DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTER FOR MEDICARE

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To: All Medicare Advantage Organizations (MAO), Prescription Drug Plan (PDP) Sponsors, and 1833 & 1876 Cost Plans

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Subject: Revised 2016 Readiness Checklist for Medicare Advantage Organizations, Prescription Drug Plans, and Cost Plans

The Centers for Medicare & Medicaid Services (CMS) is reminding organizations of critical Medicare Part C and D requirements for the Annual Election Period (AEP) and coverage beginning January 1, 2016. A separate 2016 Readiness Checklist for operational Medicare-Medicaid Plans (MMPs) will be forthcoming.

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. The Readiness Checklist is not an exhaustive list of all Medicare Advantage (MA), Prescription Drug Plan (PDP), and Cost Plan requirements.

Should you identify areas where your organization needs assistance or is not/will not be in compliance, your organization must report those problems to your Account Manager directly by email in a timely manner.

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

CY 2016 Medicare Advantage Organization, Prescription Drug Plan, and Cost Plan Readiness Checklist

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Note: Unless otherwise indicated, where a requirement applies to Medicare Advantage Organizations, it also applies to 1876 Cost Plans. References to Part D sponsors include all organization types offering Part D.

A. Systems, Data, & Connectivity

I. Health Plan Management System (HPMS) – Medicare Advantage Organizations and Part D Sponsors

- Ensure key staff members register for the Plan Connectivity Data Module within HPMS by e-mailing hpms_access@cms.hhs.gov.
- Update your organization's contact contract information in HPMS, ensuring all information is current. Changes to any HPMS contacts or Part C and Part D Information are expected to be made immediately upon the effective date of the responsibility transfer.
- 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.
- 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 – Part D Sponsors

- 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 coverable under Part D, unless the prescriber is an "Other Authorized Prescriber." Part D sponsors 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. Part D sponsors 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 contracted 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.
- Sponsors and their Pharmacy Benefit Managers (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 – Part D Sponsors

- Consistent with the Medicare Access and CHIP Reauthorization Act of 2015, for plan year 2016 and thereafter, claims for covered Part D drugs must include a valid prescriber NPI.
- Part D sponsors 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 6/9/2015)

IV. MARx – Medicare Advantage Organizations and Part D Sponsors

- Ensure your External Point of Contact 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/)
- 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) – Medicare Advantage Organizations and Part D Sponsors

- Adhere to 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/)
- ECRS transactions capture diagnosis codes related to a No-Fault, Worker's Compensation, or Liability Medicare Secondary Payer (MSP) case. 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.
- Part D sponsors 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) – Applicable organization types noted below

- **Pricing Data and Pharmacy Network Files.** (Part D Sponsors) Ensure timely and accurate submission of CY 2016 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 6/19/2015)
    - Ensure preferred cost-sharing pharmacy arrangements are accurately identified in MPF pricing files. A pharmacy may only be associated with the

plan's preferred cost-sharing network if a lower differential cost sharing applies to some tiers of formulary drugs at that pharmacy than applies at pharmacies in the standard cost-sharing network.

- 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 the Medicare Plan Finder, and/or applicable compliance actions.

(CY 2016 Pricing Data Requirements – 6/16/2015)

- **MPF File Pre-Submission Quality Assurance Testing.** (Part D Sponsors) Ensure your organization performs quality assurance activities prior to submitting MPF files to CMS. Sponsors 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, sponsors may have their pricing data suppressed on the MPF.
    - 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.
- **MPF Communications Website.** (New 2016 Medicare Advantage Organizations and Part D Sponsors) 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.

VII. User Group Calls – Medicare Advantage Organizations and Part D Sponsors

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 – Part D Sponsors

- 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. (HPMS memo 04/08/2015)

- New sponsors 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 – Part D Sponsors

- 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.
- Ensure the OMS quarterly reports are reviewed and acted upon and CMS receives a response within 30 days of the report. For additional information, the OMS User Guide is available on the Patient Safety Analysis Website under Help Documents. (HPMS memo 04/08/2015; also see Section H.VI of this document. *Improving Drug Utilization Controls in Part D*)

X. Risk Adjustment Data Submissions

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

- 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:
  - Enroll to submit data through CSSC,
  - Subscribe to receive email updates,
  - Perform certification requirements,
  - Be familiar with guidance contained on the CSSC website, and
  - Begin submission of production data within 4 months of contract effective date.

XI. Prescription Drug Event (PDE) Requirements – Part D Sponsors

- Submit timely PDE records (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.

- Promptly resolve rejected PDE records and take corrective action to prevent a recurrence of the issue.
- Establish access to Acumen's Part D Payment Process Support Website. (HPMS memo 10/24/2013)
- Establish access to Acumen's PDE Analysis and PDE Reports websites. (HPMS memo 04/21/2015)
- Have procedures 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 (See HPMS memo 4/16/14), and
  - Payment Reconciliation System (PRS) reports.

XII. Electronic Enrollment Mechanisms

- Organizations developing and offering electronic enrollment mechanisms made available via an electronic device or secure internet website must ensure that CMS' enrollment guidelines are applied to electronic enrollment mechanisms:
  - 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.
  - Comply with CMS's data security policies, at a minimum. https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/InformationSecurity/Information-Security-Library.html
- Sponsors retain complete responsibility for ensuring enrollment policies are followed, and for ensuring the appropriate handling of any sensitive beneficiary information provided as part of the online enrollment, including those facilitated by downstream entities.

- From the point at which an individual selects the plan of his or her choice on the third-party website and begins the online enrollment process, CMS holds the organization responsible for the security and privacy of the information provided by the applicant and for the timely disclosure of any breaches.
- Sponsors retain complete responsibility for ensuring the appropriate handling of any sensitive beneficiary information provided as part of the online enrollment, including those facilitated by downstream entities.

(*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®) – Medicare Advantage Organizations, Section 1876 Cost Plans, and Part D Sponsors

Prepare 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 10/9/2015)

II. Part C and Part D Reporting Requirements – Medicare Advantage Organizations and Part D Sponsors

Prepare 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. (HPMS memo 05/07/2015)

III. Reporting and Returning Medicare Advantage Organization and/or Sponsor Identified Overpayments

Every organization offering a Medicare Advantage (MA) plan and/or sponsor 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 organization or sponsor identified the overpayment. (HPMS memos 02/18/2015, 8/28/2015)

IV. Encounter Data

Part C sponsors shall submit encounter data consistent with guidance and clarifications. (HPMS memo 06/02/2015)

V. Fiscal Soundness

Use the Fiscal Soundness Module in HPMS to submit annual independently audited annual financial statements and 2016 quarterly financial statements. (HPMS memo 3/27/2015)

C. Contracting, Subcontractor Provisions, and Oversight

I. Any Willing Pharmacy (AWP) Contracting Requirements – Part D Sponsors

- To comply with the Any Willing Pharmacy requirement, a Part D plan sponsor must make standard terms and conditions available for all Part D 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 Part D sponsor 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 Part D sponsors 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 – Medicare Advantage Organizations and Part D Sponsors

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 outside of the one of the fifty U.S. 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

- Notify your CMS Account Manager at least 60 days prior to the effective date of the new contract.
- CMS recommends that sponsors making pharmacy network changes provide both those pharmacies whose network status is changing, and enrollees using those pharmacies, with notices of changes specific to their situation.
- Part D Sponsors – If making Pharmacy Benefit Manager (PBM)/ Processor changes:
    - 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.
    - 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 Part D plan sponsor and all first tier, downstream, and related entities, which must contain a provision: (A) Establishing regular updates of any prescription drug pricing standard used by the Part D sponsor consistent with §423.505(b)(21); and (B) Indicating the source used by the Part D sponsor for making any such pricing updates. See 423.505(i)(3)(vii) and MAC Pricing below.

D. Customer Service

I. Customer Service Call Centers – Medicare Advantage Organizations and Part D Sponsors

- Staff all toll-free beneficiary call centers appropriately to handle increased call volume from October 1 to February 14, which includes the AEP. Plans/Part D Sponsors 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. Call centers must be able to provide free interpreter services for Limited-English Proficient (LEP) beneficiaries. (*Marketing Guidelines, Section 80*)
    - From October 1 to February 14 - Current and prospective enrollees must be able to speak with a live customer service representative. Your organization may use alternative technologies on Thanksgiving and Christmas.
    - From February 15 through September 30, your organization may use alternative technologies to meet the customer service call center requirements for Saturdays, Sundays, and Federal holidays.

II. Limited English Speaking Beneficiaries – Medicare Advantage Organizations and Part D Sponsors

- 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.
- Inform callers that interpreter services are "free." Interpreters should be available within seven (7) minutes of reaching the Customer Service Representative (CSR).
- Make the marketing materials identified in the *Medicare Marketing Guidelines* sections 30.6, 30.7, 30.10 and the Part D Transition Letter(s) available in any language that is the primary language of five (5) percent or more of a plan sponsor's plan benefit package service area. Additionally, plan sponsors must place translated versions of these materials on the plan's website. (Excluding Employer Group/800 series-only contracts)
- Include the Multi-Language Insert with the Summary of Benefits (SB) and the Annual Notice of Changes (ANOC)//Evidence of Coverage (EOC). (Excluding Employer Group/800 series-only contracts)

(*Medicare Marketing Guidelines,* Sections 30.5, 30.5.1, 30.6, 30.7, 80.1, 100.1, and Appendix 3; 42 C.F.R. §§ 422.2264(e), 423.2264(e)); HPMS memo 09/17/2015.)

III. Customer Service Staff Knowledge – Part D Sponsors

Ensure customer service representatives are 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. The 2016 MTM program annual cost threshold increased to $3,507. (*Medicare Marketing Guidelines*, *Section 100.2.1,* HPMS memo 4/7/15)

IV. Pharmacy Technical Help Desk Call Centers – Part D Sponsors

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 – Medicare Advantage Organizations, Part D Sponsors, and Cost Plans

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 all CTM 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 02/06/2015)

E. Marketing

Market consistent with the CY2016 Medicare Marketing Guidelines (HPMS memos 06/02/2015, 8/13/2015)

I. Individuals with Disabilities - Anti-Discrimination – Medicare Advantage Organizations, Part D Sponsors, and Cost Plans

- Provide basic services and information to individuals with disabilities, upon request.
- 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.

(HPMS memo 09/09/2014, *Medicare Marketing Guidelines*, Section 30.4)

II. Formulary – Part D Sponsors

Ensure your organization's formulary is updated on the website when changes are made, and that only approved formularies are marketed. (*Medicare Marketing Guidelin*es, Section 60.5)

III. Referencing Star Ratings in Marketing Materials - Medicare Advantage Organizations, and Part D Sponsors

- Provide the overall Star Ratings information to beneficiaries through the CMS standardized Star Ratings information document, which must be distributed with any enrollment form and Summary of Benefits (SB) document.
- Ensure that any references to Star Ratings comply with the 2016 requirements.

(HPMS memo 10/05/2015 and *Medicare Marketing Guidelines*, Sections 30, 40, 50)

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

- The ANOC/EOC, 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, *Medicare Marketing Guidelines*, Section 100.1). Note that D-SNPs, 1876 Cost Plans, and New Plans/Part D sponsors should reference the HPMS memo for exceptions to this requirement.
- 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 8/13/15, *Medicare Marketing Guidelines*, Section 100.4)
- Third-Party websites that market MA and Part D sponsors' products are expected to meet applicable CMS marketing requirements. Entities that market MA and Part D sponsors' products are expected to meet applicable CMS marketing requirements. (*Medicare Marketing Guidelines*, Section 100.3)

V. Agents and Brokers – Medicare Advantage Organizations, Part D Sponsors, and Cost Plans

Implement Agent/Broker compensation rates, submissions, and training and testing requirements. (HPMS memo 05/29/2015)

VI. Disclaimers

Include the appropriate marketing disclaimer language for plans with limited access to Preferred Cost Sharing Pharmacies. (HPMS memo 06/24/15)

F. Enrollment/Disenrollment and Premium Billing

I. Timing of Annual Enrollment Period (AEP) – Medicare Advantage Organizations and Part D Sponsors

- The AEP begins on October 15 and ends on December 7. An enrollment/disenrollment election type "AEP" cannot be used after the end of the AEP.
- Submit non-AEP enrollments for January 1 effective dates beginning October 5, 2015. Beneficiaries must have a valid election period for a non-AEP enrollment for requests received after the December 7 deadline.
- Submit certain enrollments (e.g., employer group enrollments and enrollments made during an individual's Initial Coverage Election Period (ICEP)) for January 1 effective dates beginning October 5, 2015. Be advised that enrollments received after December 7, 2015 may not be processed as AEP elections. Beneficiaries must be eligible for a valid Initial Election Period or Special Enrollment Period (SEP) for requests received after the December 7 deadline.

(HPMS memo dated 09/29/2015)

II. Medicare Advantage Disenrollment – Medicare Advantage Organizations and Part D Sponsors

The Medicare Advantage Disenrollment Period (MADP) begins on January 1 and ends on February 14. A MA enrollee may disenroll from the coverage and go back to Original

Medicare. If an individual has disenrolled from a MA plan, the individual may also enroll in a stand-alone Part D plan.

III. SEP for Enrollment into a 5-Star Plan – Medicare Advantage Organizations and Part D Sponsors

Beneficiaries may enroll in a plan awarded an overall 5-star rating for 2016, provided the beneficiary is otherwise eligible for that plan. An individual may only use this SEP one time between December 8 and November 30. 5-Star plans must be prepared to accept all valid enrollment requests made using this SEP. (*Medicare Managed Care M*anual Ch. 2, sec. 30.4.4; *Medicare Prescription Drug Plan Benefit Manual* Ch. 3, sec. 30.3.8)

IV. Enrollment Processes and Notices – Medicare Advantage Organizations and Part D Sponsors

For enrollments effective January 2016 and later, electronic enrollment mechanisms via a third-party website or non-plan owned electronic device, mechanism, or software are permitted. (HPMS memo 07/06/2015)

V. Online Enrollment Center – Medicare Advantage Organizations and Part D Sponsors (Excluding MSA, 800-Series-Only, and Medicare-Medicaid plans; Optional for SNPs, RFB, and 1876 cost plans; Required for PDP and MA-PD)

- Establish and maintain a process to download enrollment at least once daily from the Online Enrollment Center (OEC) unless your organization is prohibited from participating in the OEC. (*Medicare Managed Care Manual* Ch. 2, sec. 40.1.2; *Medicare Prescription Drug Plan Benefit Manual* Ch. 3, sec. 40.1.2, AND email from CMS Plan Communications 08/27/2015)
- The Medicare Plan Finder online enrollment function will be disabled for Medicare Advantage and Prescription Drug Plans with low-performing plan icons for CY2016 to assist in guiding beneficiaries towards selecting higher performing plans.

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

- Submit enrollments and disenrollments directly to MARx following the "current calendar month" cycle. Organizations can submit enrollments and disenrollments for the current calendar month and for the calendar month prior to the current calendar month, using the User Interface (UI) or in batch submissions. Enrollment into, or disenrollment from, EGHP plans may be submitted via the UI or in batch for the current calendar month minus three months.
- 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.

VII. Premium Billing – Medicare Advantage Organizations, Medicare Cost Plans, and Part D Sponsors

- Properly process notifications from CMS of reinstatement for good cause for Part D-Income Related Monthly Adjustment Amount (IRMAA) cases. Upon disenrollment for failure to pay ~~the plan's premium or~~ Part D-IRMAA, CMS will make all decisions about reinstating beneficiaries on the basis of good cause.
- Establish a process to receive *Good Cause Requests* for disenrollments for failure to pay plan premiums. Starting with disenrollment effective dates as of January 1, 2016, plans are responsible for all aspects of the good cause process, including receiving requests, making good cause determinations, notifying the beneficiary, collecting payment, and submitting the reinstatement requests to the Retroactive Processing Contractor. Reinstatement criteria are narrowly defined. (*Medicare Managed Care Manual* Chapter 2, Section 60, and *Medicare Prescription Drug Benefit Manual Chapter* 3, Section 60)

G. Late Enrollment Penalty (LEP) and Creditable Coverage – Part D Sponsors

I. Charge the correct LEP for beneficiaries based on CMS's LEP reports (Medicare Prescription Drug Benefit Manual, Chapter 4, Section 40)

Process LEP changes, refunds due to error, or LIS redeterminations timely. Changes are reported in the Monthly Premium Withhold Report Data File, LEP report, and Transaction Reply Report (TRR). Plan sponsors need to review the reports for changes and effectuate timely. (*Medicare Prescription Drug Benefit Manual Chapter* 4 Sections 40.2 and 60.3, and HMPS memo 07/14/2014)

H. Benefits Administration & Beneficiary Protections

I. Part C Benefits and Beneficiary Protections

- Review and implement guidance and clarifications introduced in the Chapter 4 of the *Medicare Managed Care Manual*, titled "Benefits and Beneficiary Protections." (HPMS memo 11/7/2014)
- Ensure Medicare Advantage provider networks meet CMS network adequacy standards. (CY2016 MA HSD Provider and Facility Specialties and Network Adequacy Criteria Guidance)

II. Coverage Gap Discount Program (CGDP) – Part D Sponsors

- Sponsors 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)
- Ensure your organization updates electronic funds transfer (EFT) information used for the Discount Program via the online form on the Third Party Administrator's

Administrator (TPA) web site (http://tpadministrator.com). These data are collected and maintained outside of the Automated Plan Payment System (APPS).

III. Formulary – Part D Sponsors

- **Monitor Rejected Claims.** 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)
- **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 Part D sponsors' 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.** Apply a daily cost sharing rate whenever certain prescriptions (depending on the drug dispensed) are dispensed by a network pharmacy for less than a month's supply in accordance with 42 C.F.R. § 423.153(b)(4)(i). (Calendar Year (CY) 2014 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and 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 Part D sponsors 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)
- **Pharmacy & Therapeutics (P&T) Committee**. A 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.

IV. Auto-Ship Refill Programs in Part D

- Ensure your organization follows the mail-order auto ship guidance.

- 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.
- 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.

- Such confirmation is unnecessary when the beneficiary personally initiates the prescription request.
- Two exceptions authorizing automatic deliveries without prior beneficiary consent were offered to plan sponsors agreeing to meet the conditions stated Exceptions to the Auto-Ship Policy
  - Part D sponsors interested in offering automatic deliveries of <u>new</u> prescriptions (as described in the 12/12/2013 memo) will no longer need to request an exception to the auto ship policy by emailing CMS. Instead, the exception will remain available to all Part D plans, without the need to specifically submit a request. Plans are permitted to start or continue automatic shipments, provided they meet the conditions listed.
  - Employer Group Waiver Plan (EGWP) sponsors interested in offering automatic deliveries of <u>refill</u> prescriptions (as described in the 10/28/2013 memo) will no longer need to separately request an exception to the Auto-Ship policy by emailing CMS.

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

V. Quality Improvement (QI) Programs – Medicare Advantage Organizations (excludes non-network PPFS, Cost plans)

- The QI program must meet the applicable requirements for the services that it furnishes to its MA enrollees, as specified at 42 C.F.R. §422.152 and detailed in Chapter 5 of the Medicare Managed Care Manual.
- The new mandatory topic for quality improvement projects (QIPs) beginning contract year CY2016 is Promote Effective Management of Chronic Disease. (HPMS memo 07/01/2015)
- 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)

VI. Improving Drug Utilization Controls in Part D

- 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.

  (CY 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter and http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html)

- 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.)

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

I. Low Income Subsidy Benefit Administration – Part D Sponsors, excluding plan sponsors only serving U.S. Territories

- 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 Ma*nual Chapter 13, Section 70.1)

- 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, 423.800)

II. Loss of Low Income Subsidy Data File – Part D Sponsors, excluding plan sponsors only serving U.S. Territories

- In response to the Loss of Subsidy Data File (released in December of each year), set your organization's systems to charge the correct premium, deductible, and copayments effective January 1, 2016 as well as send the appropriate notification to affected beneficiaries. The only exception to this requirement is for those beneficiaries whom the organization confirms are awaiting a Social Security Administration determination on an LIS application and have been granted a grace period by the organization, if applicable. In these situations, organizations should wait until they receive the result of the SSA determination to update their systems.

- Make reasonable attempts to notify affected members to advise them of their retroactive liability for higher premiums and cost sharing when LIS status or eligibility is removed. (*Medicare Prescription Drug Benefit Manual Chapter* 13, 70.3.1)

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

III. Low Income Subsidy Deeming – Part D Sponsors, excluding only serving U.S. Territories

- Ensure your organization follows the CMS guidance for re-determination of Part D LIS eligibility for 2015. (HPMS memo 09/11/2015)
- 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, 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.

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

I. Coordination of Benefits (COB) Data Report/File Processing/Automated TrOOP balance transfer (ATBT) Process – Medicare Advantage Organizations and Part D Sponsors

Beginning in January 2016, Part D sponsors 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, sponsors 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 sponsors, this may entail re-contracting with a former processor to process prior year FIR transactions. (HPMS memo 07/02/2015)

II. Hospice

- For hospice beneficiaries, 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)
- Utilize the approved form for collection of Hospice Information for Medicare Part D Plans to facilitate communication between Part D plans, hospices, prescribers, and

pharmacists who serve beneficiaries enrolled in hospice. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Downloads/Hospice-Info-PartD.zip (HPMS memo 03/24/2015)

III. End-Stage Renal Disease (ESRD)

- 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). When a sponsor receives a daily TRR showing an ESRD beneficiary is receiving renal dialysis services, the sponsor must have controls in place to comply with this requirement.
- We strongly encourage sponsors 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 sponsors to remove the beneficiary-level PA edits on the seven categories of prescription drugs that may be used for ESRD treatment. Sponsors 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 sponsor 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

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

K. Claims Processing and Transition Process – Part D Sponsors

- CMS expects each sponsor to fully test how their 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 2016. (HPMS memo 03/25/2010)
- 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). 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 2016 formulary prior to January 1, 2016. Sending the ANOC is not sufficient to effectuate the transition. (HPMS memos 03/25/2010 and 08/27/2010)
- Ensure a transition supply has been provided by closely monitor enrollees' rejected claims after the beginning of CY 2016, among other monitoring strategies.

L. Grievances, Initial Coverage Decisions, and Appeals

I. Staffing Requirements Related to Initial Coverage Decisions and Appeals– Medicare Advantage Organizations and Part D Sponsors

Your organization 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 – Medicare Advantage Organizations and Part D Plan Sponsors

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

III. Proper Use of Adjudication Timeframe Extensions – Medicare Advantage Organizations

Under limited circumstances, Medicare Advantage organizations 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 – Medicare Advantage Organizations and Part D Sponsors

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. CMS provides two optional web-based training (WBT) courses below to supplement in-house training. http://go.cms.gov/MLNProducts. CMS strongly suggests that compliance officers incorporate these courses into their existing in-house training and use the certificate to track course completion within the organization. (HPMS memo 04/28/2014)

V. Rights of Medicare C & D Enrollees – Medicare Advantage Organizations and Part D Sponsors, as applicable below

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

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

Starting January 1, 2016, to comply with compliance training requirements, sponsors 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 Sponsors' employees. Updated training modules will be available in November 2015. (HPMS memo 06/17/2015)