DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
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TO: All Medicare Advantage Organizations (MAOs), Prescription Drug Plan Sponsors, 1876 Cost Plans, and Medicare-Medicaid Plans (MMPs)

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SUBJECT: Contract Year (CY) 2024 Readiness Checklist for Medicare Advantage Organizations, Prescription Drug Plan Sponsors, 1876 Cost Plans, and Medicare-Medicaid Plans

The Centers for Medicare & Medicaid Services (CMS) reminds organizations of critical Medicare Part C and D readiness items prior to the 2023 Annual Election Period (AEP) and coverage beginning January 1, 2024.

The Contract Year (CY) 2024 Readiness Checklist is a tool for organizations to use in preparation for the upcoming year. It does not supersede requirements as established in statutes or regulations as they relate to Medicare Advantage Organizations (MAOs), Prescription Drug Plans (PDPs), 1876 Cost Plans, and Medicare-Medicaid Plans (MMPs). CMS recommends that organizations review this checklist and take the necessary steps to fulfill requirements for CY 2024. Organizations must notify their account manager(s) of any requirements that are at risk or where technical assistance is needed to resolve any issue.

For questions or additional information on specific subject matters, refer to the applicable CMS regulations and guidance, contact your account manager, or contact the subject matter expert identified in Appendix A.

Additionally, in alignment with Executive Order 13985 (Advancing Racial Equity and Support for Underserved Communities Through the Federal Government),[1] we encourage

[1] https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government

organizations to contact the CMS Office of Minority Health (OMH) Health Equity Technical Assistance Program (HealthEquityTA@cms.hhs.gov) for support in addressing health and health care disparities and working toward health equity. Through the Health Equity Technical Assistance Program, CMS OMH subject matter experts offer personalized coaching, resources on improving care for underserved populations, data collection and analysis, and help with developing a language access plan to ensure effective communication with enrollees. Examples of how Health Equity Technical Assistance has been used in the past include:

- Helping Medicare Advantage Organizations and Part D Sponsors embed health equity into strategic plans, executive and organizational dashboards, and communication with leadership and boards;
- Helping health plans assess available data, including how to strengthen collection of demographic and social determinants of health data and use this data to tailor their interventions, communication, and services to enrollees who are members of minority and underserved communities; and
- Helping health plans implement a CMS Disparities Impact Statement to focus quality improvements on a particular population and disparity, and helping plans establish Language Access Plans and Accessibility Plans to ensure services and communication with enrollees meet the needs of those they serve, particularly members of minority and underserved communities.

Please visit the CMS OMH Health Equity Technical Assistance Program webpage for additional resources to support your organization's health equity initiatives. https://www.cms.gov/About-CMS/Agency-Information/OMH/equity-initiatives/Health-Equity-Technical-Assistance.

As we look ahead to the future, CMS is expanding the Prescription Drug Event (PDE) File Layouts from their current 512-byte length to 1000 bytes, effective January 1, 2025. This expansion is being implemented to accommodate future business needs including, but not limited to, anticipated updates to the National Council for Prescription Drug Programs (NCPDP) Telecommunication Standard, as well as to operationally implement Federal legislation. In addition, the lengths of some of the existing fields on the PDE File Layouts are increasing, requiring an overall reorganization of the fields within the PDE File Layouts. All Part D sponsors will be required to submit certification (CERT) test files prior to submitting production PDE files on January 1, 2025. CERT Testing is planned to begin on July 1, 2024. See HPMS memo titled *New 2025 Prescription Drug Event (PDE) File Layouts (FINAL)*, April 18, 2023.

Finally, on August 16, 2022, the Inflation Reduction Act of 2022 (IRA, P.L. 117-169[2]) was signed into law. While the law includes many changes to the Medicare Part D program, plans should pay particular attention to requirements in the following sections of the IRA:

[2] https://www.congress.gov/bill/117th-congress/house-bill/5376/text

- Section 11201 – Eliminates enrollee cost-sharing in the catastrophic phase of coverage for covered Part D drugs (effective January 1, 2024).
- Section 11401 - Coverage of Adult Vaccines Recommended by the Advisory Committee on Immunization Practices Under Medicare Part D (effective January 1, 2023).
- Section 11404 – Expanding Eligibility for Low-Income Subsidies Under Part D of the Medicare Program (effective January 1, 2024).
- Section 11406 - Appropriate Cost-Sharing for Covered Insulin Products Under Medicare Part D (effective January 1, 2023).

To aid plans with the implementation of IRA provisions CMS has issued a number of important HPMS memoranda that Part D sponsors should carefully review, as applicable, in preparation for the 2024 plan year, including the following:

- September 6, 2022 HPMS memo titled *Updates to Part D Member Materials for Contract Year 2023*
- September 6, 2022 HPMS memo titled *Additional Part D Updates to Contract Year 2023 Member Material Models for Medicare-Medicaid Plans and Minnesota Senior Health Options Plans*
- September 12, 2022 HPMS memo titled *Updates to PDSS Model Communications and Marketing Guidelines for Contract Year 2023*
- September 26, 2022 HPMS memo titled *Contract Year 2023 Program Guidance Related to Inflation Reduction Act Changes to Part D Coverage of Vaccines and Insulin*
- September 26, 2022 HPMS memo titled *PDE Reporting Instructions for Implementing the Cost Sharing Maximums Established by the Inflation Reduction Act for Covered Insulin Products and ACIP-Recommended Vaccines for Contract Year 2023*
- October 11, 2022 HPMS memo titled *Additional CY 2023 PDSS Model Guidance Related to Inflation Reduction Act (IRA) Changes to Part D Coverage of Insulin*
- March 3, 2023 HPMS memo titled *Other TrOOP Amount Indicator Summary Report*
- April 4, 2023 HPMS memo titled *Final Contract Year (CY) 2024 Part D Bidding Instructions*
- May 16, 2023 HPMS memo titled *Prescription Drug Event Record Reporting Instructions for the Implementation of the Inflation Reduction Act for Contract Year 2024*
- June 5, 2023 HPMS memo titled *Inflation Reduction Act (IRA) Cost Sharing Maximum Reports for Part D Sponsors*
- June 30, 2023 HPMS memo titled *Redetermination of Part D Low-Income Subsidy Eligibility for 2024*
- July 13, 2023 HPMS memo titled *Frequently Asked Questions: Inflation Reduction Act Changes to Cost Sharing for Part B Drugs for Medicare Advantage and Section 1876 Cost Plans*

- July 24, 2023 HPMS memo titled *Contract Year 2023 Program Guidance Related to Inflation Reduction Act Changes to Part D Coverage of Vaccines*

Additional guidance on implementing the IRA will be released on a rolling basis and HPMS should be reviewed regularly. CMS will be conducting monthly Part C &D User Group Calls to provide updates on the implementation of the IRA. Please see the October 7, 2022 HPMS memo titled *Part C&D User Group Calls – Inflation Reduction Act of 2022 (IRA) Implementation.*

Notes:

- Unless otherwise indicated, items that apply to MAOs also apply to 1876 Cost Plans and MMPs. Part D sponsors refers to all organizations offering Part D.
- For purposes of the MMPs, references to the account managers are the equivalent of references to the Contract Management Team (CMT).

CY 2024 Medicare Advantage Organization, Prescription Drug Plan, Cost Plan, and Medicare-Medicaid Plan Readiness Checklist

A. User Group Calls

- Ensure key staff register 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.

B. Access to Services and Information

I. Medicare Advantage Organizations and Part D Sponsors

- Ensure that services are provided in a culturally competent manner to all enrollees, including those with limited English proficiency (LEP) or reading skills and diverse cultural and ethnic backgrounds. (42 C.F.R. § 422.112(a)(8))
- Have mechanisms for providing specific information on a timely basis to current and prospective enrollees upon request. These mechanisms must include call centers that provide interpreters for non-English speaking and LEP individuals. (42 C.F.R. §§ 422.111(h)(1) and 423.128(d)(1), and the HPMS memo 12/01/2022)
- For markets with a significant non-English speaking population, provide required materials in the language of these individuals on a standing basis upon receiving a request for the materials in a non-English language or when otherwise learning of an enrollee's primary language. This requirement also applies to individualized plans of care described at 42 C.F.R. § 422.101(f)(1)(ii) and for special needs plan enrollees. (42 C.F.R. §§ 422.2267(a)(3) and 423.2267(a)(3)). Specifically,
    - Fully or highly integrated dual eligible special needs plan, as defined at § 422.2, or applicable integrated plan, as defined at § 422.561, must translate materials into the language(s) required by the Medicaid translation standard as specified through their capitated Medicaid managed care contract in addition to the language(s) required by the Medicare translation standard. (42 C.F.R §§ 422.2267(a)(4) and 423.2267(a)(4).
    - CMS has translated certain Parts C and D Contract Year (CY) 2022 model materials into Spanish and Chinese. (HPMS memo 09/25/2023)
    - It is a best practice to use translation services that adhere to generally accepted ethics and principles, demonstrate proficiency in understanding English and the language in need of translation, and translate effectively, accurately, and impartially from English to the language in need of translation using necessary specialized vocabulary, terminology, and phraseology. (HPMS memo 09/25/2023)
    - Regularly review and assess plan literature that has been translated to ensure quality translations.
- Refer to the following key resources for guidance on providing culturally and linguistically appropriate services:

  - A Practical Guide to Implementing the National CLAS Standards: For Racial, Ethnic and Linguistic Minorities, People with Disabilities, and Sexual and Gender Minorities. The toolkit may be accessed at: https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/CLAS-Toolkit-12-7-16.pdf
  - Guide to Developing a Language Access Plan. The guide may be accessed at: https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Language-Access-Plan.pdf
  - Providing Language Services: Lessons from the Field. This resource may be accessed at: https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Lessons-from-the-Field.pdf.
- Note: For MMPs, the state-specific standard applies, if it is more stringent than the Medicare standard, as provided in *Standards for Required Materials and Content* section (42 C.F.R. §§ 422.2267(a)(2) and 423.2667(a)(2)) of the CY 2024 State-specific Marketing Guidance for MMPs.

C. Individuals with Disabilities – Auxiliary Aids ("Accessible Formats") and Use of TTY Numbers

I. 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 format as referenced in Section 504 of the Rehabilitation Act of 1973. Provide required materials on a standing basis in an accessible format upon receiving a request for the materials or when otherwise learning of the enrollee's need for an accessible format (42 C.F.R §§ 422.2267(a)(3) and 423.2267(a)(3).
- Provide a toll-free TTY number, which should appear in conjunction with the customer service number in the same font size as the other phone numbers.
- MAOs and Part D sponsors may use their own TTY number, 711 for Telecommunications Relay Service, or state relay services, if the number is accessible from TTY equipment. (Section 504 of the Rehabilitation Act of 1973)
- Use Section 1557 best practices outlined in the attachment to an April 26, 2019 HPMS memo titled *Communications Accessibility for Individuals with Disabilities Best Practices for Medicare Health and Part D Prescription Drug Programs*.

D. Precluded Providers and Prescribers

I. Medicare Advantage Organizations and Part D Sponsors

- Provide beneficiary notices about precluded providers and prescribers.
- An MAO must not make payment for a health care item, service, or drug that is furnished, ordered, or prescribed by an individual or entity that is included on the preclusion list. (42 C.F.R. § 422.222)

- A Part D sponsor must reject or must require its Pharmacy Benefit Manager (PBM) to reject, a pharmacy claim for a Part D drug if the individual who prescribed the drug is included on the preclusion list. (42 C.F.R. § 423.120(c)(6))
- The Preclusion List consists of individuals or entities that:
    - Are currently revoked from Medicare, are under a reenrollment bar, and for whom CMS has determined that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program.
    - Have engaged in behavior for which CMS could have revoked the individual or entity to the extent applicable had they been enrolled in Medicare, and CMS determines that the underlying conduct that would have led to the revocation is detrimental to the best interests of the Medicare program.
    - Have been convicted of a felony under federal or state law within the previous 10 years, regardless of whether they are or were enrolled in Medicare, and CMS deems detrimental to the best interests of the Medicare program.

  42 C.F.R. §§ 423.100 et seq. and 422.2; HPMS memoranda 11/02/2018, 12/14/2018, 01/09/2019, 08/12/2019, 12/08/2020, and FAQs 12/16/2020; https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/Preclusion-List.

E. Systems, Data, & Connectivity

I. HPMS – Medicare Advantage Organizations and Part D Sponsors

- Ensure key staff members register for the Plan Connectivity Module within HPMS by e-mailing hpms_access@cms.hhs.gov. (HPMS memo 08/16/2022)
- Update your organization's contract and contact data information in HPMS and ensure that your organization has a process in place to keep the data on the HPMS contract and contact 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 multiple purposes within HPMS and other systems, as well as in support of information displayed publicly. Refer to the HPMS contacts definitions to assist you with completing the contact information sections. (*HPMS Basic Contract Management User Manual and Contact Definitions*)

II. Internal and Downstream Entities – Medicare Advantage Organizations and Part D Sponsors

- Adequately test your internal and downstream entity information technology (IT) systems to ensure any modifications don't result in unexpected errors. Some examples include:
    - Changes to claims systems that inadvertently lead to inaccurate provider claims.
    - Configuration error changes that incorrectly result in Explanations of Benefits (EOBs) not being sent to beneficiaries.

- File transfer issues to print vendors that lead to beneficiaries not receiving identification (ID) cards.
- IT systems changes that result in incorrect pharmacy copay determinations or missing transition fill determinations.

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

- Have controls in place to ensure downloaded applications are processed in the plan's system and submitted to MARx timely.
- Review and implement guidance regarding software improvements to the enrollment and payment systems.
- Ensure familiarity with the requirements and process that MAOs and PDPs must use to designate staff that will be responsible for granting access to data in the CMS systems, as well as the responsibilities of an External Point of Contact (EPOC). (HPMS memo 09/29/2023)
- An individual's access to Identity Management (IDM) will be locked when 60 days lapses between system logins. To unlock the account, the individual must login to IDM, answer their challenge questions, and reset their password. (*EIDM User Guide*)
- Submit information about 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 *Advantage Prescription Drug (MAPD) Plan Communications User Guide available at https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/mapdhelpdesk/Plan_Communications_User_Guide*)

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

- Drug Pricing and Pharmacy Network Data Files (Part D sponsors). Submit timely and accurately the CY 2024 drug pricing and pharmacy network data for posting on the MPF.
  - Part D sponsors will use the HPMS Part D Pricing File Submission Module to submit their drug pricing and pharmacy network data for posting on the MPF. Ensure that your organization has access to the module and performs quality assurance checks before submission so that the files are complete and accurate. Part D sponsors also have the option to submit their Part D pricing and pharmacy network files using an Application Programming Interface (API).
  - 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 at least some tiers of formulary drugs at that pharmacy than applies at pharmacies in the standard cost-sharing network (excludes MMPs).

  - Confirm drug pricing and pharmacy network data files for MPF are complete, correct, and accurate, and that only pharmacies under contract for 2024 are included in the submission. Incorrect data may result in suppression from the MPF and/or applicable compliance actions. (HPMS memo 06/02/2023 and 08/07/2023)
  - Part D sponsors should review and be familiar with enhancements to the MPF and the related HPMS modules that support Part D drug pricing and pharmacy network submissions, plan benefit and drug pricing reviews, suppressions and exclusions, and Online Enrollment Center (OEC) management. (HPMS memo 05/18/2023)
- 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 MPF suppressions and Part D program compliance or enforcement actions, as a result of inaccurate data submissions.
  - If your organization receives an outlier notification for your 2024 drug pricing and pharmacy network data which was previously a known exception in 2023, your organization must re-confirm that the data continue to be accurate. If you do not confirm these data, your organization's pricing data may be suppressed on the MPF.
  - MPF submissions must be complete and accurate in all respects, and 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.
- HPMS Part D Pricing File Submission Module (Part D sponsors). Ensure your organization has access to the HPMS Part D Pricing File Submission Module for both Part D pricing file submissions and the QA validation results. Updates and announcements relating to the pricing file submission and QA validation processes are posted in the module's Documentation section. (HPMS memo 06/02/2023 and 08/07/2023)

V. Patient Safety Quality Analysis – Part D Sponsors

- Ensure your organization's Medicare compliance officer (MCO) authorizes users to access the Patient Safety reports, which are available via the Patient Safety Analysis Web Portal. We recommend that at least one user from each contracted organization have access to the 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 Web Portal to compare your performance to overall averages and monitor progress in improving Part

D patient safety measures over time. Several of the measures are included in Part D Star Ratings or are 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 encouraged to use the Patient Safety Analysis Web Portal to view and download the reports, respond to outlier notices, and engage in performance monitoring.
- Sponsors can view the Patient Safety Analysis Web Portal User Guide, located under the Portal's Help Documents. Other information provided under the Help Documents includes each measure's Patient Safety Report User Guide, diagnosis codes, and the National Drug Code (NDC)/medication lists used to calculate the measures. The Patient Safety Analysis Web Portal can be accessed at https://PartD.ProgramInfo.us/User_Security. (HPMS memo 04/20/2023)

VI. Drug Management Programs (DMPs) – Part D Sponsors

- All Part D sponsors are required to implement a DMP that meets the requirements set forth at 42 C.F.R. § 423.153(f). Under its DMP, a Part D sponsor is permitted for the safety of the beneficiary, after case management and notification, to limit at-risk beneficiaries' access to coverage of frequently abused drugs (opioids and benzodiazepines) to a selected prescriber(s) and/or network pharmacy(ies), or implement beneficiary-specific claim edits for such drugs.
- Ensure your organization can effectively support the activities needed to have a DMP, including systems processes (e.g., MARx – See Section D.III.), required case management and beneficiary notices, call center scripts and triage processes for enrollees submitting information to the plan or requesting appeals, claims system edits to operationalize coverage limitations for frequently abused drugs, and outreach and education (e.g., communications to network prescribers and pharmacies).
- Ensure your organization's MCO authorizes users to access the Overutilization Monitoring System (OMS), available via the Patient Safety Analysis Web Portal. At least one user from each contracted organization must have access to Summary and Confidential Beneficiary Reports to view and send information via the OMS.
- 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 C.F.R. § 423.153(f) and applicable guidance.
    - The *OMS User Guide* is available on the Patient Safety Analysis Web Portal at https://PartD.ProgramInfo.us/User_Security under Help Documents.
    - DMP program guidance, FAQs and other relevant documents are available on the Improving Drug Utilization Controls in Part D page at

https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization under Downloads.

VII. Opioid Safety Edits- Part D Sponsors

- Ensure your Pharmacy & Therapeutics (P&T) committee develops specifications, including claim billing transaction communications to pharmacist(s), for your plan's implementation of the following formulary-level POS safety edits:
    - Opioid care coordination safety edit based on a beneficiary's cumulative 90 morphine milligram equivalent (MME) dose per day with or without prescriber and/or pharmacy counts.
    - Hard safety edit limiting opioid naïve beneficiaries to a 7-day supply.
    - Soft safety edits for duplicative long-acting opioid therapy and concurrent use of opioids and benzodiazepines.
    - Optional cumulative opioid MME hard safety edit to be set at a minimum threshold of 200 MME or more with or without prescriber and/or pharmacy counts.
- Submit information on the opioid naïve safety edit, care coordination safety edit, and optional hard MME edit in the Opioid Safety Edits module in HPMS. CY 2024 opioid safety edits may be revised by sending an email to PartD_OM@cms.hhs.gov with the subject line "Opioid Safety Edit Request to Revise – [applicable contract ID number(s)]." Include in the email the following information:
    - The contract ID(s) associated with the change.
    - The intended revisions to the opioid safety edit(s).
    - The proposed implementation date of the revision.
    - A justification for the mid-year change of the opioid safety edit.

  See 42 C.F.R. § 423.153(c)(2), Calendar Year (CY) 2018, 2019 and 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, HPMS memoranda 10/23/2018 and 07/05/2023, and Frequently Asked Questions about Formulary-Level Opioid Point-of-Sale Safety Edits guidance posted on the Improving Drug Utilization Review Controls in Part D at https://www.cms.gov/Medicare/Prescription-Drug-coverage/PrescriptionDrugCovContra/RxUtilization.

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

- MAO payment is primarily based on data submitted to CMS in accordance with section 1853(a)(3)(B) of the Social Security Act and 42 C.F.R. §§ 422.310(b) and 422.310(d). In order to receive proper payment, MAOs must be certified to submit data through the EDS and, if applicable, RAPS.
- In the Announcement of Calendar Year (CY) 2024 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies, CMS announced that it will continue

calculating 100 percent of the risk score for MA plans using diagnoses from MA encounter data and FFS claims for CY 2024.

- Given that no RAPS data will be included in the calculation of MA risk scores for CY 2024, MAOs will not be required to submit data with 2023 dates of service to RAPS. However, RAPS will remain available to MAOs for submitting corrections to data from prior payment years.
- 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.csscoperations.com/.
- Register for Risk Adjustment EDS and RAPS User Group webinars announced via HPMS memo.
- Assistance with data submission can be obtained by emailing csscoperations@palmettogba.com, or by calling 1-877-534-2772.
- Activities checklist risk adjustment data 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.
    - Begin submission of production data within four months of contract effective date.
    - Regularly review HPMS to receive memoranda on topics including:
        - Submission Requirement Updates.
        - Edit Changes.
        - Submission Deadlines.
    - Request access to the Risk Adjustment/Encounter Data Module in HPMS by contacting HPMS_Access@cms.hhs.gov to download reports designed to improve the completeness of encounter data reporting including:
        - Encounter Data Report Cards: The report cards are intended to provide MAOs with information on encounter data submissions in order to drive self-assessment and improvement by MAOs. (HPMS memo 10/04/2019)
        - Submission Performance Reports: The reports provide contract level performance measures and thresholds. (HPMS memo 08/20/2018)
    - Specific to MMPs: MMPs shall submit encounter data consistent with MMP guidelines that can be found in HPMS memoranda (dated 10/24/2013 and 8/10/2016), relevant provisions of the three-way contract, guidance found on the CSSC website at https://www.csscoperations.com/ and in the applicable *Medicare- Medicaid Capitated Financial Alignment Model Quality Withhold Technical Notes*. The technical notes are available at https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-

Office/FinancialAlignmentInitiative/MMPInformationandGuidance/MMPQualityWithholdMethodologyandTechnicalNotes

IX. Prescription Drug Event (PDE) Requirements and Direct and Indirect Remuneration (DIR) Requirements – Part D Sponsors

- As a condition of payment, all Part D plans must submit data and information necessary for CMS to carry out payment provisions. (Sections 1860D-15(c)(1)(C) and (d)(2) of the Social Security Act and 42 C.F.R. § 423.322(a))
- PDE data is used to determine plan payments for Part D and is submitted through the Prescription Drug Front-End System (PDFS) and processed by the Drug Data Processing System (DDPS). 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.csscoperations.com/, as well as memoranda available on HPMS. Assistance with data submission can be obtained by emailing csscoperations@palmettogba.com or by calling 1-877-534-2772.
- Effective January 1, 2025, CMS is expanding the PDE File Layouts from their current 512-byte length to 1000 bytes. All Part D sponsors will be required to submit certification (CERT) test files prior to submitting production PDE files on January 1, 2025. CERT Testing is planned to begin on July 1, 2024. CMS will provide CERT Testing requirements in advance. (HPMS memo 4/18/2023)
- Establish access to the Part D Payment Process Support Website. (HPMS memo 09/19/2019)
- 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 change. (HPMS memo 10/06/2011)
- Establish access to the PDE Reports portals. (HPMS memoranda 09/19/2019 and 04/28/2023)
- 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 memo 12/20/2019)

  - Payment Reconciliation System (PRS) reports. (HPMS memoranda 06/23/2017 and 04/30/2019)
- Section 1860D-15(f)(1)(A) of the Social Security Act requires Part D sponsors to fully disclose to CMS any information necessary for carrying out the payment provisions of Part D, including the calculation of reinsurance and risk-sharing. Therefore, Part D sponsors are required to report drug costs and DIR associated with the Medicare prescription drug benefit to CMS. Each year CMS issues an HPMS memo that provides reporting guidance. Consistent with section 1860D-15(d)(2)(A) of the Social Security Act, CMS's payments to a Part D sponsor are conditioned upon the provision of this requisite data. (HPMS memo 05/03/2023)
  - Each year, prior to the Part D Payment Reconciliation, CMS requests Part D sponsors verify that the contact information in HPMS is accurate. For the purposes of the Part D payment reconciliation, the contact information in HPMS for the Executive Officers, Medicare Compliance Officer, reconciliation contacts, and DIR contacts must be accurate. (HPMS memo 02/17/2023)
  - Each year, Part D sponsors must prepare and submit the DIR Submission Information and upload the Summary DIR Report and Detailed DIR Report into HPMS for all the Part D PBPs that they offered. (HPMS memo 05/03/2023)
  - Part D sponsors should ensure that PDE records are submitted in accordance with previously released guidance regarding the elimination of the deductible and reduced cost sharing for adult vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) and covered insulin products under Part D. (HPMS memo 05/16/2023)
  - With respect to PDE records submitted for covered insulin and ACIP-recommended Part D adult vaccines in 2023, Part D plan sponsors will be required to report a supplemental file within 6 months of the end of a coverage year, to allow CMS to determine the total IRA Subsidy Amount (IRASA) to be paid to the Part D sponsor. The supplemental file format and submission method, and updates to the Part D Payment Reconciliation calculations and reports, will be released in a separate memorandum issued in the spring of 2024. (HPMS memo 9/26/2022)
- Effective January 1, 2024, section 11201 of the IRA eliminates beneficiary cost-sharing in the catastrophic phase; Part D sponsors must be prepared to correctly adjudicate this change to the Part D benefit. (HPMS memo 05/16/2023)
- Effective January 1, 2024, pursuant to the pharmacy price concessions provision finalized in the May 9, 2022 final rule (CMS-4192-F), CMS requires the application of all pharmacy price concessions at the point of sale. If the payment to a Part D pharmacy may be reduced by up to a certain amount, the maximum possible reduction in payment must be treated as a pharmacy price concession and reflected in the negotiated price available at the point of sale and reported to CMS on a PDE record. (HPMS memo 10/14/2022 titled *Reporting Estimated Remuneration Applied*

to the Point-of-Sale Price and HPMS memo 06/02/2023 titled *Reminder of Regulatory Requirements for Pharmacy Price Concessions*)

X. Prescriber Real-Time Benefit Tool (RTBT) – Part D Sponsors

- Sponsors must support one or more prescriber RTBTs capable of integrating with at least one e-Prescribing system or electronic health record (EHR) used by prescribers to provide complete, accurate, timely, clinically appropriate, patient-specific formulary and benefit information to the prescriber in real time for assessing coverage under the Part D plan.
- The formulary and benefit information provided through the prescriber RTBT must include enrollee cost-sharing information, clinically appropriate formulary alternatives, when available, and the formulary status of each drug presented, including any utilization management requirements applicable to each alternative drug. (42 C.F.R. § 423.160(b)(7))

F. Reporting

I. Healthcare Effectiveness 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 05/15/2023)
- Prepare to sign up for the 2023 HOS or HOS-M if the MAO is planning on sponsoring a fully integrated dual eligible special needs plan (FIDE SNP) in 2024 that will be considered for 2024 frailty payment. (HPMS memo 05/15/2023)

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

- MAOs and Part D Sponsors that are required to submit Part C and/or Part D Reporting Requirements data through HPMS are responsible for obtaining and maintaining access to Acumen's Monitoring Parts C & D Reporting Web Portal. (HPMS memo 07/11/2023)
- MAOs and Part D sponsors must collect and report data in accordance with the applicable Part C and Part D reporting requirements; select a contractor to conduct independent data validation; and submit information to CMS according to the requirements and established deadlines. (42 C.F.R. §§ 422.516(a) and (g); §§ 423.514(a) and (j), https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/ReportingRequirements; https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_ReportingOversight)
- Refer to the Medicare Part C and D Reporting Requirements Data Validation Procedure Manual found at: https://www.cms.gov/Medicare/Prescription-Drug-

Coverage/PrescriptionDrugCovContra/PartCDDataValidation. Companies that provide management consulting services to your organization or assist with your reporting procedures, reporting processes, or information systems used in storing, compiling, or reporting the Part C and/or Part D Reporting Requirements data to CMS may not also serve as your data validation contractor for any given reporting period. Management consultation activities include performing mock audits, preassessments, and any other types of reviews on reported data. Sponsors should also update their Data Validation Contractor and Data Validation Pre-Assessment Contractor in HPMS.

- MMPs must also meet Core Reporting Requirements and applicable State-Specific Reporting Requirements and participate in performance measure validation as required. (https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/MMPInformationandGuidance/MMPReportingRequirements)

III. Quality Withhold Requirements – MMPs only

- We remind MMPs that a percentage of their capitated rate is withheld and will be repaid retrospectively subject to performance consistent with established quality requirements. CMS strongly encourages MMPs to review the current demonstration methodology and plan ahead to maximize the chances of fully recouping the withheld amounts. (https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/MMPInformationandGuidance/MMPQualityWithholdMethodologyandTechnicalNotes)

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

- Consistent with section 1128J(d) of the Social Security Act, 42 CFR § 422.326, and 42 CFR § 423.360, every MAO 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

- MAOs and Part D sponsors are required to use the Fiscal Soundness Module in HPMS to submit, on an annual basis, independently audited annual financial statements, and quarterly financial statements for 2024. The *Fiscal Soundness Reporting Requirements* (FSRR), relevant HPMS memoranda, and other important information are available at: https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/FSRR.

VI. Health Risk Assessment (HRA) Screening Requirements – Special Needs Plans

- All SNPs are required to include in their HRAs one or more questions on each of the following domains: housing stability, food security, and access to transportation (42

C.F.R. § 422.101(f)(1)(i)). SNPs must select questions covering each of these three domains from a list of screening instruments specified by CMS that is included in section 90 of Chapter 16-B of the Medicare Managed Care Manual at: https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/mc86c16b.pdf.

G. 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 requires 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.
    - Provide the applicable standard terms and conditions document to the requesting pharmacy within seven business days of receipt of the request. (Section 1860D-4(b)(1)(A) of the Social Security Act; 42 C.F.R. § 423.120(a)(8)(i) and 423.505(b)(18); 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 memoranda 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 50 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 account manager at least 60 days prior to the effective date of a new contract. For MMPs, notify your Contract Management Team (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 change 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 - Benefits and Beneficiary Protection*, 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.

IV. State Medicaid Agency Contracts – Medicare Advantage Organizations offering D-SNPs

- MAOs offering D-SNPs whose integration level is for the notification of skilled nursing facility and hospital admissions should ensure that notification process is ready to begin for January 1, 2024. (42 C.F.R. § 422.107(d) and section 20 of Chapter 16-B of the Medicare Managed Care Manual at: https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/mc86c16b.pdf).
- MAOs offering D-SNPs that meet the definition at 42 C.F.R. § 422.561 for applicable integrated plans should:
    - Implement the integrated appeals and grievances procedures set forth at 42 C.F.R. §§ 422.629-634 (see further discussion in Section M, below).
    - Use the integrated coverage decision letter (Form CMS-10716) (and available models for expedited grievances and appeals decision notices) in lieu of existing notices (HPMS memo 11/20/2020; 42 C.F.R. §§ 422.629-634).
- MAOs offering D-SNPs must establish and maintain one or more enrollee advisory committees (EAC) for each state in which the D-SNP is operational. (42 C.F.R. § 422.107(f))
    - The EAC must include a reasonable representative sample of individuals enrolled in the D-SNP(s).
    - D-SNPS must use EACs to solicit input on ways to improve access to covered services, coordination of services, and health equity or underserved enrollee populations.

H. Customer Service

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

- Ensure compliance with standards found at 42 C.F.R. §§ 422.111(h)(1) and 422.112(a)(8), 423.128(d)(1), and the call center monitoring HPMS memo dated 12/01/2022. These include operating hours of 8:00 a.m. to 8:00 p.m. of customer service call centers that serve current and prospective enrollees.

- For MMPs specifically: MMPs must operate a toll-free call center for both current and prospective enrollees per the three-way contract and the State-specific Marketing Guidance for MMPs. MMPs should refer to the Disclosure Requirements, Provision of Specific Information, Call Centers (42 C.F.R. §§ 422.111, 422.111(h)) section of the State-specific Marketing Guidance for MMPs-specific customer service call center requirements.

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

- Ensure compliance with standards found at 42 C.F.R. § 423.128(d)(1) and the call center monitoring HPMS memo dated 12/01/2022.

III. Medication Therapy Management (MTM) Programs – Part D Sponsors

- Have an MTM program that meets the requirements for the program year as established in 42 C.F.R. § 423.153(d).
- Target beneficiaries for the MTM program who meet the eligibility requirements defined at 42 C.F.R. § 423.153(d)(2)(i) and/or (ii). The 2024 MTM program annual cost threshold is $5,330.
- Offer a minimum level of MTM services to all MTM enrollees set forth at 42 C.F.R. § 423.153(d)(1)(vii).
- Pursuant to 42 C.F.R. § 423.2265(b)(13), include on website a separate section or page with required information about the sponsor's MTM program, including eligibility requirements that reflect both groups of targeting criteria and a summary of services.
- Ensure CSRs are familiar with the plan's MTM program, including eligibility criteria and how to direct beneficiaries to the plan's MTM program page or section.

  HPMS memo 04/21/2023 for CY 2024 Medication Therapy Management Program Guidance and Submission Instructions; 42 C.F.R. §§ 423.153(d), 423.2265(b)(13), and 422.111(j).

IV. Complaints Tracking Module - Medicare Advantage Organizations and Part D Sponsors

- Resolve at least 95 percent 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 percent of all CTM complaints designated without an issue level within 30 days. MAOs and Part D sponsors are urged to make interim contact with beneficiaries if their complaints will take more than seven days to resolve.
- Following the *Complaints Tracking Module (CTM) Standard Operating Procedures SOP*, all complaints should be reviewed by plans at intake, including verifying the contract assignment and issue level. If necessary, submit any Plan Request changes as soon as possible, and no later than the Star Ratings operational deadline for the following year. (HPMS memoranda 05/10/2019, 08/04/2020, and 03/21/2022)

I. Communications Consistent with C.F.R. Parts 422 and 423, Subparts V

- Market[3] consistent with the Subparts V of both 42 C.F.R. Parts 422 and 423. MMPs must also market consistent with the State-specific Marketing Guidance for MMPs as applicable.

I. Required Materials – Medicare Advantage Organizations and Part D Sponsors

- Ensure your organization is using the updated CY 2024 required materials on the Marketing Models, Standard Documents, and Educational Material and Part D Model Materials websites. All required materials have been posted and are located at: https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/MarketngModelsStandardDocumentsandEducationalMaterial and https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Part-D-Model-Materials. (HPMS memoranda 05/31/23, 08/08/23)
- For MMPs specifically: Ensure your organization is using the updated state-specific CY 2024 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. (Includes the June 30 HPMS memo titled *Contract Year 2024 Enrollee Material Model Updates for MMPs.)*

II. 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 provided to all prospective enrollees when an enrollment form is provided. For online enrollment, the Star Ratings information document and Summary of Benefits (SB) document must be made available electronically (e.g., via link) prior to the completion and submission of an enrollment request. (42 C.F.R. §§ 422.2267(e)(13) and 42 C.F.R. § 423.2267(e)(17))
- Ensure that any references to Star Ratings comply with the current marketing requirements. (42 C.F.R. §§ 422.2263(c) and 42 C.F.R. § 423.2263(c))
- MAOs 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. (42 C.F.R. §§ 422.2267(e)(13) and 42 C.F.R. § 423.2267(e)(17))

[3] Regulations at 42 CFR §§ 422.2260 and 423.2260 define marketing as communication materials and activities which meet specific intent and content standards. See May 10, 2023 HPMS memo titled *Definition of Marketing* for more information.

- MAOs and Part D sponsors must clearly identify which contract year their Star Ratings reference. (42 C.F.R. §§ 422.2263(c) and 42 C.F.R. § 423.2263(c))

III. Websites – Medicare Advantage Organizations and Part D Sponsors

- Ensure that your organization's website and all electronic Information and Communications Technology (ICT) are 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. § 794(d))
- The Summary of Benefits, Annual Notice of Change, Evidence of Coverage, Provider and/or Pharmacy Directories; Formulary and Utilization Management Forms for physicians and enrollees; and Low-Income Subsidy Premium Summary Chart must be posted on the website by October 15 for the upcoming contract year. (42 C.F.R. §§ 422.2265(b) and 423.2265(c)) Note that the LIS Premium Summary Chart does not apply to MMPs.
- Ensure your organization's formulary is updated on the website when changes are made. (42 C.F.R. 423.128(d)(2)(ii) and the State-specific Marketing Guidance for 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. (42 C.F.R. §§ 422.2265(b) and 423.2265(b))
- MAOs, PDPs, and their third parties' websites used to market their products are expected to meet applicable CMS marketing requirements. (42 C.F.R. §§ 422.2265 and 423.2265, and State-specific Marketing Guidance for MMPs)
- Ensure your organization's internal coverage criteria are publicly available per CMS requirements. (42 C.F.R. § 422.101(b)(6)(ii))

IV. Beneficiary Real Time Benefit Tool – Part D Sponsors

- Part D sponsors must implement, and make available directly to enrollees, in an easy-to-understand manner, the following complete, accurate, timely, clinically appropriate, patient-specific formulary and benefit real-time information in their beneficiary-specific portal or computer application:
    - Enrollee cost-sharing amounts.
    - Formulary medication alternatives for a given condition.
    - Formulary status, including utilization management requirements applicable to each alternative medication, as appropriate for each enrollee and medication presented. (42 C.F.R. § 423.128(d)(4))

V. Agents and Brokers - Medicare Advantage Organizations and Part D Sponsors

- Implement agent/broker compensation rates, submissions, and training and testing requirements. (HPMS memo 06/21/2023)

- 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. (Three-way contract, State-specific Marketing Guidance for MMPs)

VI. Beneficiary Opioid Education – Part D Sponsors

- Sponsors should develop and provide opioid information to beneficiaries in accordance with 42 C.F.R. § 423.128(b)(11).

J. Enrollment/Disenrollment

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

- The AEP period begins October 15 and ends on December 7. An enrollment/disenrollment election type AEP cannot be used after the end of the AEP.
- 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, 2023. Enrollments received after December 7, 2023 may not be processed as AEP elections. Beneficiaries must be eligible for a valid election period such as an Initial Election Period (IEP) or a Special Enrollment Period (SEP) for requests received after the December 7 deadline.
- Disenroll an MA plan member whose temporary absence from the service area exceeds six (6) consecutive months (up to twelve (12) consecutive months if the plan includes a visitor/travel benefit). Disenroll a PDP member whose temporary absence from the service area exceeds twelve (12) consecutive months. (*Medicare Managed Care Manual Chapter 2 – Medicare Advantage Enrollment and Disenrollment, Section 50.2.1; Medicare Prescription Drug Benefit Manual Chapter 3 – Eligibility, Enrollment and Disenrollment,* Section 50.2.1.1)
- Establish a process to receive Good Cause reinstatement requests from individuals disenrolled 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 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 – Medicare Advantage Enrollment and Disenrollment*, Section 60, and *Medicare Prescription Drug Benefit Manual Chapter 3 – Eligibility, Enrollment and Disenrollment*, Section 60) (Excludes MMPs)
- 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. (Excludes MMPs)

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, MA plan enrollees may disenroll or switch to another MA plan (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. (42 C.F.R. § 422.62(a)(3); *Medicare Managed Care Manual Chapter 2 – Medicare Advantage Enrollment and Disenrollment*, Section 30.5; *Medicare Prescription Drug Benefit Manual Chapter 3 – Eligibility, Enrollment and Disenrollment*, Section 30.3.8, #8.D)

III. 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.
- Sponsors retain complete responsibility for following enrollment policies, and appropriate handling of any sensitive beneficiary information provided as part of the electronic 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 – Medicare Advantage Enrollment and Disenrollment, Section 40.1.2; Medicare Prescription Drug Benefit Manual Chapter 3 – Eligibility, Enrollment and Disenrollment, section 40.1.2; *Medicare Managed Care Manual Chapter 17, Subchapter D Medicare Cost Plan Enrollment and Disenrollment Instructions*, Section 40.1.3

IV. SEPs for Dually Eligible and Other LIS-Eligible Individuals – Medicare Advantage Organizations and Part D Sponsors (Excludes MMPs in capitated model Financial Alignment Initiative (FAI) Demonstration States that have secured a demonstration waiver)

- Properly determine eligibility for those using the codified SEPs for dually eligible and other LIS-eligible individuals.
    - 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 dually eligible/LIS status.
    - Dually eligible and other LIS-eligible individuals are eligible for a SEP to change plans once per calendarquarter during the first 3 quarters of the year (January – September).
    - Note: Once a dually eligible or other LIS-eligible individual is identified by a Part D sponsor as a potential at-risk or at-risk beneficiary under a DMP, he or she cannot use the quarterly dual/LIS SEP to change plans for as long as he or she is a potential at-risk or at-risk beneficiary.

42 C.F.R. § 423.38(c)(4); *Medicare Managed Care Manual Chapter 2 – Medicare Advantage Enrollment and Disenrollment*, Section 30.4; *Medicare Managed Care Manual Chapter 17*, *Subchapter D Medicare Cost Plan Enrollment and Disenrollment Instructions*, Section 30.4; *Medicare Prescription Drug Benefit Manual Chapter 3 - Eligibility,Enrollment and Disenrollment,* Section 30.3

V. SEP for Enrollments 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 2024, provided the beneficiary is otherwise eligible for that plan. An individual may use this SEP only one time between December 8, 2023 and November 30, 2024. Five-star plans must be prepared to accept all valid enrollment requests made using this SEP (42 C.F.R. §§ 422.62(b)(15) and 423.38(c)(20); *Medicare Managed Care Manual Chapter 2 –Medicare Advantage Enrollment and Disenrollment*, Section 30.4.4; *Medicare Prescription Drug Benefit Manual Chapter 3 – Eligibility, Enrollment and Disenrollment*, Section 30.3.8)

VI. Enrollment Processes and Notices - Medicare Advantage Organizations and Part D Sponsors (Excludes MMPs)

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

VII. Online Enrollment Center (OEC) – Medicare Advantage Organizations and Part D Sponsors (Excluding MSA, 800-Series-Only, and MMPs; Optional for SNPs, RFB, and 1876 Cost Plans; Required for PDPs and MA-PDs)

- Organizations must promptly retrieve enrollment requests and should check for requests regularly from the HPMS OEC Management Module unless your organization is prohibited or has opted-out from participating in the OEC. HPMS will provide the CY 2023 and 2024 OEC transactions in separate files, which will be distinguishable by the contract year in the file name. Organizations should ensure both contract years 2023 and 2024 enrollment files are promptly processed. (*Medicare Managed Care Manual Chapter 2 – Medicare Advantage Enrollment and Disenrollment*, Section 40.1.2; *Medicare Prescription Drug Benefit Manual Chapter 3 – Eligibility, Enrollment and Disenrollment, Section* 40.1.2. and HPMS memo 08/30/2023)
- Ensure your organization's ability to conform to and accept the OEC record layout. (HPMS memo 08/19/2022)
    - Have controls in place to ensure downloaded applications are appropriately processed in the plan's system and submitted to MARx timely.
    - 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 (HPMS memo 08/19/2022; *Medicare Managed Care Manual Chapter 2 – Medicare Advantage Enrollment and Disenrollment* and *Medicare Prescription Drug Benefit Manual Chapter 3 – Eligibility, Enrollment and Disenrollment*, Section 10; *Medicare Managed Care Manual Chapter 17, Subchapter D Medicare Cost Plan Enrollment and Disenrollment Instructions*, Section 10.1)

VIII. 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. MMP enrollment transactions must be performed 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. MMP retroactive enrollment transactions must be performed per the three-way contract.

(42 C.F.R. §§ 422.66(b)(5) and 423.36(c); *Medicare Managed Care Manual Chapter 2 – Medicare Advantage Enrollment and Disenrollment*, Section 60.4; *Medicare Prescription Drug Benefit Manual Chapter 3 – Eligibility, Enrollment and Disenrollment*, Section 60.3)

IX. Late Enrollment Penalty (LEP) and Credible Coverage – Part D Sponsors (excludes MMPs)

- Charge the correct LEP for beneficiaries based on CMS LEP reports. 42 C.F.R. §§ 423.46(a) and (b)
    - 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 - Creditable Coverage Period Determinations and the Late Enrollment Penalty*, Sections 40, 50, 60, 70; HMPS memo 01/10/2018)

K. Benefits Administration and Beneficiary Protections

I. Benefits and Beneficiary Protections – Applicable organization types noted below

- 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 https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/MarketngModelsStandardDocumentsandEducationalMaterial. (Exclude MMPs and dual-eligible enrollees in MA plans per 42 C.F.R. § 422.111(k)(5)))
- Part D sponsors, as specified in 42 C.F.R. § 423.128(e), must furnish claims information (Part D Explanation of Benefits (EOB)) directly to enrollees in a form easily understandable when prescription drug benefits are provided under qualified prescription drug coverage. Part D sponsors implement systems and processes necessary to provide for the generation of Part D EOBs for all plan members. EOB templates and instructions are available at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Part-D-Model-Materials.
- Ensure on an ongoing basis that MA and MMP provider networks meet network adequacy requirements. (42 C.F.R. §§ 422.112(a)(1) and 422.116; *Medicare Advantage and Section 1876 Cost Plan Network Adequacy Guidance*, available at https://www.cms.gov/medicare/medicare-advantage/medicareadvantageapps?redirect=/medicareadvantageapps/, and *Health Service Delivery (HSD) Instructions for Medicare-Medicaid Plans (MMPs) Annual Medicare Network Submission* available at https://www.cms.gov/Medicare-Medicaid-

Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/MMPInformationandGuidance/MMPApplicationandAnnualRequirements)

- Part D sponsors must ensure that each plan provides convenient access to network pharmacies consistent with the standards found at 42 C.F.R. § 423.120(a)(1). Quarterly access reports for retail pharmacy networks as well as preferred cost-sharing pharmacy networks are available in HPMS.
- 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. (42 C.F.R. §§ 422.101(e)(1) and 422.214, *Medicare Managed Care Manual Chapter 4 - Benefits and Beneficiary Protections*, Section 10.2)

II. Billing and Anti-Discrimination Requirements Applicable to Dually Eligible Enrollees – Medicare Advantage Organizations

- Adopt measures to protect dually 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 Parts A and B services from individuals enrolled in the Qualified Medicare Beneficiary Program (QMB) program, a dually eligible program which exempts individuals from Medicare cost-sharing liability. (42 C.F.R. § 422.504(g)(1)(iii); *Calendar Year (CY) 2019 and 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter*)
- 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 the zero-dollar Medicare cost-sharing amounts for dually eligible enrollees only apply to Parts A and B services. LIS copayments still apply for Part D benefits. Note: For Part D, some MMPs are required in their three-way contracts to have zero-dollar cost-sharing amounts, and some MMPs choose to have zero-dollar cost-sharing amounts even when not required to do so. (Calendar Year (CY) 2019 and 2020 *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. MAOs 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, Chapter 4 – Benefits and Beneficiary Protections*, Section 10.5.2)

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

- Sponsors should be familiar with their responsibilities to participate under the CGDP. (42 C.F.R. § 423.2300)
- Sponsors should be prepared to repay manufacturers for negative invoice amounts caused by PDE adjustments. Such amounts are included in quarterly invoices and should be paid to manufacturers via the CGDP portal within 38 calendar days of invoice receipt. (HPMS memoranda 01/22/2014 and 03/25/2015)
- The CGDP portal is accessed from the TPAdministrator.com website (http://www.tpadministrator.com) via the following links:
    - On the Home page: CGDP Portal graphic link or the "CGDP Portal" link located on the Topics link.
    - On the Archives page: CGDP Portal graphic link.
- Sponsor CGDP Onboarding Training can be accessed from the TPAdministrator.com website (http://www.tpadministrator.com) under the Topics link for Training, then under Onboarding.
- Sponsor CGDP Portal User Guides can be accessed from the TPAdministrator.com website (https://www.tpadministrator.com/) under the Topics link for References, then under the CGDP Sponsor Portal Users Guides.
- 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. 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. Also validate any debit blocks and velocity filters which may be in place.
- To access the Bank Account Change forms, sponsors can select the Payee/Payer Bank Account Change Form link on the TPAdministrator.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 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 complies with policies governing midyear formulary changes, including the provision of notice to beneficiaries and other entities outlined in 42 C.F.R. § 423.120(b)(5). (*Medicare Prescription Drug Benefit Manual Chapter 6 – Part D Drugs and Formulary requirements*, Section 30.3). For instance, for the 2024 formulary:
    - Part D sponsors may immediately substitute new generic drugs provided they meet all requirements under 42 C.F.R. § 423.120(b)(5)(iv), including providing advance general notice to affected beneficiaries about any specific changes made.
    - Permitted midyear formulary changes requiring advance direct notice require 30 days' notice, or at the time the beneficiaries request a refill, notice of the change and an approved month's supply.
- 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 42 C.F.R. §§ 423.120(b)(1)(i) through (iv) have been met, including the determination by an objective party of whether the disclosed financial interests are conflicts of interest and the management of any recusals due to any conflicts.

V. Mail-Order and Auto-Ship (Automatic Delivery) Programs – Part D Sponsors (Excludes PACE)

- CMS expects Part D sponsors to work with their mail-order pharmacies to develop and implement protocols for providing access to urgently needed medications. Further, beneficiaries should be informed of their options when requesting a rush order, with clear steps detailed in all applicable beneficiary materials. (*Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter*)
- If permitting network pharmacies to offer a voluntary, opt-in auto-ship program for new prescriptions or refills of established therapies, ensure your organization follows the mail-order auto-ship guidance described in the 2020 Final Call Letter:
    - Permit enrollees to opt-out of the auto-ship program at any time.
    - An auto-ship program needs to receive consent from the enrollee after an initial fill of a new drug to activate auto-ship for any subsequent refills of that drug (consent to auto-ship a specific drug may not be assumed or activated at the same time as an initial fill).
    - Pharmacy requires enrollees to opt-in to auto-ship refills on a drug-by-drug basis.
    - For refills, the enrollee is to receive a minimum of two shipping reminder, to include all relevant information, including the name of the drug, applicable cost-

sharing amount or information on how to determine the amount prior to shipping, scheduled shipping date or date range, and how to cancel the order prior to shipping.

- We expect sponsors offering such programs to have a full refund policy whereby they require the pharmacy to return any cost-sharing paid by the enrollee (and delete the claim, and the sponsor deletes the PDE) for any auto-shipped prescriptions that an enrollee reports as unneeded or otherwise unwanted, regardless of whether the drug is returned by the enrollee (or representative).
- Promptly discontinue automatic deliveries after information becomes available from CMS, the beneficiary, their provider, or an authorized representative that the beneficiary has entered a skilled nursing facility or elected hospice coverage.

HPMS memos dated 12/12/2013, 03/21/2014, and 09/22/2014; and CY 2014, 2016, and 2020 Medicare Advantage Capitation Rates and Medicare Advantageand Part D Payment Policies and Final Call Letter

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 CCIP Resource Document*, available at https://www.cms.gov/Medicare/Health-Plans/Medicare-Advantage-Quality-Improvement-Program/Overview)

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

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

- In order to establish the correct premium, cost sharing, and deductible levels with the correct effective dates for current, prior, and prospective enrollees, Part D sponsors should refer to the Weekly/Monthly Transaction Reply Report (TRR). Part D sponsors will receive data indicating new or modified LIS eligibility status for former, current, and prospective members of their Part D plan via the weekly TRR. (*Medicare Prescription Drug Benefit Manual Chapter 13 – Premium and Cost-Sharing Subsidies for Low-Income Individuals*, Section 70.1)
- 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 the 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 - Premium and Cost-Sharing Subsidies for Low-Income Individuals*, Section 70.3.1 and 42 C.F.R. §§ 423.466, 423.800)

- Refer to *Medicare Prescription Drug Benefit Manual Chapter 13 - Premium and Cost-Sharing Subsidies for Low-Income Individuals* for the CMS requirements for accepting specific forms of BAE to establish a more favorable low-income copayment status of a full benefit dually eligible beneficiary and beneficiaries who applied to the SSA for the LIS.
- Refer to the *Medicare Prescription Drug Benefit Manual Chapter 13 - Premium and Cost-Sharing Subsidies for Low-Income Individuals* for the CMS requirements for accepting specific forms of BAE to establish a more favorable low-income copayment status of a full benefit dually eligible beneficiary, beneficiaries who applied to the SSA for the LIS.
- Provide beneficiaries access to 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 BAE 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 – Premium and Cost-Sharing Subsidies for Low-Income Individuals*, Section 70.5)
- Follow CMS' process for assisting beneficiaries without BAE documentation as outlined in *Medicare Prescription Drug Benefit Manual Chapter 13 – Premium and Cost-Sharing Subsidies for Low-Income Individuals*, Section 70.5. When assisting beneficiaries with securing BAE, please refer to the process outlined in the HPMS memo 02/17/2017.

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), sponsors must set their systems to charge the correct premium, deductible, and copayments. CMS expects sponsors to notify these beneficiaries that they will lose this extra help and to provide information about changes in their plan benefits as a result of this loss. The only exception to this requirement is for those beneficiaries whom the sponsor confirms are awaiting a Social Security Administration (SSA) determination on an LIS application and have been granted a grace period by the sponsor. In these situations, sponsors should wait until they receive the result of the SSA determination to update their systems. (HPMS memo 11/30/2009)
- Sponsors should make reasonable attempts to notify affected members within 30 days of notification to advise them of their retroactive liability for higher premiums and cost-sharing, when LIS eligibility is removed. (*Medicare Prescription Drug Benefit Manual*

Chapter 13 – Premium and Cost-Sharing Subsidies for Low-Income Individuals, Section 70.2)
HPMS memos 11/30/2009, 08/12/2014, 09/10/2015, and 07/20/2016

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

- Ensure your organization follows the CMS guidance for re-determination of Part D LIS eligibility for 2024. (HPMS memo 06/22/2022)
- Take appropriate actions in response to CMS deeming. (HPMS memo 06/22/2022)

M. Coordination of Benefits (COB) and True Out-of-Pocket (TrOOP) Cost Accumulation

I. COB Requirements – Part D Sponsors

- Sponsors must be able to receive and process coordination of benefits-other health insurance (COB-OHI) files to ensure appropriate prescription drug claim payment. Sponsors must be able to submit updated 4Rx and OHI information to CMS. (*Medicare Prescription Drug Benefit Manual Chapter 14 – Coordination of Benefits*, Section 50; *Medicare Advantage Prescription Drug (MAPD) Plan Communications User Guide*, Section 3.7 available at https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/mapdhelpdesk/Plan_Communications_User_Guide)
- Sponsors must be prepared to coordinate benefits with other payers of prescription drugs consistent with requirements described in 42 C.F.R. Part 423 Subpart J and *Medicare Prescription Drug Benefit Manual Chapter 14 – Coordination of Benefits.*

II. Automated TrOOP balance transfer (ATBT) Process – Part D Sponsors

- Sponsors must ensure that their 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 07/02/2015)
- Refer to Prescription Drug Benefit Manual *Chapter 14 – Coordination of Benefits,* Section 50.13 for guidance on updating your organization's Business Associate Agreement with the Part D Transaction Facilitator to reflect all upcoming contracts.

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

- As outlined in the HPMS memo dated 07/18/2014 (and updated in the HPMS memo dated 11/15/2016), organizations are strongly encouraged to implement the beneficiary-level Prior Authorization (PA) requirements for beneficiaries in hospice for the categories of prescription drugs: analgesics, antinauseants (antiemetics), laxatives, and antianxiety drugs (anxiolytics).

- 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 03/24/2015)
- In accordance with the HPMS email dated 01/26/2018, 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)

IV. End-Stage Renal Disease (ESRD) - Part D Sponsors (Applicable to MMPs only if this population is eligible for continued enrollment under your demonstration)

- Sponsors should not pay for drugs and biological products 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 42 C.F.R. Part 413).
- 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 05/12/2015)
    - 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 05/12/2015 and 11/14/2014)
    - Use sponsor-specific reporting provided through the Additional Beneficiary Information Initiatives (ABII) portal to coordinate benefits for enrollees identified as having at least one dialysis date of service in the reporting period.

V. Drugs Available Under Part A or Part B – Medicare Advantage Organizations and Part D Sponsors

- MAOs 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))
- CMS maintains the Additional Beneficiary Information Initiatives (ABII) web portal, in addition to the MARx system, to improve the coordination of benefits process by providing Part D plans with additional information about their enrollees for the

purposes of determining payment under Part B or Part D. We strongly encourage Part D sponsors to ensure access to the ABII web portal and maintain an updated list of individuals authorized to access the data. (HPMS memos 08/14/2018, 04/01/2019, 11/25/2019, 07/08/2020)

VI. Transition Requirements – Part D Sponsors

- Part D sponsors should re-review the guidance in Chapter 6 of the Medicare Prescription Drug Benefit Manual related to the transition requirements at 42 C.F.R. § 423.120(b)(3) in preparation for each new contract year. These requirements are especially important at the start of a contract year when a plan receives the most new enrollees and/or the plan's formulary changes. As a best practice, CMS also recommends that sponsors fully test how their transition policy works within their claims adjudication systems, including pharmacy notification, in order to ensure that the transition policy has been programmed correctly into systems prior to the start of the contract year.
- Ensure that your organization's transition policy is inclusive of an Implementation Statement, addresses each Transition Attestation and accurately reflects the requirements as outlined in 42 C.F.R. § 423.120 (b)(3)(iii). The transition fill days' supply is at least 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 C.F.R. § 423.120 (b)(3) and applicable MMP three-way contracts. (*Medicare Prescription Drug Benefit Manual Chapter 6 – Part D Drugs and Formulary requirements*, Section 30.4, and HPMS memos 08/19/2016 and 08/26/2016)

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

I. Timeframes for Adjudicating Part B Drug Requests – Medicare Advantage Organizations

- Pursuant to CMS-4180-F, there are shorter adjudication timeframes for Part B drug requests than the timeframes that apply to requests for medical items and services. MAOs must adjudicate requests in accordance with the rules at 42 C.F.R. §§ 422.568, 422.570, 422.572, 422.584, 422.590 (and §§ 422.631 and 422.633 for Applicable Integrated Plans) and effectuate favorable decisions in accordance with the rules at §§ 422.618 and 422.619.

II. Staffing Requirements Related to Initial Coverage/Organization Determinations 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 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(a)(4) and 423.562(a)(5)). 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. § 423.566(d)) If an MA organization expects to issue a partially or fully adverse medical necessity decision, the organization determination must be reviewed by a physician or other appropriate health care professional with expertise in the field of medicine or health care that is appropriate for the services at issue, including knowledge of Medicare coverage criteria. (42 CFR § 422.566(d))
- 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(h) and 423.590(f)).

- Applicable Integrated Plans must be staffed to meet the following requirements regarding integrated organization determinations and integrated reconsiderations:
  - If the Applicable Integrated Plan expects to issue a partially or fully adverse medical necessity (or any substantively equivalent term used to describe the concept of medical necessity) decision based on the initial review of the request, the integrated organization determination or integrated reconsideration must be reviewed by a physician or other appropriate health care professional. Any physician or other health care professional who reviews an integrated organization determination must have:
    - A current and unrestricted license to practice within the scope of his or her profession. (42 C.F.R. § 422.629(k)(3))
    - Sufficient medical and other expertise, including knowledge of Medicare and Medicaid coverage criteria before the applicable integrated plan issues the integrated organization determination. (42 C.F.R. § 422.629(k)(3))
    - Individuals making an integrated reconsideration must not be individuals who were involved in any previous level of review or decision-making nor a subordinate of any such individual. (42 C.F.R. § 422.629(k)(4))

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, 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 determination requests and appeals. (42 C.F.R. §§ 422.566(a) and (d), 423.566(a) and (d))

IV. Online Appeals Training Courses – Medicare Advantage Organizations and Part D Sponsors

- An organization's Medicare Compliance Officer (MCO); staff involved with initial coverage/organization determinations, 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/Medicare/Appeals-and-Grievances/MMCAG/Training. CMS strongly suggests that MCOs incorporate these courses into their existing in-house training and use the certificate to track coursecompletion within the organization. All Part D procedures and most Part C procedures apply to Applicable Integrated Plans.

V. Rights of Medicare Parts C & D Enrollees – Medicare Advantage Organizations including Applicable Integrated Plans and Part D Sponsors

- Enrollees of MAOs and Part D sponsors have the right to have a grievance heard and resolved, the right to a timely organization/coverage determination and the right to appeal. 42 C.F.R. §§ 422.562(b), 423.562(b)
- 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. 42 C.F.R. § 423.128(b)(7)(i) and (ii)

VI. Continuation of Benefits While an Appeal is Pending – Applicable Integrated Plans and MMPs Only

- Applicable Integrated Plans and MMPs must provide ongoing Medicare and Medicaid services if a member files a timely appeal requesting continuation of benefits of previously approved services. (42 C.F.R. § 422.632 for Applicable Integrated Plans and relevant sections of the three-way contract for MMPs)
- To ensure that enrollees have the opportunity to file a timely appeal and continue these services without interruption, these plans must provide enrollees with notice at least 10 days in advance of the effective date for any termination, reduction, or suspension of previously approved services. (42 C.F.R. § 422.631(d)(2)(i) for Applicable Integrated Plans and relevant sections of the three-way contract for MMPs)

O. Compliance Programs

I. Medicare Advantage Organizations and Part D Sponsors

- MAOs and Part D sponsors must adopt and implement an effective compliance program which must include measures to prevent, detect, and correct non-compliance with CMS' program requirements as well as measures that prevent, detect and correct fraud, waste, and abuse. (42 C.F.R. §§ 422. 503(b)(4)(vi) and 423.504(b)(4)(vi))
- CMS strongly recommends all MAOs and Part D sponsors routinely review and share throughout the organization information from the CMS Part C and Part D Compliance and Audits webpage and memoranda from the HPMS. The webpage (https://www.cms.gov/medicare/compliance-and-audits/part-c-and-part-d-compliance-and-audits) provides:
    - Materials CMS uses to conduct program audits.
    - Part C and Part D Program Audit and Enforcement Reports.
    - Information pertaining to compliance and enforcement actions.

P. Public Health Emergencies and States of Disaster

I. Medicare Advantage Organizations and Part D Sponsors

- Carefully review updated information on emergencies at https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Current-Emergencies/Current-Emergencies-page.
- Encourage members to maintain routine care via all applicable means including telehealth visits.

Q. Utilization Management Committee

I. Medicare Advantage Organizations and Part D Sponsors

- MAOs that use utilization management policies and procedures, including prior authorization, must establish a Utilization Management Committee that is led by a plan's medical director.
- The Utilization Management Committee must meet all the requirements established at § 422.137, including requirements for committee composition and responsibility.
- Beginning January 1, 2024, an MA plan may not use any utilization management policies for basic or supplemental benefits unless those policies and procedures have been reviewed and approved by the Utilization Management Committee.