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To: All Medicare Advantage Organizations (MAOs), Prescription Drug Plan (PDP) Sponsors, 1876 Cost Plans and Medicare-Medicaid Plans (MMP)

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Subject: 2019 Readiness Checklist for Medicare Advantage Organizations, Prescription Drug Plans, Medicare-Medicaid 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, 2019.

The Contract Year (CY) 2019 Readiness Checklist summarizes a subset of key operational requirements solely for the purpose of providing a tool to be used in preparation for the upcoming year. It does not supersede requirements as established in statutes, regulations, manual chapters, Health Plan Management System (HPMS) memos, and other sub-regulatory guidance as they relate to Medicare Advantage, Prescription Drug Plans, 1876 Cost Plans, and Medicare-Medicaid Plans. For ease of use, CMS combined the stand alone MMP checklist with the MA/MA-PD, PDP, and 1876 Cost Plan checklist. Organizations should review this checklist and take the necessary steps to fulfill these requirements for the 2019 benefit year.

In follow up to this checklist, account managers and plan sponsors will participate in strategic conversations, with a goal of more open and direct conversations about preparedness and process improvements. Organizations must notify their account manager(s) of any requirements that are at risk or where technical assistance needed to resolve any issue. CMS account managers will follow up with organizations regarding their self-assessments prior to the new year, at which time we invite you to share suggestions for improving the process.

The checklist's appendix lists points of contact for specific subject matters. For additional information regarding the elements within the checklist, please refer to the appropriate CMS

guidance, contact your account manager, or contact the subject matter expert identified in Appendix A.

Notes:

- Unless otherwise indicated, requirements that apply to Medicare Advantage Organizations also apply to 1876 Cost Plans and Medicare-Medicaid Plans (MMPs). Part D sponsors refers to all organizations offering Part D.
- Note: For purposes of the MMPs, references to account managers is the equivalent of the contract management team.

**CY 2019 Medicare Advantage Organization, Prescription Drug Plan, Cost Plan, and  
Medicare-Medicaid Plan Readiness Checklist**

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## **A. New Medicare Cards (formerly the Social Security Number Removal Initiative (SSNRI)) – Medicare Advantage Organizations and Part D Sponsors**

The Centers for Medicare & Medicaid Services (CMS) is removing Social Security Numbers (SSNs) from all Medicare cards by April 2019. A new Medicare Beneficiary Identifier (MBI) is replacing the SSN-based Health Insurance Claim Number (HICN) on Medicare cards. There is a transition period where CMS will accept either the HICN or the MBI when organizations are submitting data to the agency. The transition period will run through December 31, 2019. Stakeholders may submit either the MBI or HICN during the transition period. As a reminder, your organization should only use the MBI information in the crosswalk for data submission to CMS systems. Do not share the MBIs directly with your plan enrollees until the new Medicare card mailing to beneficiaries has been completed.

(HPMS memos 09/29/2016, 11/18/2016, 05/02/2017, 12/14/2017, 02/16/2018, 03/01/2018, 03/30/2018, HPMS email May 14, 2018, Medicare Managed Care Manual, Chapters 2 and 17D, Medicare Prescription Drug Benefit Manual, Chapter 3)

## **B. Individuals with Disabilities – Accessible Formats and Use of TTY Numbers – Medicare Advantage Organizations and Part D Sponsors**

- Make available all plan materials, services, and information, including those produced or distributed by contracted providers, in accessible formats (e.g., Braille, large print, audio, etc.) to individuals with disabilities upon request. (HPMS Memo dated August 30, 2017, and Section 504 of the Rehabilitation Act of 1973)
- A toll-free TTY number must appear in conjunction with the customer service number in the same font size as the other phone numbers. Sponsors may use their own TTY number, 711 for Telecommunications Relay Service, or state relay services, as long as the number is accessible from TTY equipment. (Medicare Communications and Marketing Guidelines, Sections 30.5)

## **C. Precluded Providers**

MA Organizations must comply with the new beneficiary notice and claim payment requirements regarding precluded providers in 42 C.F.R. §§ 422.222 et seq. and 423.120(c)(6). (See <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/PreclusionList.html>).

## **D. 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](mailto:hpms_access@cms.hhs.gov). (HPMS memo 08/14/2018)
- Update your organization's contact and data information in HPMS, and ensure that your organization has a process in place 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

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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. Medicare Advantage Prescription Drug (MARx) System – Medicare Advantage Organizations and Part D Sponsors

- Review and implement guidance regarding software improvements to the enrollment and payment systems. (HPMS memo 02/27/2018)
- Ensure your External Point of Contact (EPOC) is notified of the changes regarding the Enterprise Identity Manager (EIDM) users. (HPMS memo 9/15/2017)
- An individual's access to EIDM will be locked when 60 days lapses between system logins. To unlock the account, the individual must login to EIDM, answer their challenge questions, and reset their password. (EIDM Users Guide)
- Submit information about beneficiary-specific claim edits or limitations on a beneficiary's access to coverage for frequently abused drugs (i.e., opioids and benzodiazepines) implemented under the plan's drug management program and monitor MARx reports for potential and at-risk beneficiaries in accordance with 42 C.F.R. § 423.153(f). (Section 8 in the Medicare Advantage and Part D Plan Communications User Guide. Updated technical user guide to be released).

## III. Medicare Plan Finder Data (MPF) – Applicable organization types noted below

- **Pricing Data and Pharmacy Network Files.** (Part D Sponsors) Submit timely and accurately the CY 2019 pricing data for posting on the MPF. (Office of Communications email 5/22/2018, HPMS Memo 7/06/2018)
  - Accurately identify preferred cost-sharing pharmacy arrangements in the 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. (Excludes MMP)
  - Confirm pricing and pharmacy network data files for MPF are complete, correct, and accurate, and that only pharmacies under contract for 2019 are included for display. Incorrect data may result in suppression from the MPF, and/or applicable compliance actions.
- **MPF File Pre-Submission Quality Assurance Testing.** (Part D Sponsors) Perform 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 2019 pricing and pharmacy data which was previously a known exception in 2018, your organization must re-confirm that the data continue to be accurate. If you do not confirm these data, your organization's pricing data may be suppressed on the MPF.



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- 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' 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.** (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](https://PartD.ProgramInfo.us/User_Security).

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

Ensure key staff register for the CMS Part C & D User Calls at

[https://www.cms.gov/Outreach-and-Education/Training/CTEO/](https://www.cms.gov/Outreach-and-Education/Training/CTEO/Compliance_Training_Education_and_Outreach.html)

[Compliance\\_Training\\_Education\\_and\\_Outreach.html](https://www.cms.gov/Outreach-and-Education/Training/CTEO/Compliance_Training_Education_and_Outreach.html). Participants should call fifteen minutes before start time to ensure timely access to the call.

### V. Patient Safety Analysis Website – Part D Sponsors

- Ensure your organization's Medicare compliance officer (MCO) authorizes users to access the Patient Safety reports, available via the Patient Safety Analysis Website. At least one user from each contracted organization must have access to Summary and Confidential Beneficiary Reports to view and respond to beneficiary-level overutilization issues.
- Access the monthly Patient Safety Reports via the Patient Safety Analysis Website to compare your performance to overall averages and monitor progress in improving Part D patient safety measures over time. Several of the measures are Part D Star Ratings or Display Measures.
- These actionable reports include contract-level patient safety summary reports for expanded analyses and information and detailed beneficiary-claim level and outlier reports. Sponsors are required to use the website to view and download the reports, respond to outlier notices, and engage in performance monitoring.  
(HPMS memo 04/06/2018)

### VI. Overutilization Monitoring System – Part D Sponsors

- Ensure your organization's MCO authorizes users to access the Overutilization Monitoring System (OMS), available via the Patient Safety Analysis Website. At least one user from each contracted organization must have access to Summary and Confidential Beneficiary Reports to view and respond to beneficiary-level overutilization issues.
- Review and act upon OMS quarterly reports and send information to CMS within 30 days of the report, as well as send information to CMS about potential at-risk beneficiaries that the sponsor identifies in accordance with 42 CFR §423.153(f) and applicable guidance. (OMS User Guide will be available in Fall 2018 on the Patient Safety Analysis Website under Help Documents. Improving Drug Utilization Controls in Part D at <https://www.cms.gov/Medicare/Prescription-Drug->

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[Coverage/PrescriptionDrugCovContra/RxUtilization.html](#))

(HPMS memos 1/19/2018, 04/06/2018 and 07/20/2018)

## VII. Risk Adjustment Data Submissions – Including Risk Adjustment Processing System (RAPS) and Encounter Data (EDS) – Medicare Advantage Organizations

- Medicare Advantage Organization (MAO) payment is primarily based on data submitted to CMS. In order to receive proper payment, MAOs 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, <https://www.csscooperations.com>, as well as memos available on HPMS. Register for monthly Risk Adjustment for EDS & RAPS User Group webinars through <https://tarasc.info/>. (HPMS memo 6/11/2018).

Assistance with data submission can be obtained by emailing [csscooperations@palmettogba.com](mailto:csscooperations@palmettogba.com), or by calling 1-877-534-2772.

- Activities checklist for EDS and RAPS submission include:
  - 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.

Specific to MMPs: MMPs shall submit encounter data consistent with MMP guidelines that can be found in HPMS Memos (dated October 24, 2013, April 29, 2014, May 23, 2014, and August 10, 2016) and in the applicable Medicare-Medicaid Capitated Financial Alignment Model Quality Withhold Technical Notes. The technical notes for Demonstration Years 2 through 5 are available at: <https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/MMPInformationandGuidance/Downloads/QualityWithholdGuidanceDY2-503142018.pdf>

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

- Establish access to the Part D Payment Process Support Website. (HPMS memo 2/16/2016 and 10/12/2016)
- Submit original PDEs within 30 days following Date Claim Received or Date of Service (whichever is later).
- Within 90 days:
  - Resolve rejected PDE records and re-submit following receipt of rejected record status from CMS, and
  - Submit adjustments and deletions following discovery of issue requiring

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change.

(HPMS memo 10/06/2011)

- Establish access to the PDE Analysis and PDE Reports websites. (HPMS memo 4/10/2018)
- 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) Reports,
  - Coverage Gap Invoice Report,
  - Part D Potential Exclusion Warning Report and Part D Exclusion from Reconciliation Report, (HPMS memos 1/06/2014, 4/16/2014 2/23/2017, and 1/12/2018), and
  - Payment Reconciliation System (PRS) reports (HPMS memo 6/23/2017).

## **IX. Electronic Enrollment Mechanisms – Medicare Advantage Organizations and Part D Sponsors (Excludes MMPs)**

- Organizations developing and offering electronic enrollment mechanisms made available via an electronic device or secure internet website must apply CMS' enrollment guidelines for electronic enrollment mechanisms, including:
  - Submit all materials and web pages related to the enrollment process for CMS approval per established processes for the review and approval of communications and marketing materials and other enrollment request mechanisms.
  - 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>
- Sponsors retain complete responsibility for following enrollment policies, and 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.
- CMS must be notified in a timely manner of security and/or privacy breaches, should they occur.

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

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Manual Chapter 17-D, Section 40.1.3 – Electronic Enrollment)

## E. 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 and Part D Sponsors

Prepare to submit HEDIS, HOS, and CAHPS measures to the appropriate entity by the specified due date. (HPMS memo 8/15/2018)

### 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. (<https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/ReportingRequirements.html>)
- MMPs must also meet Core Reporting Requirements and applicable State-Specific Reporting Requirements, and participate in performance measure validation as required.

### III. Quality Withhold Requirements – MMPs only

- MMPs are reminded that a percentage of their capitated rate is withheld and will be repaid retrospectively subject to performance consistent with established quality requirements. In general, the percentage withheld increases by one percentage point each of the first three demonstration years. CMS strongly encourages MMPs to review the current demonstration methodology and plan ahead to maximize the chances of fully recouping the withheld amounts.
- More information about the demonstration year (DY) 2 through 5 quality withhold methodology is available at: <https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/MMPInformationandGuidance/Downloads/QualityWithholdGuidanceDY2-503142018.pdf>.

### IV. Reporting and Returning Sponsor Identified Overpayments – Medicare Advantage Organizations and Part D Sponsors

Every MA organization and Part D sponsor 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.

### V. Fiscal Soundness – Medicare Advantage Organizations and Part D Sponsors

Annually, use the Fiscal Soundness Module in HPMS to submit independently audited annual financial statements and 2019 quarterly financial statements. The CMS Fiscal Soundness Reporting Requirements, relevant HPMS memos, and other important information is available at: <https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/FSRR.html>

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## **F. 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 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.
- CMS expects Part D sponsors to:
  - Have standard contracting terms and conditions readily available for requesting pharmacies no later than September 15 of each year for the immediately succeeding benefit year, and
  - Provide the applicable standard terms and conditions document to the requesting pharmacy within seven business days of receipt of the request.

(HPMS memo 8/13/2015, 42 C.F.R. § 423.505(b)(18))

### **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 7/23/2007, 9/20/2007, and 8/26/2008)

\* 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 – Medicare Advantage Organizations and Part D Sponsors**

- Notify your CMS account manager at least 60 days prior to the effective date of the new contract. For MMPs, notify your CMT per the terms of the three-way 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.

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## G. Customer Service

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

- Staff all toll-free beneficiary call centers appropriately to handle increased call volume from October 1 to March 31, which includes the AEP. MA organizations and Part D Sponsors must operate a toll-free call center for both current and prospective enrollees 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 and telephone-to-telephone typewriter (TTY) services. From October 1 to March 31, 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 Day.
- From April 1 through September 30, your organization may use alternative technologies to meet the customer service call center requirements for Saturdays, Sundays, and Federal holidays. Messages must be returned within one business day.
- For MMPs specifically: MMPs must operate a toll-free call center for both current and prospective enrollees per the three-way contract, the Medicare Communications and Marketing Guidelines, and the State-specific MMP Marketing Guidance. Per the “Contract Year 2019 Marketing and Beneficiary Communications Guidance for Medicare-Medicaid Plans” HPMS Memo dated August 20, 2018, MMPs should refer to section 80.1 of the CY 2018 State-specific Marketing Guidance for MMP-specific customer service call center requirements.

### II. Pharmacy Technical Help Desk Call Centers – Part D Sponsors (Medicare Communications and Marketing Guidelines, Section 80.5)

Ensure pharmacy technical support is available at all times when 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 Day. (Medicare Communications and Marketing Guidelines, section 80.5)

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

- All MA organizations and Part D sponsors’ call centers must have interpreter services available to call center personnel to answer questions from non-English speaking or LEP beneficiaries. This requirement is in place regardless of the percentage of non-English speaking or LEP beneficiaries in a service area. Inform callers that interpreter services are free. Interpreters should be available within eight (8) minutes of reaching the Customer Service Representative (CSR). Please refer to the annual call center monitoring memo released each fall for more detail.
- Make the communications identified in the Medicare Communications and Marketing Guidelines sections 30.3, 100.4, available in any language that is the primary language

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of five (5) percent or more of an MA organization or Part D sponsor's plan benefit package service area (or, for MMPs, the state-specific standard, if it is more stringent than the Medicare standard, as provided in section 30.5 of the CY 2018 State-specific Marketing Guidance). Additionally, Medicare Advantage organizations and Part D sponsors must place translated versions of certain materials on the plan's website. (Excluding Employer Group/800 series-only contracts).

(Medicare Communications and Marketing Guidelines, Sections 30.3, 80.1, 80.2, 70.1.1, and 70.1.2; 42 C.F.R. §§ 422.2268(a)(7), 423.2268(a)(7))

### **IV. Customer Service Staff Knowledge of Medication Therapy Management (MTM) – Part D Sponsors**

Ensure CSRs are familiar with the plan's Medication Therapy Management (MTM) program, including eligibility criteria and additional information required to be available on a dedicated MTM program page linked from the Medicare drug plan website, and how to direct beneficiaries to the plan's MTM program page. The 2019 MTM program annual cost threshold increased to \$4,044. (Medicare Communications and Marketing Guidelines, Section 70.1.3, Appendix 1; HPMS memo 04/06/2018, Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter).

### **V. Complaints Tracking Module – Medicare Advantage Organizations and Part D Sponsors**

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. MA organizations and Part D sponsors are urged to make interim contact with beneficiaries if their complaints will take more than seven days to resolve. (HPMS memo 2/6/2015, 12/30/2015)

### **H. Communications Consistent with the Medicare Communications and Marketing Guidelines – Medicare Advantage Organizations and Part D Sponsors**

Market consistent with the CY2019 Medicare Communications and Marketing Guidelines (HPMS 7/20/2018)

#### **I. Model Materials**

- Ensure your organization is using the updated year (CY) 2019 model materials on the Marketing Models, Standard Documents, and Educational Material and Part D Model Materials websites. The updated models include: the ANOC; the EOC; the ANOC Errata Notice; the EOC Errata Notice; the Provider Directory; the Part D Explanation of Benefits (EOB); the Low Income Subsidy (LIS) Rider; the Transition Letter; and the Formulary (Comprehensive and Abridged). All models, and standardized documents have been posted and are located at: <http://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/MarketngModelsStandardDocumentsandEducationalMaterial.html> and <http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Part-D-Model-Marketing-Materials.html>. (HPMS memo 07/24/2018) (Excludes MMPs)

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- For MMPs specifically: Ensure your organization is using the updated state-specific CY 2019 model materials. These model materials are posted at: <https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/MMPInformationandGuidance/MMPMarketingInformationandResources.html>.

### II. Formulary – Part D Sponsors

Ensure your organization's formulary is updated on the website when changes are made. (Medicare Communications and Marketing Guidelines, Sections 70.1.1 and 100.4)

### III. Referencing Star Ratings in Marketing Materials – Medicare Advantage Organizations and Part D Sponsors (Excludes MMPs)

- 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 2019 requirements.
- Medicare Advantage organizations and Part D sponsors are not permitted to display or release their Star Ratings information until CMS releases the Star Ratings on Medicare Plan Finder.
- Medicare Advantage organizations and Part D sponsors must clearly identify which contract year their Star Ratings references.

(HPMS memo July 20, 2018, Medicare Communications and Marketing Guidelines, Sections 40.6, 100.4, Appendix 2)

### IV. Websites – Medicare Advantage Organizations and Part D Sponsors

- Ensure that your organization's website and all electronic Information and Communications Technology (ICT) is accessible to people with disabilities. Monitor website compliance with Section 508 standards and remediate any identified issues. (Section 508 of the Rehabilitation Act (29 U.S.C. 794d))
- The SB, ANOC, EOC, Provider and/or Pharmacy Directories; Formulary and Utilization Management Forms for physicians and enrollees; and LIS Premium Summary Chart must be posted on the website by October 15 for the upcoming contract year (Medicare Communications and Marketing Guidelines, Section 70.1.2) Please note that the LIS Premium Summary Chart does not apply to MMPs.
- Provider and Pharmacy Directories are expected to be accurate, updated within 30 calendar days of receipt of updated or corrected information from the provider/pharmacy, and contain all required data elements. (Medicare Communications and Marketing Guidelines, Section 100.3, Medicare Advantage and Section 1876 Cost Plan Provider Directory Model, HPMS memo 8/16/2016)
- MAOs, PDPs, and their third-parties' websites that market their products are expected to meet applicable CMS marketing requirements. (Medicare Communications and Marketing Guidelines Section 90.4)



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## **V. Agents and Brokers – Medicare Advantage Organizations and Part D Sponsors**

- Implement Agent/Broker compensation rates, submissions, and training and testing requirements. (HPMS memo 05/25/2018)
- For MMPs specifically: Only those MMPs in states that permit the use of independent agents/brokers must implement agent/broker compensation rate requirements. All MMPs must implement agent/broker submissions and training and testing requirements. (HPMS memo 5/25/2018, three-way contract, State-specific Marketing Guidance)

## **VI. Access to Preferred Cost Share Pharmacies – Disclaimers – Part D Sponsors (Excludes MMPs)**

- Include the appropriate disclaimer language for plans with limited access to Preferred Cost Sharing Pharmacies. (Medicare Communications and Marketing Guidelines, Appendix 2)
- All disclaimers can be found in the Medicare Communications and Marketing Guidelines, Appendix 2.

## **I. Enrollment/Disenrollment**

### **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 3, 2018. 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 3, 2018. Enrollments received after December 7, 2018 may not be processed as AEP elections. Beneficiaries must be eligible for a valid Initial Election Period (IEP) or Special Enrollment Period (SEP) for requests received after the December 7 deadline.
- 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. (Medicare Managed Care Manual Chapter 2, Section 50.2.1, and HPMS memo 4/30/2010)
- 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 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. Organizations are responsible for all aspects of the good cause process, including receiving requests, making good cause determinations, notifying

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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)

### **II. Medicare Advantage Open Enrollment – Medicare Advantage Organizations**

The Medicare Advantage Open Enrollment Period (MA OEP) begins on January 1 and ends on March 31. During this time, MAO enrollees may disenroll or switch to another MAO (either with or without Part D coverage) or switch to Original Medicare and enroll in a stand-alone PDP. In addition, new Medicare beneficiaries enrolled in a MA plan during their Initial Coverage Election Period (ICEP) can also make one election during the first 3 months they have Medicare to make a change to their coverage. The MA OEP does not allow individuals enrolled in Medicare Savings Accounts or other Medicare health plan types (such as cost plans or PACE) to make enrollment changes.

(Medicare Managed Care Manual Chapter 2, Section 30.5, and Medicare Prescription Drug Benefit Manual Chapter 3, Section 30.3.8 #8.D, and HPMS memo 07/31/2018)

### **III. SEP Changes for Dual Eligible and other LIS-Eligible Individuals (Excludes MMPs in capitated model FAI Demonstration States that have secured a demonstration waiver)**

- Make systems changes as needed and properly determine eligibility for those using the newly codified SEPs for dual eligible and other LIS-eligible individuals, effective 01/01/2019:
  - Those who have been assigned into a plan by CMS/State (e.g., auto-assignment, reassignment, passive enrollment).
  - Those who gain, lose, or have a change in their dual eligible /LIS status.
  - Dual eligible and other LIS-eligible individuals can only change plans once per calendar quarter during the first three quarters of the year (January – September). Once a dual eligible or other LIS-eligible individual is identified by a Part D sponsor as a ‘potential at-risk’ or ‘at-risk’ beneficiary under a drug management program, he or she cannot use the dual/LIS SEP to change plans for as long as he or she is a ‘potential at-risk’ or ‘at-risk’ beneficiary.

(Medicare Managed Care Manual Chapter 2, Section 30.4 & Chapter 17D, Section 30.4, Medicare Prescription Drug Benefit Manual Chapter 3, Section 30.3, and HPMS memo 07/31/2018)

### **IV. SEP for Enrollment into a 5-Star Plan – Medicare Advantage Organizations and Part D Sponsors (Excludes MMPs)**

Beneficiaries may enroll in a plan awarded an overall 5-star rating for 2019, provided the beneficiary is otherwise eligible for that plan. An individual may only use this SEP one time between December 8, 2018 and November 30, 2019. 5-Star plans must be prepared to accept all valid enrollment requests made using this SEP. (Medicare Managed Care Manual Chapter 2, sec. 30.4.4; Medicare Prescription Drug Plan Benefit Manual Chapter 3, sec. 30.3.8)

### **V. Enrollment Processes and Notices – Medicare Advantage Organizations and Part D**

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## **Sponsors (Excludes MMPs)**

Electronic enrollment mechanisms via a third-party website or non-plan owned electronic device, mechanism, or software are permitted.

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

- Establish and maintain a process to download enrollments at least once daily from the Online Enrollment Center (OEC) unless your organization is prohibited from participating in the OEC. (Medicare Managed Care Manual Chapter 2, sec. 40.1.2; Medicare Prescription Drug Plan Benefit Manual Chapter 3, sec. 40.1.2.)
- The OEC uses Coordinated Universal Time (UTC) which is four hours earlier than Eastern Daylight Time. Calculate the application date on enrollments received via the OEC to be 11 hours earlier than the time and date CMS “stamps” on the request. Use the adjusted application date to determine eligibility for election periods and proper effective date for coverage. (Administrative Console site on the OEC AND email to plans, April 8, 2016)

## **VII. 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, EGWP plans may be submitted via the UI or in batch for the current calendar month minus three months. MMPs must perform enrollment transactions per the three-way contract.
- 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](http://www.reedassociates.org). MMPs must perform retroactive enrollment transactions per the three-way contract.

(Medicare Managed Care Manual Chapter 2, Section 60.4, Medicare Prescription Drug Benefit Manual Chapter 3, Section 60.3)

## **J. Late Enrollment Penalty (LEP) and Creditable Coverage – Part D Sponsors (Excludes MMPs)**

### **I. Charge the correct LEP for beneficiaries based on CMS LEP reports (Medicare Prescription Drug Benefit Manual, Chapter 4, Sections 40, 60)**

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). Sponsors need to review the reports for changes and effectuate timely. (Medicare Prescription Drug Benefit Manual Chapter 4, Sections 40.2 and 60 and HMPS memo 01/10/2018)

## **K. Benefits Administration & Beneficiary Protections – Medicare Advantage Organizations and**

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## Part D Sponsors

### I. Benefits and Beneficiary Protections

- MAOs, as specified in 42 C.F.R. § 422.111(b)(12), implement systems and processes necessary to provide for the generation of Part C EOBs for all plan members. EOB templates and instructions are available at <http://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/MarketingModelsStandardDocumentsandEducationalMaterial.html>.
- Ensure MA and MMP provider networks meet network adequacy requirements. (42 C.F.R. § 422.112(a)(1), Medicare Advantage and Section 1876 Cost Plan Network Adequacy Guidance<sup>1</sup>, Health Service Delivery (HSD) Instructions for Medicare-Medicaid Plans (MMPs) and Minnesota Dual Special Needs Plans (MN D-SNPs) Annual Medicare Network Submission<sup>2</sup>)
- Part D Sponsors must ensure that their retail pharmacy networks meet the access criteria established under 42 C.F.R. § 423.120(a). Part D Sponsors must ensure that their retail pharmacy networks have a sufficient number of pharmacies that are able to dispense drugs directly to patients (other than by mail-order) to ensure convenient access requirements have been met.
- When applicable, include the disclaimer entitled, “Part D Sponsors with Limited Access to Preferred Cost Sharing Pharmacies.”
- Regional Preferred Provider Organizations must ensure they pay non-contracted providers at least the Original Medicare payment rate in those portions of their service area where they are meeting access requirements by non-network means. (Medicare Managed Care Manual Chapter 4, Section 10.2)
- Medicare Advantage organizations must ensure their organization and its contracted hospitals and critical access hospitals (CAHs) implement the provisions of the NOTICE Act. Under the NOTICE Act, hospitals and CAHs must deliver the Medicare Outpatient Observation Notice (MOON) to any beneficiary (including an MA enrollee) who receives observation services as an outpatient for more than 24 hours. See the final at: <https://www.federalregister.gov/articles/2016/08/22/2016-18476/medicare-program-hospital-inpatient-prospective-payment-systems-for-acute-care-hospitals-etc>

### II. Billing and Anti-discrimination Requirements Applicable to Dual Eligible Enrollees – Medicare Advantage Organizations

- Adopt measures to protect dual eligible enrollees from improper billing and educate network providers about applicable billing requirements. All MAOs and other Part C providers and suppliers, including pharmacies, must refrain from collecting Medicare cost sharing for covered Parts A and B services from individuals enrolled in the Qualified Medicare Beneficiary Program (QMB) program, a dual eligible program which exempts individuals from Medicare cost-sharing liability.

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<sup>1</sup> See: <https://www.cms.gov/Medicare/Medicare-Advantage/MedicareAdvantageApps/index.html?redirect=/MedicareAdvantageApps/>

<sup>2</sup> See August 7, 2018 HPMS memo

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- For MMPs and PACE organizations specifically:
  - Coinsurance, copays, and deductibles are zero for all Medicare Parts A and B services furnished to enrollees.
  - Note that zero Medicare cost-sharing amounts for dual eligible enrollees only apply to Parts A and B services. Low Income Subsidy copayments still apply for Part D benefits. (Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter; 42 C.F.R. § 422.504(g)(1).
- To reinforce billing requirements, simplify compliance, and prevent improper billing, CMS strongly encourages organizations to affirmatively inform providers if member cost-sharing liability is zero. MA organizations can provide real-time information and indicators through automated eligibility-verification systems, online provider portals and phone query mechanisms and clearly indicate members owe \$0 directly on the Explanations of Payment statements for providers and on member identification cards.
- Organizations should verify procedures to ensure that providers do not discriminate against enrollees based on their payment status, e.g., specifically, providers may not refuse to serve enrollees because they receive assistance with Medicare cost-sharing from a State Medicaid program. (Medicare Managed Care Manual, Ch. 4, Section 10.5.2)

### III. 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 memo 1/22/2014)
- Part D Sponsors should make sure that the data displayed in HPMS is the most current information and reflects the correct personnel listed for the following fields:
  - HPMS field “Third Party Administrator (TPA) Liaison” for the TPA Primary Contact role
  - HPMS field “Coverage Gap Discount Program (CGDP) Payment Contact” for the TPA Payment Initiator role (if different from the Primary Contact).
- Ensure your organization updates the appropriate Bank Account Change Form on the TPA Website if there have been any changes to the accounts used for sending or receiving payments. Also validate any debit blocks and velocity filters which may be in place.
- These data are collected and maintained outside of the Automated Plan Payment System (APPS). The Bank Account Change Forms are now located in the CGDP Portal. To access the forms, sponsors can select the Payee/Payer Bank Account Change Form link on the TPAAdministrator.com website under the EFT Information link. This will take the user to the CGDP Portal log in page.
  - Once logged in to the Portal, select the “My Profile” link and then choose either “Request Payee Account Modification” (account for receiving

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payments) or “Request Payer Account Modification” (account for sending payments).

- Fill out the form and follow the online instructions.

### IV. Formulary – Part D Sponsors

- Ensure that your organization’s transition policies accurately reflect the updated requirements as outlined in 42 CFR § 423.120 (b)(3)(iii), which are effective January 1, 2019. As a result of these updates, the transition fill days' supply will now be a month's supply, as defined in the applicable plan benefit package, for both the retail and long-term care settings.
- Ensure your organization properly administers CMS’ transition policy as outlined in 42 CFR § 423.120 (b)(3) and applicable three-way contracts and HPMS memo 08/19/2016 for MMPs. (Medicare Prescription Drug Benefit Manual Chapter 6, Section 30.4 and HPMS memo 8/19/2016).
- Ensure that your organization complies with policies governing midyear formulary changes, including the provision of notice to beneficiaries and other entities outlined in 42 CFR § 423.120(b)(5). (Medicare Prescription Drug Benefit Manual Chapter 6, Section 30.3). For instance, for the 2019 formulary:
  - Part D sponsors may immediately substitute new generic drugs provided they meet all requirements under 42 CFR §423.120(b)(5)(iv) including providing advance general notice that such substitutions may occur and then direct notice to affected beneficiaries about any specific changes made.
  - Permitted midyear formulary changes requiring advance direct notice will now require 30 days’ notice or, at the time beneficiaries request a refill, notice of the change and an approved month’s supply.
- 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)
- 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).
- 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.

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## V. Mail-Order and Auto-Ship Refill Programs – Part D Sponsors

- Part D Sponsors offering mail-order benefits must provide access to urgently needed medications, and inform beneficiaries of their options when requesting rush orders. The required steps must be included in all beneficiary communication and marketing materials that relate to mail-order benefits.
- Ensure your organization follows the mail-order auto-ship guidance:
  - Part D sponsors should require their network retail and mail-order pharmacies to obtain patient consent to deliver a prescription, new or refill, prior to each delivery. Such confirmation is unnecessary when the beneficiary personally initiates the refill or new prescription request.
- Two exceptions to the 2014 Call Letter auto-ship guidance, authorizing automatic deliveries without prior beneficiary consent are available to sponsors agreeing to meet the conditions stated in the applicable Exceptions to the Auto-Ship Policy memos:
  - Part D sponsors interested in offering automatic deliveries of new prescriptions (as described in the 12/12/2013 memo) are not required to request an exception to the auto-ship policy from CMS. Instead, the exception will remain available to all Part D sponsors, without the need to specifically submit a request. Part D sponsors are permitted to start or continue automatic shipments, provided they meet the conditions detailed in the memo.
  - Employer Group Waiver Plan (EGWP) sponsors interested in offering automatic deliveries of refill prescriptions (as described in the 10/28/2013 memo) may do so and are not required to request an exception to the auto-ship policy from CMS.
- If a beneficiary has experience using mail-order home delivery, or other automatic shipment 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 experience using mail-order, home delivery, or other automatic shipment programs under the plan, then a new prescription for that beneficiary is not eligible for auto-ship, and your organization should receive consent from the beneficiary before that prescription is filled.

(HPMS memos dated 10/28/2013, 12/12/2013, 03/21/2014, 9/22/2014 and Calendar Year 2014 & 2016 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letters)

## VI. Quality Improvement (QI) Program, Chronic Care Improvement Program (CCIP) – Medicare Advantage Organizations (excludes non-network PFFS/MSA, Cost plans, PACE)

- Ensure that your MAO/MMP's QI Program (inclusive of the CCIP) meets the applicable requirements for the services that it furnishes to enrollees.

(42 C.F.R. § 422.152, Medicare Advantage QIP and CCIP Resource Document, Chapter 5 of the Medicare Managed Care Manual)

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## **VII. Improving Drug Utilization Controls – Part D Sponsors Drug Management Programs – Part D Sponsors**

- Implement a drug management program in compliance with the regulatory requirements finalized in CMS-4182-F (83 FR 16739), published April 16, 2018. Under the new rules, Part D sponsors are permitted after case management and notification to limit at-risk beneficiaries' access to coverage of controlled substances that CMS determines are "frequently abused drugs" (i.e., opioids and benzodiazepines) to a selected prescriber(s) and/or network pharmacy(ies), or implement beneficiary-specific claim edits for such drugs, for the safety of the beneficiary. 42 CFR §423.153(f).
- Part D sponsors should ensure they can effectively support the activities needed to establish a drug management program, including as needed, modifying existing systems processes (e.g., MARx, OMS – See sections D.II. and D.V.); creating new processes and procedures (e.g., required beneficiary notices, call center scripts and triage processes for enrollees submitting information to the plan or requesting appeals, system edits to reject claims from non-selected pharmacies and prescribers for at-risk beneficiaries with coverage limitations for frequently abused drugs); and outreach and education (e.g., communications to network pharmacies).
- Ensure your P&T committee develops specifications, including claim billing transaction communications to pharmacist(s), for your plan's implementation of the following formulary-level POS opioid safety edits to prospectively prevent opioid chronic use or misuse, and adverse events:
  - Opioid care coordination safety edit based on a beneficiary's cumulative 90 morphine milligram equivalent (MME) dose per day with or without prescriber and pharmacy counts,
  - 7 days supply limit hard safety edit for opioid naïve patients,
  - Soft safety edits for duplicative long-acting opioid therapy and concurrent use of opioids and benzodiazepines, and
  - Optional cumulative opioid MME hard safety edit to be set at a minimum threshold of 200 MME or more with or without prescriber/pharmacy counts.

(Calendar Year (CY) 2018 and 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter and HPMS memo "Submission Template – CY 2019 Opioid Safety Edit and Participation in Drug Management Programs"), HPMS memo 8/ 8/2018, additional guidance expected in Fall 2018 on drug management programs and formulary-level POS opioid safety edits).

## **L. Low Income Subsidy (LIS) and Best Available Evidence (BAE) – Part D Sponsors**

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

- Apply the correct CMS LIS levels to enrollees by immediately applying any updates received via the daily TRR to establish the correct premium, cost sharing, and deductible levels with the correct effective dates for prior, current, and prospective enrollees. (Medicare Prescription Drug Benefit Manual Chapter 13, Section 70.1)



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- Reimburse LIS eligible beneficiaries, or others, who have paid or are holding receivables on behalf of the beneficiaries, any excess premiums or cost-sharing paid by the beneficiaries, 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)
- Meet CMS requirements for accepting specific forms of BAE to establish:
  - 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), and
  - A beneficiary is institutionalized or enrolled in a home community based waiver program and qualifies for zero cost-sharing.
- 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.
- 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)
- Follow CMS' process for assisting beneficiaries 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 HPMS memo 2/17/2017.

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

- Organizations should take action once they receive the Loss of Subsidy Data File (released in December of each year) by setting systems to charge the correct premium, deductible, and copayments as well as send the appropriate notification to affected beneficiaries. The only exception to this requirement is when the organization confirms a beneficiary is awaiting a Social Security Administration (SSA) determination on an LIS application and the beneficiary has 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 beneficiaries to advise them of their retroactive liability for higher premiums and cost sharing when LIS status or eligibility is removed. (Medicare Prescription Drug Benefit Manual Chapter 13, 70.3.1)  
(HPMS memos 11/30/2009, 08/12/2014, 09/10/2015, and 07/20/2016)

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## **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 2019. (HPMS memo 8/7/2018)
- Take appropriate actions in response to CMS deeming. (HPMS memo 7/24/2017)
- 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.

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

### **I. Automated TrOOP balance transfer (ATBT) Process –Part D Sponsors**

- Ensure that financial information reporting (FIR) processors are contracted to handle transactions for the current as well as all prior years covered under the enhanced ATBT process. (HPMS memo 7/02/2015)
- Update your organization's Business Associate Agreement with the Part D Transaction Facilitator to reflect all upcoming contracts per the Prescription Drug Benefit Manual Chapter 14.

### **II. Hospice – Part D Sponsors (Applicable to MMPs only if this population is eligible for continued enrollment under your demonstration)**

- Organizations must implement the beneficiary-level Prior Authorization (PA) requirements for beneficiaries in hospice for the following categories of prescription drugs: analgesics, anti-nauseants (antiemetics), laxatives, and anti-anxiety drugs (anxiolytics). The FAQ document can be found at <http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/index.html>. (HPMS memo 7/18/2014, 11/15/2016)
- Organizations should utilize the standard PA form to facilitate coordination between Part D sponsors, hospices, and prescribers who serve beneficiaries enrolled in hospice. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Downloads/Hospice-Info-PartD.zip> (HPMS memo 3/24/2015)
- Ensure your organization's hospice contact information in HPMS is up to date. The Hospice Contact should be knowledgeable about CMS guidance governing coverage of Part D drugs for beneficiaries enrolled in hospice, be able to update beneficiary plan records to reflect hospice status, and be prepared to coordinate drug coverage with hospice providers. (HPMS memo 03/24/2015, HPMS email 01/26/2018)

### **III. End-Stage Renal Disease (ESRD) – Part D Sponsors (Applicable to MMPs if this population is eligible for enrollment under your demonstration)**

- Sponsors should 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.

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- 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 5/12/2015)
  - 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 5/12/2015 and 11/14/2014)

### **IV. Drugs Available under Part A or Part B – Medicare Advantage Organizations**

Organizations must coordinate all benefits administered by the plan, including drugs for which payment may be available under Part A or Part B. (42 C.F.R. § 422.112(b)(7))

### **V. Transition Claims Processing – Part D Sponsors**

- CMS expects each sponsor to fully test how their transition policy works within its claims adjudication system, including pharmacy notification, in order to ensure that the transition policy has been programmed correctly into systems prior to the start of 2019. (HPMS memo 3/25/2010)
- 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 CY2018 to CY2019). 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 CY2019 formulary prior to January 1, 2019. Sponsors may not use the ANOC to effectuate the transition. (HPMS memos 3/25/2010 and 8/27/2010)
- Ensure a transition supply has been provided by closely monitoring enrollees' rejected claims, among other monitoring strategies.

### **N. Grievances, Initial Coverage/Organization Decisions, and Appeals**

#### **I. Part D Denial Notices – Part D Sponsors**

All Part D Sponsors must use the OMB-approved standardized Notice of Denial of Medicare Part D Prescription Drug Coverage. The revised notice must be provided to Part D enrollees when a plan issues a fully or partially adverse coverage determination. (HPMS memo 8/02/2017)

#### **II. Staffing Requirements Related to Initial Coverage/Organization Decisions and Appeals– Medicare Advantage Organizations and Part D Sponsors**

- Organizations must employ a medical director who is responsible for the clinical accuracy of all initial coverage/organization decisions and appeals that involve medical

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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 and 423.562) In addition, organizations must be staffed to satisfy the following requirements:

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

### **III. Appropriateness of Clinical Decision-Making – Medicare Advantage Organizations and Part D Sponsors**

Organizations must ensure that clinical and administrative staff and delegated entities involved in processing initial coverage/organization decisions and appeals comply with all CMS and plan coverage rules. Organizations must demonstrate that clinical decision-making involves the consideration of the CMS-approved EOB, drug formulary, appropriate CMS regulations and guidance, required drug compendia, previous claims history, and all submitted clinical information. Organizations also must 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/organization decision requests and appeals.

### **IV. Proper Use of Adjudication Timeframe Extensions – Medicare Advantage Organizations**

Under limited circumstances, organizations may extend the adjudication timeframe for organization determinations and reconsiderations. Organizations must comply with the use of extensions per the regulatory requirements at 42 C.F.R. §§ 422.568, 422.572, and 422.590, and any applicable provisions in the three-way contract for MMPs only.

### **V. Online Appeals Training Courses – Medicare Advantage Organizations and Part D Sponsors**

An organization's MCO, staff involved with initial coverage/organization decisions, appeals, and grievances, and CSRs, should be trained in Part C and Part D processes. CMS provides two optional web-based training courses below to supplement in-house training. <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/WebBasedTraining.html>. CMS strongly suggests that MCOs incorporate these courses into their existing in-house training and use the certificate to track course completion within the organization.

### **VI. Rights of Medicare C & D Enrollees – Medicare Advantage Organizations and Part D Sponsors**

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

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and appeal requests.

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

- Organizations must demonstrate that they maintain an effective compliance program which includes measures and internal controls to prevent, detect, and correct Medicare program non-compliance and fraud, waste, and abuse. 42 C.F.R. §§ 422.503 and 423.504. CMS strongly recommends all MCOs and personnel routinely review and share throughout the organization information from the CMS Compliance and Audit webpage and memorandums from the HPMS. The webpage provides:
  - Useful resources to assist your organization in understanding and implementing compliance program requirements,
  - Materials CMS uses to conduct program audits,
  - Annual Program Audit and Enforcement Reports, and

Information pertaining to compliance and enforcement actions.

<https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/index.html>.