific marketing guidance document. (*Marketing Guidelines, Section 80; State-specific Marketing Guidance, Section 80.1*)

II. Limited English Speaking Beneficiaries

A. All plan sponsors' 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.

B. Plan sponsors must make the marketing materials identified in the state-specific MMP marketing guidance document section 30.5 in any language that that meets the more stringent of either the Medicare standard (the primary language of five (5) percent or more of a plan sponsor's plan benefit package service area) or the state's standard. Additionally, plan sponsors must place translated versions of these materials on the plan's website. (*State-specific Marketing Guidance, Section 30.5*)

C. Plan sponsors must include the Multi-Language Insert with the Summary of Benefits and the ANOC/EOC.

(Medicare Marketing Guidelines and State-specific Marketing Guidance, Sections 30.5, 30.5.1, 100.1, and Appendix 3; 42 C.F.R. §§ 422.2264(e), 423.2264(e)); HPMS memo 09/09/2014.)

III. Customer Service Staff Knowledge

A. Ensure staff is familiar with the plans' Medication Therapy Management (MTM) program, including eligibility criteria and additional information required to be available on a dedicated Medication Therapy Management Program page linked from the Medicare drug plan website, and how to direct beneficiaries to the plans' MTM program page. (*Medicare Marketing Guidelines*, *Section 100*)

B. Ensure staff is familiar with the Best Available Evidence (BAE) process and aware of what forms of evidence are considered acceptable proof of Low Income Subsidy (LIS) and how to use the BAE assistance process to verify that an individual has LIS because of their Medicaid status. (*CTM SOP-Plan Version Section I*)

C. Ensure staff is familiar with Medicare Part D coverage determination, appeal and grievance requirements and how to assist beneficiaries and/or direct them to appropriate staff to document and process complaints and requests for coverage decisions. (Medicare Prescription Drug Benefit Manual, Chapter 18)

IV. Pharmacy Technical Help Desk Call Centers

    A. Ensure that pharmacy technical help desk call centers will be staffed appropriately to handle increased call volume during the AEP and opt-in and passive enrollment start dates. Part D Sponsors must meet CMS standards. (*Medicare Marketing Guidelines, Appendix 5*)

    B. Ensure pharmacy technical support is available at all times any network pharmacy is open. Sponsors 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

    A. Be advised of the new release of the Complaints Tracking Module (CTM) Standard Operating Procedures (SOP), and the republishing of the CTM Exclusion Criteria.

      In addition to announcing the revised SOP, the HPMS memo provides suggested examples of satisfactory CTM resolution notes.
      (HPMS memo 6/28/2013)

    B. Plan sponsors should be prepared to resolve at least 95% of Complaints Tracking Module (CTM) complaints designated as "immediate need" within two calendar days, complaints designated as "urgent" within seven days, and resolve at least 95% of CTM all complaints designated without an issue level within 30 days. Plan sponsors are urged to make interim contact with beneficiaries if their complaints will take more than seven days to resolve. (HPMS memo 12/22/2011)

    C. Plan sponsors must prominently display the CMS developed complaint form on their websites and have a direct link to the www.Medicare.gov website and the web site of the Medicare Ombudsman. Plan sponsors should use the following link, https://www.medicare.gov/MedicareComplaintForm/ to direct beneficiaries directly to the complaint form. (HPMS memo 11/10/2011, 42 CFR §§ 422.504 and 423.505)

E. Marketing

I. Anti-Discrimination

    A. Ensure your organization is able to provide basic services and information to individuals with disabilities, upon request.

    B. Ensure your organization makes available all plan materials and information, including those produced or distributed by contracted providers, in alternative formats (e.g., braille, large print, and audio) to individuals with disabilities upon request.

    (HPMS memo 09/09/2014, *Medicare Marketing Guidelines, Section 30.6*)

II. Post-Enrollment Marketing Materials

A. Annual Notice of Change (ANOC) and Evidence of Coverage (EOC)/Member Handbook

    i. Ensure your documents are accurate prior to mailing the ANOC/EOC (Member Handbook).

    ii. Ensure *errata* sheets are sent timely upon identification of inaccuracies in the ANOC/EOC (Member Handbook).

    iii. Ensure that new enrollees with effective dates of October 1, November 1, or December 1 receive both an EOC (Member Handbook) for the current contract year and an ANOC/EOC (Member Handbook) for the upcoming contract year. For these members, the combined ANOC/EOC (Member Handbook) for the upcoming year, as well as the formulary and pharmacy/provider directory (if the plan is required to send a hard copy) for the upcoming year, must be received by one month after the effective date of enrollment, but not later than December 15th. (*State-specific Marketing Guidance, Section 60.7)*

    iv. Ensure than an ANOC is sent for member receipt by September 30th for the upcoming coverage year, and the EOC (Member Handbook) is sent consistent with the requirements of section 60.7 of the state-specific MMP marketing guidance document *(State-specific Marketing Guidance, Section 60.7)*

    v. Indicate the actual mail date in HPMS within 15 days of mailing of the ANOC/EOC (Member Handbook). *(State-specific Marketing Guidance, Section 60.7)*

III. Formulary

A. Ensure your organization's CMS-approved formulary matches the marketed formulary both in print and on the website.

B. Ensure your organization's formulary is updated on the website when changes are made.

(Medicare Marketing Guidelines and State-specific Marketing Guidance, Section 60.5)

IV. Websites – Medicare Advantage Organizations, Part D Sponsors, and Cost Plans

A. Ensure your organization's website contains the general requirements (e.g. customer service number, required translated materials).

B. Ensure your organization includes all required content and documents as outlined in the Medicare Marketing Guidelines and State-specific Marketing Guidance (e.g. rights and responsibilities, Summary of Benefits, link to CMS appointment of representative, information on how to file a grievance/coverage determination/appeal), immediate access to the coverage determination and appeals processes).

(Medicare Marketing Guidelines and State-specific Marketing Guidance, Section 100)

V. **Agents and Brokers   Note: This section does not apply to MMPs in states where agent/broker activity is prohibited for the demonstration.**

A. If applicable, ensure all agents/brokers (employed/captive or independent, if applicable) selling Medicare products are annually trained and tested (passing score is 85%) on Medicare rules, regulations, and detail specific plan products that they sell. This means that training and testing must take place prior to the broker/agent selling the product.

B. If applicable, ensure your organization's training curricula contain the minimum information and required elements listed in the annual guidelines HPMS memo Agent Broker Training and Testing.

C. If applicable, ensure your organization follows all CMS rules and guidance for compensation of independent agents and brokers, when utilized for the sale of MMP products. Employed and captive agents/brokers who only sell for one Plan/Part D Sponsor are exempt from compensation requirements, except where noted (e.g., referral/finder fee). However, all other marketing and sale requirements must be met.

NOTE: Per 42 CFR 422.2274(a) and 423.2274(a), Section 120.4 of the *Medicare Marketing Guidelines* will apply on January 1, 2015.

D. If applicable, ensure your organization has processes in place for oversight of Agent/Broker marketing and sales activities, if applicable.

(Medicare Marketing Guidelines and State-specific Marketing Guidance, Section 120)

F. Enrollment/Disenrollment

I. **Enrollment Processes and Notices**

A. Ensure your organization sends individuals a welcome letter and other required material for new enrollees in the MMP.

II. **Enrollment Processing**

A. Ensure your organization meets the plan data due date each month for submitting transactions as indicated in the Plan Communications User Guide. Normal processing time ends at 8:00 PM Eastern Time (ET) but occasionally the timeframe changes due to special processing. Advance notification will be given if there is a change in the normal processing timeframe. Review and process CMS TRR and other MARx reports in a timely and consistent manner, and take appropriate actions to resolve rejections and correct errors. *(Plan Communications User Guide)*

B. Ensure a process is in place to transmit sponsor-generated enrollment transactions that include active 4Rx data, and for state-generated enrollments, to transmit active 4Rx data on an update transaction within 72 hours of availability of the TRR transmitting the enrollments. (42 C.F.R. § 423.32(c))

Of note plan sponsors may enter more than one 4Rx entry allowing current and future 4Rx information. The data will be differentiated by the effective date of each 4Rx entry. (*Plan Communication Guide*)

H. Benefits Administration & Beneficiary Protections

I. **Prescriptions Covered Under Part D – Requirement for Physicians and Eligible Prescribers to enroll in Medicare, or opt-out of Medicare**

Beginning June 1, 2015, CMS is requiring that physicians and eligible professionals who prescribe covered Part D drugs be enrolled in Medicare, or have a valid record of opting out of Medicare, in order for their prescriptions to be covered under Part D per 42 CFR § 423.120(c)(6).

II. **Explanation of Benefits**

    i. Ensure that enrollees who utilize their prescription drug benefits in a given month receive their Explanation of Benefits (EOB) by the end of the month following the month in which they utilized their prescription drug benefits. (*Medicare Marketing Guidelines)*

III. **Advance Directives**

    Comply with federal and state regulations which include maintaining written policies and procedures regarding advance directives for all adult individuals receiving medical care by or through the Medicare Advantage organization. (*Managed Care Manual Chapter 4, Section 70,* and 42 C.F.R. § 422.128)

IV. **Benefits**

    A. If your plan does not offer a visitor/travel benefit to retain enrollees when they are outside of their service area for six (6) to twelve (12) months, then ensure that you disenroll beneficiaries who are absent from the plan's service area for six (6) months. (*Managed Care Manual, Chapter 4, Section 100.7,* and HPMS memo 4/30/2010)

V. **Formulary**

    A. Implement processes to rely on the FDA Comprehensive NDC Structured Product Labeling (SPL) Data Elements file (NSDE file) to help determine which NDCs represent currently marketed Part D drugs.. (HPMS memos 5/14/2012 and 08/16/2012)

    B. Ensure your organization allows overrides of edits on topical ophthalmic products when appropriate to prevent unintended interruptions in drug therapy. (HPMS memo 6/2/10)

    C. Ensure that the POS claims adjudication is consistent with the HPMS-approved formulary and that no unauthorized utilization management (UM) edits are in place. (HPMS memo 10/22/2010)

D. Ensure your organization routinely monitors 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)

E. Ensure your organization properly administers its CMS-approved formulary by applying only approved quantity limits, and approved utilization management practices, and allowing claims for formulary drugs dispensed in the smallest commercially available package size when the day supply exceeds the plan's supply benefit. (*Medicare Prescription Drug Manual, Chapter 6, Section 30.3.3*)

VI. Daily Cost Sharing Requirements

Beginning January 1, 2014, establish and apply a daily cost sharing rate for Part D drugs whenever certain prescriptions (depending on the drug dispensed) are dispensed by a network pharmacy for less than a 30 days' supply in accordance with 42 CFR § 423.153(b)(4)(i). This requirement only applies for Part D drugs to which the MMP applies LIS cost-sharing levels. (*Calendar Year 2014 Medicare Advantage and Part D Final Call Letter*)

VII. Auto-Ship Refill Programs in Part D

A. Ensure your organization follows the mail-order auto ship guidance as stated in the March 21, 2014 HPMS memo.

　i. If a beneficiary has experience using mail-order or other automatic delivery programs under the plan, sponsors do not need to establish an additional opt-in procedure to acquire explicit consent to fill initial scripts.

　ii. 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 your organization should receive consent from the beneficiary before that prescription is filled.

　iii. Only the initial prescriptions needing this explicit consent are for those prescriptions electronically transmitted (by fax or electronic prescription) directly to a mail-order pharmacy or other automatic delivery program for beneficiaries who have not previously elected to utilize those services under the plan.

B. Exceptions to the Auto-Ship Policy

　i. Two exceptions authorizing automatic deliveries without prior beneficiary consent were offered to plan sponsors agreeing to meet the conditions stated. Plans that requested either exception, for all or part of 2014, do not need to submit a new request for 2015.

ii. Sponsors interested in requesting an exception for the first time must submit the sponsor name and contract numbers that the automatic delivery program will be applied to, as well as an attestation that the automatic delivery program meets all of the conditions detailed in the 2014 memos no later than December 19, 2014 to PartDPolicy@cms.hhs.gov.

(HPMS memo dated 09/22/2014 and *Calendar Year 2014 Medicare Advantage and Part D Final Call Letter*)

VIII.   Pharmacy & Therapeutics (P&T) Committee

Ensure your organization's P&T committee members come from various clinical specialties that adequately represent the needs of sponsors' enrollees, including:

- A majority of the P&T committee members must be practicing physicians, practicing pharmacists or both.

- At least one P&T committee practicing pharmacist and one practicing physician must be an expert in the care of elderly or disabled persons.

- At least one P&T committee practicing pharmacist and one practicing physician must be independent and free of conflict with respect to the Part D sponsor and pharmaceutical manufacturers.

(*Medicare Prescription Drug Benefit Manual Chapter 6, Section 30.1*)

IX. Quality Improvement (QI) Programs

A. The QI program must meet the applicable requirements for the services that it furnishes to its enrollees, as specified at 42 CFR §422.152 and 42 CFR §438.240 and detailed in the three-way contract.

B. The initial QIP Plan Section is due during the CMS-determined submission window in the fall of the first year of implementation. CMS and the states will provide details regarding required MMP submissions, including number of and type of topics prior to submission. (HPMS memo 10/17/2014)

C. The QIP Annual Update is due during the CMS-determined submission window in the fall of the first year of implementation following approval of the QIP 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)

D. Readers may visit the HOS website at http://www.HOSonline.org for webinars addressing how the HOS data can be used for quality improvement activities and for additional resources to help MAOs use their HOS results to target quality improvement activities. CMS encourages each MAO to work in collaboration with their QIO to examine their results. (HPMS memo 08/01/2014)

E. Effective August 1, 2014, sponsors 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)

X. Improving Drug Utilization Controls in Part D

A. Ensure your organization implements 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. (*2013 Call Letter*, HPMS memo 9/6/2012, and http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html)

B. 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)

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

I. Best Available Evidence (BAE) Policy

A. 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)

B. Meet the 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.

C. 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.

D. 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. 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*)

E. Follow CMS' process for assisting individuals without BAE documentation. Sponsors 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, Sponsors are required to use the process outlined in *Medicare Prescription Drug Benefit Manual Chapter 13, Section 70.5.3*.

F. Ensure websites contain a link to the CMS website BAE page (http://www.cms.gov/Medicare/Prescription-Drug-

Coverage/PrescriptionDrugCovContra/Best_Available_Evidence_Policy.html)
containing CMS policy guidance. (*Medicare Drug Benefit Manual Chapter 13, Section 70.5* and HPMS memo 08/04/2008).

II. **Low Income Subsidy Benefit Administration**

A. Ensure your organization applies 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 Chapter 13*)

B. 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 a sponsor receives information that necessitates a retroactive claims adjustment, the sponsor must process the adjustment and issue refunds or recovery notices within 45 days of the sponsor'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 and § 423.800)

III. **Loss of Low Income Subsidy Data File**

A. In response to the Loss of Subsidy Data File (released in December of each year), notify state so they can correct, as all demonstration enrollees should be dually eligible and thus deemed eligible for the full Low Income Subsidy.

   (HPMS memos 11/30/2009 and 7/31/2013)

IV. **Low Income Subsidy Deeming**

A. Ensure your organization follows the CMS guidance for re-determination of Part D LIS eligibility for 2014. (HPMS memo 07/31/2013)

   Beginning in July 2011, CMS runs its re-deeming process daily and communicates the re-deemed records with Part D sponsors via the daily TRR. Beneficiaries who have been re-deemed are identified with the transaction reply code (TRC) 121.

B. 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 E18, Loss of Subsidy Data File* ([http://www.cms.hhs.gov/MMAHelp and HPMS memo](http://www.cms.hhs.gov/MMAHelp)07/31/2013).

C. 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.*

V. LIS Match Rate

Ensure your organization maintains accurate LIS information, which is vital to ensuring all low-income beneficiaries are charged the correct premiums and co-payments for their prescription drugs. Part D sponsors must be able to process the LIS History (LISHIST) files received from CMS, and reconcile against their data systems' enrollees' LIS status. (HPMS memos 8/30/2006, 10/30/2006, 11/26/2008, 11/23/2009, and 12/09/2010)

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

Medicare Prescription Drug Manual Chapter 14 – Coordination of Benefits **and HPMS memo 03/02/2012**

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

A. Ensure a revised business associate agreement (BAA) that reflects the recent Health Insurance Information Technology for Economic and Clinical Health (HITECH) Act is executed between sponsors and Relay Health, the transaction facilitator. Sponsors must provide an updated implementation form to the Transaction Facilitator to notify the Transaction Facilitator of new contract IDs that should be added to the existing BAA. If the existing BAA does not cover a new contract ID because that contract ID falls under different legal entity, a new BAA must be submitted.

NOTE: The BAA requirement is applicable not only to sponsors directly reporting the TrOOP accumulators to the transaction facilitator, but also to sponsors using a processor for the automated TrOOP balance transfer process. Therefore, it is critical that each Part D sponsor has a signed agreement with the Transaction Facilitator.

B. Establish/maintain systems and procedures for at least weekly COB data report/file processing. (*Medicare Prescription Drug Benefit Manual Chapter 14, Medicare Secondary Payer Manual Chapter 6*) and the *Plan Communication User Guide (PCUG)*).

   i. Organizations are required to not only receive COB information but also to apply it to their system(s).

   ii. Organizations utilize the Electronic Correspondence Referral System (ECRS) (https://www.cob.cms.hhs.gov/ECRS) to send COB updates to CMS (ECRS user guide is available on the CMS website at https://www.cms.gov/manuals/downloads/msp105c05_att1.pdf).

iii. CMS receives daily COB updates from the Benefits Coordination & Recovery Center (BCRC), and CMS subsequently sends the COB file to the MAOs and Part D sponsors.

C. Medicare Hospice and ESRD

i. If this population is eligible for enrollment under your demonstration, ensure that your organization has fully implemented hospice guidance dated July 18, 2014. This means that all Part D sponsors should have in place beneficiary-level Prior Authorization (PA) requirements on four categories of prescription drugs; analgesics, antinauseants (antiemetics), laxatives, and antianxiety drugs (anxiolytics). Plans should also be using a verbal or written statement from the prescriber or the hospice provider indicating the drugs are unrelated to the terminal illness and related conditions, and should also have implemented processes to update beneficiary hospice enrollment and disenrollment data as specified in the guidance.   Please review the guidance as well as the Hospice FAQs. The updated FAQ document can be found at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/index.html

ii. ESRD – If this population is eligible for enrollment under your demonstration, ensure your organization does 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). Thus, when a sponsor receives a TRR showing an ESRD beneficiary is receiving renal dialysis services, the sponsor must have controls in place to comply with this requirement. Similar to the approach for hospice, we strongly encourage sponsors to place beneficiary-level PA requirements on the five categories of drugs that are always used for ESRD treatment. However, for the seven categories of prescription drugs that may be used for ESRD treatment, CMS issued revised guidance effective October 2014. Because the majority of the drugs in the categories that may be used for ESRD treatment are used for other purposes, we strongly encourage sponsors to remove the beneficiary-level PA requirements on these drugs.   Part D sponsors are not expected to place ESRD PA requirements on these categories of drugs, take special measures beyond their normal compliance and utilization review activities, or to retrospectively review paid claims in order to determine whether drugs in these seven categories were used for ESRD treatment or for payment recovery.   The seven categories of drugs are listed in Table 5 of the *2014 Call Letter*.

D. Interpret the COB file correctly. (2008 Regional Prescription Drug Event Data Technical Assistance Participant Guide, HPMS memo 11/24/2008, *Medicare Secondary Payer Manual Chapter 6, Managed Care Manual, Chapter 4, Section 130*)

i. The information on the COB file is collected by the BCRC for establishing payer order. For Medicare Secondary Payer (MSP) purposes, the BCRC determines

payer order responsibilities avoiding duplication of payment and preventing Medicare from paying primary when it is secondary.

ii. Replace the entire beneficiary record for each changed record. The COB file contains information regarding the beneficiary's other health insurance information (OHI). The OHI is either primary to Medicare, or supplemental to Medicare. If an enrollee's OHI record has been added, changed, or deleted, this will trigger a full replacement of that enrollee's detail (DTL) and subordinate primary (PRM) and supplemental (SUP) records.

iii. CMS annually creates and issues full replacement COB files to all Part D plan sponsors, based on sponsors' enrollees as of the date the full replacement file is processed. These files will include both the record updates that would normally be included in the daily COB notification files and the full replacement COB data for all enrollees with other coverage. These combined daily update/full replacement COB files contain no special identifiers to distinguish them from the normal daily files, but they may be identifiable based on the date of receipt and large size of the files. The full replacement files include the last 27 months of other coverage information.

E. Follow the COB notification process and request the beneficiary provide new or updated other prescription drug coverage information when the other drug coverage information exists on the COB file. (*2010 Call Letter and update* via HPMS memo 07/21/2009)

i. Forward credible changes to other prescription drug coverage information reported by beneficiaries to the BCRC via ECRS.

ii. Coordinate benefits with State Pharmacy Assistance Programs (SPAPs), AIDS Drug Assistance Programs (ADAPs), Indian Health Service (IHS), and other entities providing prescription drug coverage, beneficiaries, and others, paying on behalf of beneficiaries for a period not to exceed three years from the date on which the prescription for a covered Part D drug was filled. (42 C.F.R. §423.466(b))

iii. Ensure your organization correctly identifies its members who are also an SPAP or ADAP enrollee, and send the member's SPAP/ADAP 4Rx data back to the pharmacy in the claim response so that the pharmacy may appropriately bill the SPAP or ADAP for their portion of the enrollee's cost sharing. To assist with the coordination of the SPAPs and ADAPs, NCPDP maintains a list of BIN/PCN on the NCPDP website. The BCRC precludes Part D sponsors from updating SPAP and ADAP information. Only those programs may update the information with the BCRC.

II. Information Reporting Transactions (Nx or N)

Ensure organization correctly processes Nx (N1, N2, N3) transactions received from the Part D Transaction Facilitator, which identify supplemental payments and thus impact

the TrOOP accumulators, including N transactions providing information on SPAP/ADAP payments.

III. **TrOOP Balance Transfer (TBT) and Financial Information Reporting (FIR) Version 1.2**

   A. Ensure your organization accurately tracks, accumulates, and reports TrOOP for all enrollees.

   B. Ensure your organization promptly addresses TBT problems identified through the exceptions reports. Sponsors must successfully resolve identified problems with enrollee automated TBT Transactions within 15 days of notification of the problem.

   C. Ensure your organization has provided a valid email address for which to receive the Daily Cumulative FIR Aging Report. Because of the time constraints associated with responding to TBT transactions, the use of an email address is critical. To prevent any delay in response due to turnover, a general email address as opposed to a personal email address is recommended.

IV. **Direct Member Reimbursement**

   - Ensure your organization follows the guidance specified for direct member reimbursement, which is outlined in:

     o Section 50.4.3 and Table 50.4.3-1 of the *Medicare Prescription Drug Manual – Chapter 14*. This section provides guidance to ensure consistent handling of out-of-network claims for both LIS and non-LIS eligible beneficiaries as well as paper claims for drugs accessed from network pharmacies.

     o Section 30.3 of the *Medicare Prescription Drug Benefit Manual - Chapter 18*. This section defines a request for reimbursement as coverage determination.

K. Claims Processing and Transition Process

I. **Point of Sale (POS) Claims Processing**

   A. Maintain payment systems to ensure they are set up to charge beneficiaries the lesser of a drug's negotiated price or applicable copayment amount. (*Medicare Prescription Drug Benefit Manual Chapter 5*)

   B. Maintain claims systems and oversight adequate to ensure that network pharmacies distribute a copy of the standardized pharmacy notice when a prescription cannot be filled under Part D and the issue cannot be resolved at the POS. (Section 40.3.1 of *Medicare Prescription Drug Manual, Chapter 18*)

   C. Part B covers all dialysis-related drugs furnished to renal dialysis for end stage renal disease (ESRD) patients, including the Part D drugs, except oral-only ESRD drugs and biologicals. (HPMS memo 02/17/2011)

II. **Federal Disaster or Public Health Emergency Declarations**

   Ensure your organization is prepared to follow CMS guidance regarding pharmacy and provider access during a Federal Disaster or other Public Health Emergency Declaration.

(HPMS memos 06/16/2008, 07/20/2009, 11/7/2012, and *Medicare Prescription Drug Benefit Manual Chapter 5, Medicare Managed Care Manual, Chapter 4, Section 30.9*)

We advise sponsors to consult the U.S. Department of Homeland Security's Federal Emergency Management Agency's (FEMA) website (see http://www.fema.gov/hazard/dproc.shtm) for information about the disaster or emergency declaration process and the distinction between types of declarations. Sponsors should also consult the Department of Health and Human Services (DHHS) or CMS websites for any detailed guidance that may be posted.

III. Transition Process

A. CMS expects sponsors to fully test how their transition policy works in their 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 2015. (HPMS memo 3/25/2010)

B. 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 CY2014 to CY2015). Sponsors 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 2015 formulary prior to January 1, 2015. Sending the ANOC is not sufficient to effectuate the transition. (HPMS memo 3/25/2010, 8/27/2010)

One way to ensure a transition supply has been provided is to closely monitor current enrollees' rejected claims after the beginning of CY 2015.

C. Effectuate a meaningful transition for:

  i. New enrollees into prescription drug plans at the beginning of a contract year,

  ii. Newly eligible Medicare beneficiaries from other coverage at the beginning of a contract year,

  iii. Individuals who switch from one plan to another after the beginning of a contract year, and

  iv. Enrollees residing in long-term care (LTC) facilities. Specifically, during the transition period specified in the MMP's three-way contract, sponsors will ensure that the transition for beneficiaries residing in LTC settings will provide for a total supply of at least 91- to 98-days, with refills provided consistent with the dispensing increment; and after the transition period has expired, a 31-day emergency supply of non-formulary Part D drugs is available while an exception or prior authorization is requested. (*State-specific Three-way Contract*)

D. Ensure the Sponsor provides access to a transition supply of medication within the transition period specified in the MMP's three-way contract, including for those beneficiaries whose first 90 days cross contract years (e.g., effective date of enrollment is November 1st or December 1st). (*State-specific Three-way Contract*)

E. Ensure enrollees receive the required notice explaining their right to ask for an exception.

F. Ensure that reasonable efforts are made to notify prescribers of enrollees who receive a transition notice after adjudication of a temporary fill. ((42 C.F.R. § 423.120(b)(3)(v)), (HPMS memo 12/20/2010))

G. Ensure that the transition policy provides refills for transition prescriptions dispensed for less than the written amount due to quantity limits for safety purposes or drug utilization edits that are based on approved product labeling.

H. Ensure systems are in place to continue to provide necessary drugs to an enrollee via an extension of the transition period, on a case-by-case basis, to the extent that his or her exception request or appeal has not been processed by the end of the minimum transition period. (*Medicare Prescription Drug Benefit Manual Chapter 6*)

I. Ensure that cost-sharing for a temporary supply of drugs provided under its transition process will never exceed the statutory maximum co-payment amounts for low-income subsidy (LIS) eligible enrollees.

IV. Retroactive Claims Adjustments, Underpayment Refunds, and Overpayment Recoveries

After receiving information that necessitates a retroactive claims adjustment, process the adjustment and issue refunds or recovery notices within 45 days of the sponsor's receipt of complete information regarding the claims adjustment. (42 CFR § 423.466(a))

L. Grievances, Initial Coverage Decisions, and Appeals

I. Requirement to Employ a Medical Director

Your organization must employ a medical director who is responsible for the clinical accuracy of all initial coverage decisions (organization or coverage determinations) and appeals (reconsiderations or redeterminations) 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. Your organization should also refer to the three-way contract for additional qualifications related to the medical director. (42 C.F.R. §§ 422.562, 423.562)

II. Requirement Related to Who Must Review Initial Coverage Decisions

Ensure your organization has adequate staff 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 (organization or coverage determination) 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. §§ 422.566, 423.566)

III. Appropriateness of Clinical Decision-Making

Your organization must ensure that clinical and administrative staff and delegated entities involved in processing initial coverage decisions (organization or coverage determinations) 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. MMP sponsors are expected to solicit necessary clinical documentation from providers and prescribers to the extent this documentation is needed to properly adjudicate coverage requests and appeals. MMP sponsors are expected to give great weight to prescriber supporting statements for exception requests. (HPMS memo 08/27/2014)

IV. Online Appeals Training Courses (HPMS memo 04/28/2014)

Ensure your organization's compliance officer, staff involved with initial coverage decisions, appeals, and grievances, and customer service representatives, are trained in Part C and Part D processes as applicable for an MMP. 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.

  A. Medicare Part D: Coverage Determinations, Appeals and Grievances. This course covers requirements found at 42 CFR Part 423, Subpart M and Chapter 18 of the Prescription Drug Benefit Plan Manual.

  B. Medicare Part C Appeals: Organization Determinations, Appeals and Grievances. This course covers requirements found at 42 CFR Part 422, Subpart M and Chapter 13 of the Medicare Managed Care Manual.

V. Rights of Enrollees

  A. Ensure that for Part D benefits 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.

  B. Ensure that the Part D systems are properly transmitting codes to network pharmacies that instruct the pharmacies to provide enrollees with a notice at point of sale in certain circumstances where the prescription cannot be filled under the Part D benefit. The notice provided at point of sale explains the enrollee's right to contact the plan to request a coverage determination.

  C. Ensure enrollees are afforded all rights and protections of grievances, initial coverage decisions, and appeals processes. (*three-way MMP contract*, *Prescription Drug Benefit Manual, Chapter 18 - Part D Enrollee Grievances, Coverage Determinations, and Appeals* and, to the extent not superseded by the three-way

MMP contract, *Medicare Managed Care Manual, Chapter 13 – Beneficiary Grievances, Organization Determinations, and Appeals*)

CMS continues to identify areas of significant non-compliance during plan audits with respect to how MAOs and Part D plan sponsors are processing initial coverage requests, plan level appeals, and grievances.

- CMS expects MMPs to have internal controls in place to detect and promptly correct potential deficiencies in operations impacting organization and coverage determinations, plan appeals, and grievances.

D. Ensure that Part C Reconsideration Dismissal Procedures have been properly implemented

As of January 1, 2014, in addition to being responsible for dismissing reconsideration requests when appropriate and providing timely notification of dismissals to enrollees or another party, MMPs (as applicable) are responsible for informing enrollees and other parties about the right to request IRE review of the dismissal. MAOs no longer automatically forward such reconsideration cases to the IRE for review. HPMS memo 09/10/2013

VI. Oversight of Entities Performing Delegated Functions

If your organization delegates functions related to coverage determinations, appeals or grievances, your organization remains responsible for ensuring compliance with all CMS requirements. Therefore, you must be able to demonstrate that you are routinely monitoring and overseeing the delegated functions, ensuring corrective action is implemented in response to identified compliance issues, reporting non-compliance to your Contract Management Team and that this oversight is integrated into your overall compliance program.

NOTE: The role of Medical Director may not be a delegated function.

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

Prescription Drug Benefit Manual Chapter 9 and Medicare Managed Care Manual Chapter 21; **42 C.F.R. §§ 422.503(b)(4)(vi) and 423.504(b)(4)(vi), and HPMS memo 07/30/2013**

I.   Focus your internal monitoring efforts by reviewing the common conditions, improvement strategies, and best practices from the 2013 program audits as described in the HPMS memo dated August 27, 2014.

II. CMS encourages plan sponsors to utilize CMS' audit protocols, available on CMS' website http://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Program-Audits.html, to conduct internal audits and identify any operational deficiencies in need of correction.

III. Adopt and implement an effective compliance program that includes all of the requirements stated at 42 C.F.R. §§ 422.503(b)(4)(vi), 423.504(b)(4)(vi) and the three-way contract. Those requirements include, but are not limited to:

A. Standards of Conduct and written policies and procedures that describe compliance expectations, address FWA, implement compliance operations, provide guidance to employees and first tier, downstream, and related entities (FDRs) on dealing with suspected, detected or reported compliance issues, identify how to communicate issues, describe investigation and resolution processes, and include a policy on non-intimidation and non-retaliation.

B. A governing body that is knowledgeable on the content and operations of the Medicare Compliance Program and conducts oversight of the program; a Compliance Officer and Compliance Committee that report directly to and are accountable to the Chief Executive Officer (CEO) or other senior management; a Compliance Officer that has express authority to meet with the governing body at his/her discretion; and a Compliance Officer that is an employee of the sponsor, or its parent or affiliate.

C. Effective training and education on the Standards of Conduct and on reporting suspected or detected noncompliance for all employees, governing body, and volunteers, to be made part of orientation for new employees, and at least annually thereafter; and FWA training for all employees, governing body, volunteers, and FDRs at orientation and at least annually thereafter.

D. Effective lines of communications between the Compliance Officer and employees, managers, directors, governing body, FDRs, and plan members that are accessible to all, and that allow compliance and potential fraud, waste and abuse issues to be reported, including at least one method of anonymous reporting; and prominent publication to employees, board members, first tier, downstream, and related entities, and plan members of the reporting methods.

E. Implementation of well-publicized disciplinary standards that: identify non-compliant and unethical behavior and FWA; articulate expectations for reporting non-compliance and FWA and assist in the resolution of issues; and that are timely, consistently, and effectively enforced.

F. Implementation of an effective system for routine-monitoring, auditing and identification of risks, that includes, among other things: a baseline assessment of your organization for Medicare program noncompliance and FWA risks; internal monitoring and audits to evaluate sponsor's and first tier, downstream, and related entities' compliance with Medicare Parts C and D requirements; and monthly screening of employees, board members, consultants, volunteers, and FDRs against the OIG and GSA exclusion lists to identify persons and entities excluded from participation in federal health care programs, and effective monitoring activities to prevent and detect FWA.

G. Implementation of procedures and a system for prompt response to compliance issues as they are raised; the investigation of potential problems identified through self-evaluation and audit; the prompt and thorough correction of problems identified; procedures for the voluntary self-reporting of issues to CMS or its

designee, as appropriate; and the prompt repayment of claims for drugs, items, or services prescribed or provided by excluded providers.

H. Accountable for and oversees key functions performed by FDRs; clear and defined processes and analysis for evaluating whether a contracted entity is a FDR; effective oversight program to ensure FDRs comply with CMS requirements and timely corrective actions.

I. An advisory committee (or similar body), including robust enrollee participation, as described in MMPs' three way contracts.