

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid  
Services  
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**DATE:** October 30, 2024

**TO:** All Medicare Advantage Organizations, Prescription Drug Plan Sponsors, 1876 Cost Plans, Medicare-Medicaid Plans, and Programs for All Inclusive Care for the Elderly

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**SUBJECT:** Contract Year 2025 Readiness Checklist for Medicare Advantage Organizations, Prescription Drug Plan Sponsors, 1876 Cost Plans, Medicare-Medicaid Plans, and Programs for All Inclusive Care for the Elderly

The Centers for Medicare & Medicaid Services (CMS) reminds organizations of critical Medicare Part C and D readiness items for coverage beginning January 1, 2025.

The Contract Year (CY) 2025 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, Medicare-Medicaid Plans (MMPs), and PACE. CMS recommends that organizations review this checklist and take the necessary steps to fulfill requirements for CY 2025. 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.

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.

**CY 2025 Medicare Advantage Organization, Prescription Drug Plan, Cost Plan, and Medicare-Medicaid Plan Readiness Checklist**

- For purposes of the MMPs, references to the account managers are the equivalent of references to the Contract Management Team (CMT).
- PACE organizations should also review requirements found at 42 C.F.R. 460.

**CY 2025 Medicare Advantage Organization, Prescription Drug Plan, Cost Plan, and Medicare-Medicaid Plan Readiness Checklist**

<b>A.</b>	<b>Inflation Reduction Act (IRA)</b> .....	<b>4</b>
<b>B.</b>	<b>Health Equity</b> .....	<b>5</b>
<b>C.</b>	<b>User Group Calls</b> .....	<b>6</b>
<b>D.</b>	<b>Access to Services and Information</b> .....	<b>6</b>
<b>E.</b>	<b>Individuals with Disabilities – Auxiliary Aids (“Accessible Formats”) and Use of TTY Numbers</b> .....	<b>8</b>
<b>F.</b>	<b>Precluded Providers and Prescribers</b> .....	<b>8</b>
<b>G.</b>	<b>Systems, Data, &amp; Connectivity</b> .....	<b>9</b>
<b>H.</b>	<b>Reporting</b> .....	<b>17</b>
<b>I.</b>	<b>Contracting, Subcontractor Provisions, and Oversight</b> .....	<b>19</b>
<b>J.</b>	<b>Customer Service</b> .....	<b>21</b>
<b>K.</b>	<b>Communications Consistent with C.F.R. Parts 422 and 423, Subparts V</b> .....	<b>22</b>
<b>L.</b>	<b>Enrollment/Disenrollment</b> .....	<b>24</b>
<b>M.</b>	<b>Benefits Administration and Beneficiary Protections</b> .....	<b>28</b>
<b>N.</b>	<b>Failure to Collect and Incorrect Collections of Premiums and Cost Sharing</b> .....	<b>34</b>
<b>O.</b>	<b>Low Income Subsidy (LIS) and Best Available Evidence (BAE)</b> .....	<b>34</b>
<b>P.</b>	<b>Coordination of Benefits (COB) and True Out-of-Pocket (TrOOP) Cost Accumulation</b> .....	<b>36</b>
<b>Q.</b>	<b>Grievances, Initial Coverage/Organization Decisions, and Appeals</b> .....	<b>39</b>
<b>R.</b>	<b>Compliance Programs</b> .....	<b>41</b>
<b>S.</b>	<b>Public Health Emergencies and Disaster Declarations</b> .....	<b>41</b>
<b>T.</b>	<b>Utilization Management Committee</b> .....	<b>42</b>

## CY 2025 Medicare Advantage Organization, Prescription Drug Plan, Cost Plan, and Medicare-Medicaid Plan Readiness Checklist

### A. Inflation Reduction Act (IRA)

- CMS first calls your attention to the Inflation Reduction Act of 2022 (IRA, P.L. 117-169), signed into law August 16, 2022. The IRA makes significant changes to the Medicare Part D program, many of which take effect in CY 2025, including:
- Section 11201 – Medicare Part D Benefit Redesign, which includes reducing the annual out of pocket cap to \$2,000 for 2025, eliminating the coverage gap phase of the benefit, and sunsetting the Coverage Gap Discount Program (CGDP), which is replaced by the Manufacturer Discount Program (MDP) beginning January 1, 2025. The redesign also involves changes to the liability of enrollees, Part D sponsors, manufacturers, and CMS. Other Part D program changes that have been made in the context of the Part D benefit design include:
  - Costs counted toward true out-of-pocket costs (TrOOP)
  - Policy for drugs not subject to the defined standard deductible
  - Definition of enhanced alternative (EA) benefit design
  - EGWP prospective reinsurance amount
- Section 11202 – Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans and MA-PD Plans, which requires each PDP sponsor offering a prescription drug plan and each MA organization offering an MA-PD plan to provide enrollees with the option to pay cost sharing under the plan in monthly amounts. CMS named this program the Medicare Prescription Payment Plan.
- To aid plans with the implementation of IRA provisions CMS has issued a number of important Health Plan Management System (HPMS) memos that Part D sponsors should carefully review, as applicable, in preparation for the 2025 plan year, including the following:
  - November 17, 2023 HPMS memo titled *Medicare Part D Manufacturer Discount Program Final Guidance*
  - January 26, 2024, HPMS memo titled *PACE Participation in the Manufacturer Discount Program beginning January 1, 2025*
  - February 29, 2024, HPMS memo titled *Medicare Prescription Payment Plan: Final Part One Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Response to Relevant Comments*
  - March 8, 2024, HPMS memo titled *2025 Prescription Drug Event (PDE) File Layout Updates for all Part D Plan Sponsors, and Additional 2025 Changes to PDE Reporting for PACE Organizations*
  - April 1, 2024 *Calendar Year (CY) 2025 Rate Announcement*
  - April 1, 2024 *Final Part D Redesign Program Instructions*
  - April 15, 2024, HPMS memo titled *Prescription Drug Event Record Reporting Instructions for the Implementation of the Inflation Reduction Act for Contract Year 2025*

## CY 2025 Medicare Advantage Organization, Prescription Drug Plan, Cost Plan, and Medicare-Medicaid Plan Readiness Checklist

- April 19, 2024 HPMS memo titled *Medicare Part D Manufacturer Discount Program: Frequently Asked Questions*
- April 25, 2024, HPMS memo titled *Technical Memorandum on the Changes to True Out-of-Pocket (TrOOP) Costs and the Calculation of the Maximum Monthly Cap for the Medicare Prescription Payment Plan*
- May 3, 2024, HPMS memo titled *2025 Prescription Drug Event (PDE) Record Reporting Instructions for PACE Organizations*
- May 20, 2024, HPMS memo titled *Correction - VBI Model Prescription Drug Event (PDE) Reporting Guidance for CY 2025*
- June 17, 2024, HPMS memo titled *Clarification of True Out-of-Pocket Costs for Calendar Year 2025*
- July 16, 2024, HPMS memo titled *Medicare Prescription Payment Plan: Final Part Two Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Response to Relevant Comments*
- August 5, 2024, HPMS memo titled *Update: Clarification of True Out-of-Pocket (TrOOP) Costs for Calendar Year 2025*
- September 6, 2024 HPMS memo titled *Medicare Part D Manufacturer Discount Program: Important Updates and Upcoming Deadlines* and September 17, 2024 HPMS email with the subject *Medicare Part D Manufacturer Discount Program: Important Updates and Upcoming Deadlines - CORRECTION*
- September 13, 2024 HPMS email with subject line *Medicare Prescription Payment Plan Public-Facing Resources*
- September 13, 2024 HPMS memo titled *Reporting Routing Values for the Medicare Prescription Payment Plan*
- September 19, 2024 HPMS memo titled *Release of Manufacturer Discount Program Quarterly Invoice File Layouts and 2025 Updates to Coverage Gap Discount Program Quarterly Invoice and Dispute File Layout*
- October 1, 2024 HPMS memo titled *Frequently Asked Questions Related to the Medicare Prescription Payment Plan*
- Additional guidance implementing the IRA will be released on a rolling basis and HPMS should be reviewed regularly. CMS will continue to conduct monthly Part C & D User Group Calls to provide updates on the implementation of the IRA.  
<https://www.mscginc.com/registration/>. Please see the October 7, 2022 HPMS memo titled *Part C&D User Group Calls – Inflation Reduction Act of 2022 (IRA) Implementation*.

### B. Health Equity

- In alignment with the goals of various equity-focused Presidential Executive

## CY 2025 Medicare Advantage Organization, Prescription Drug Plan, Cost Plan, and Medicare-Medicaid Plan Readiness Checklist

Orders,<sup>1</sup> we encourage organizations to contact the CMS Office of Minority Health (CMS OMH) Health Equity Technical Assistance Program ([HealthEquityTA@cms.hhs.gov](mailto: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.
  - 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>.

### C. User Group Calls

- Ensure key staff register for the CMS Part C & D User Calls at <https://www.mscginc.com/registration/>.

### D. 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 12/01/2023)

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<sup>1</sup> Equity-focused presidential Executive Orders include (but are not limited to): [Executive Order 13166](#), [Executive Order 13985](#), and [Executive Order 14091](#). **Error! Hyperlink reference not valid.**

## CY 2025 Medicare Advantage Organization, Prescription Drug Plan, Cost Plan, and Medicare-Medicaid Plan Readiness Checklist

- 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 (SNP) enrollees. (42 C.F.R. §§ 422.2267(a)(3) and 423.2267(a)(3)). Specifically:
  - Fully integrated dual special needs plans (FIDE SNPs) or highly integrated dual eligible special needs plan (HIDE SNPs), as defined at § 422.2, or applicable integrated plans, 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) 2025 model materials into Spanish and Chinese. (HPMS memo 10/28/2024)
  - 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 09/2/2024)
  - 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>
  - Improving Access to Care for People with Disabilities <https://www.cms.gov/priorities/health-equity/minority-health/resource-center/health-care-professionals-researchers/improving-access-care-people-disabilities>.
- 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 2025 State-specific Marketing Guidance for MMPs.

**CY 2025 Medicare Advantage Organization, Prescription Drug Plan, Cost Plan, and Medicare-Medicaid Plan Readiness Checklist**

**E. 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)

**F. 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 memos 11/02/2018, 12/14/2018, 01/09/2019, 08/12/2019, 12/08/2020, and FAQs 12/16/2020;

## CY 2025 Medicare Advantage Organization, Prescription Drug Plan, Cost Plan, and Medicare-Medicaid Plan Readiness Checklist

<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/Preclusion-List>.

### G. 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](mailto:hpms_access@cms.hhs.gov). (HPMS memo 06/10/2024)
- Update your organization’s contract-level contact information in HPMS and ensure that your organization has a process in place to update this information throughout the year. It is critical to enter and update contract-level contact information as it is used for multiple purposes within HPMS and other systems, as well as to support publicly displayed information. 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 do not result in unexpected errors. Some examples include:
  - Claims systems changes that lead to inaccurate provider claims.
  - Configuration system errors that result in failures to send required notices to enrollees, such as Explanation of Benefits (EOBs) .
  - File transfer issues with print vendors that result in failures to send enrollee 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 (Excludes MMPs)

- 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 a plan’s External Point of Contact (EPOC). (HPMS memo 10/11/2024)

## CY 2025 Medicare Advantage Organization, Prescription Drug Plan, Cost Plan, and Medicare-Medicaid Plan Readiness Checklist

- 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. (*IDM 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/files/document/plan-communications-user-guide-june-28-2024-version-179.pdf>)
- 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 2025 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 2025 are included in the submission. Incorrect data may result in suppression from the MPF and/or applicable compliance actions. (HPMS memo 06/07/2024)
    - 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 05/31/2024)
  - 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 because of inaccurate data submissions.
    - If your organization receives an outlier notification for your 2025 drug pricing and pharmacy network data which was previously a known exception in 2024,

## CY 2025 Medicare Advantage Organization, Prescription Drug Plan, Cost Plan, and Medicare-Medicaid Plan Readiness Checklist

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 06/07/2024)

### 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 monitor performance.
- 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](https://PartD.ProgramInfo.us/User_Security). (HPMS memo 04/24/2024)

### 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

## CY 2025 Medicare Advantage Organization, Prescription Drug Plan, Cost Plan, and Medicare-Medicaid Plan Readiness Checklist

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](https://PartD.ProgramInfo.us/User_Security) under Help Documents.
  - DMP program guidance, FAQs, and other documents are available on the CMS Part D Overutilization webpage at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization>.

### 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 for initial opioid prescriptions.
  - 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 2025 opioid safety edits may be revised by sending an email to [PartD\\_OM@cms.hhs.gov](mailto:PartD_OM@cms.hhs.gov) with the

## CY 2025 Medicare Advantage Organization, Prescription Drug Plan, Cost Plan, and Medicare-Medicaid Plan Readiness Checklist

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 memos 10/23/2018, 12/19/2022, and 07/05/2024, and Frequently Asked Questions about Formulary-Level Opioid Point-of-Sale Safety Edits guidance posted on the CMS Part D Overutilization webpage at <https://www.cms.gov/Medicare/Prescription-Drug-coverage/PrescriptionDrugCovContra/RxUtilization>.

### VIII. Data Submission to the Encounter Data System (EDS) and the Risk Adjustment Processing System (RAPS) – Medicare Advantage Organizations and PACE

- 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.
- The requirements for data submission at 42 C.F.R. § 422.310 also apply to supplemental benefits. MA organizations should review and familiarize themselves with the requirements related to reporting of supplemental services. The February 21, 2024, HPMS memo “Submission of Supplemental Benefits Data on Medicare Advantage Encounter Data Records” and associated technical instructions provided submitting organizations with details on how to successfully submit encounter data records (EDRs) for supplemental services. Supplemental dental services can be submitted starting in September 2024 and CMS is releasing guidance and technical instructions for the submission of this new data format. (see the August 22, 2024, HPMS memo “Submission of Supplemental Benefits Data on Medicare Advantage Encounter Data Records – Dental Services Submission Instructions and Other Supplemental Service Updates”). Starting in 2024, CMS requires MA organizations to:
  - Report supplemental services submitted on an 837I or 837P with specific paperwork (PWK) segment identifiers.
  - Report supplemental dental services using the 837D format. (Plans should note that 837D submissions do not require the use of specific PWK segment identifiers.)
- Information about becoming certified to submit data, guidance regarding data submission to CMS, and other resources can be found on the Customer Service Support Center (CSSC) website, <https://www.csscooperations.com/>.

## CY 2025 Medicare Advantage Organization, Prescription Drug Plan, Cost Plan, and Medicare-Medicaid Plan Readiness Checklist

- Starting with 2021 dates of service, MA organizations are not required to submit data to RAPS. However, RAPS will remain available to MA organizations for submitting corrections to data from prior payment years.
- RAPS data will be included in the calculation of risk scores for PACE organizations for CY 2025. However, as noted in the January 29, 2024 HPMS memo titled “PACE Organization Risk Adjustment Submissions to the Encounter Data System,” PACE organizations should be transitioning their submission of data to the EDS rather than RAPS.
- Register for Risk Adjustment for EDS and RAPS User Groups announced via HPMS memo.
- Assistance with data submission can be obtained by emailing [csscooperations@palmettogba.com](mailto:csscooperations@palmettogba.com), or by calling 1-877-534-2772.
- Activities checklist for encounter and risk adjustment data submission includes:
  - 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 memos 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](mailto: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 memos (dated 10/24/2013 and 8/10/2016), relevant provisions of the three-way contract, guidance found on the CSSC website at <https://www.csscooperations.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/plans/mmp-quality-withhold-methodology-technical-notes>

## CY 2025 Medicare Advantage Organization, Prescription Drug Plan, Cost Plan, and Medicare-Medicaid Plan Readiness Checklist

### 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.csscooperations.com/Error!> **Hyperlink reference not valid.**, as well as memos available on HPMS. Assistance with data submission can be obtained by emailing [csscooperations@palmettogba.com](mailto:csscooperations@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 began on July 1, 2024 for non-PACE Part D sponsors and on September 1, 2024 for PACE organizations. (HPMS memos 4/18/2023, 5/10/2024, 6/28/2024)
- Beginning with PDEs for dates of service on or after January 1, 2025, PACE organizations must populate additional PDE fields that have not been populated by PACE organizations in past years. PACE organizations must submit this information in order to participate in the Manufacturer Discount Program created by section 11201(c) of the Inflation Reduction Act of 2022, and to conform with regulatory provisions and oversight activities, including the regulatory requirement to account for the maximum pharmacy price concession in the negotiated price. (HPMS memo 3/8/2024)
- Establish access to the Part D Payment Process Support Website and PDE Reports Portals. (HPMS memo 09/19/2019 and 4/26/2024).
- 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.
  - Submit adjustments and deletions following discovery of issue requiring change. (HPMS memo 10/06/2011)
- 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.

## CY 2025 Medicare Advantage Organization, Prescription Drug Plan, Cost Plan, and Medicare-Medicaid Plan Readiness Checklist

- Coverage Gap Invoice Report.
  - Manufacturer Discount Program Invoice Reports. (See generally, HPMS memo 11/17/2023)
  - Part D Potential Exclusion Warning Report and Part D Exclusion from Reconciliation Report. (HPMS memo 12/20/2019)
  - Payment Reconciliation System (PRS) reports. (HPMS memos 06/23/2017 and 04/30/2019)
  - Submit PDE records consistent with the reporting instructions for the implementation of the IRA for contract year 2025. (HPMS memos 4/15/2024 and 5/3/2024)
  - 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 03/14/2024)
    - 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 02/16/2024)
    - 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 03/14/2024)
  - 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

## CY 2025 Medicare Advantage Organization, Prescription Drug Plan, Cost Plan, and Medicare-Medicaid Plan Readiness Checklist

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.

### H. 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 05/06/2024)
  - Prepare to sign up for the 2025 HOS or HOS-M if the MAO is planning on sponsoring a fully integrated dual eligible special needs plan (FIDE SNP) in 2026 in order to be considered for 2026 frailty payment.
- 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 06/24/2024)
  - 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](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/PartCDDDataValidation>. 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 cannot also serve as your data validation contractor for any given reporting period. Management consultation activities include performing mock audits, preassessments, and any other

## CY 2025 Medicare Advantage Organization, Prescription Drug Plan, Cost Plan, and Medicare-Medicaid Plan Readiness Checklist

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/plans/mmp-reporting-requirements>)

### 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/plans/mmp-quality-withhold-methodology-technical-notes>)

### 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.
- Refer to the HPMS memos below:
  - Risk Adjustment Related Overpayments:
    - April 15, 2022, HPMS memo titled *Reminder of Existing Obligation to Submit Accurate Risk Adjustment Data*
    - March 15, 2024, HPMS memo titled *Support for Use of Encounter Data in Overpayment Reruns*
    - May 21, 2024, HPMS memo titled *Follow Up to May 1, 2024 “Use of Encounter Data in Overpayment Reruns” User Group for All Organizations Who Submit Risk Adjustment Data*
  - PDE/DIR Related Overpayments:
    - April 6, 2018 HPMS memo titled *Reopening Process and Updates to the PDE/DIR-related Overpayment Reporting*. See also, 89 FR 30448, 30460 (April 23, 2024)

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

- MAOs and Part D sponsors are required to submit independently audited annual financial statements, and quarterly financial statements for 2025. The *Fiscal Soundness Reporting Requirements* (FSRR), relevant HPMS memos, and other important information are available at: <https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/FSRR>.

## CY 2025 Medicare Advantage Organization, Prescription Drug Plan, Cost Plan, and Medicare-Medicaid Plan Readiness Checklist

### 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.

### I. Contracting, Subcontractor Provisions, and Oversight

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

- To comply with the AWP 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 memos 07/23/2007, 09/20/2007, and 08/26/2008)
- Offshore subcontractor is defined as a first tier/downstream/related entity located outside of the one of the 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.

## CY 2025 Medicare Advantage Organization, Prescription Drug Plan, Cost Plan, and Medicare-Medicaid Plan Readiness Checklist

- 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.
- For 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.
  - 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, 2025. (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 must:
  - Implement the integrated appeals and grievances procedures set forth at 42 C.F.R. §§ 422.629-634 (see further discussion in Section O, below).
  - Use the integrated coverage decision letter (Form CMS-10716) (and may use available models for expedited grievances and appeal 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.
- MAOs are notified that CMS will be conducting outreach regarding CY 2024 D-SNP EACs. This research will cover: the number of D-SNP enrollees attending EAC meetings, topics discussed, challenges in maintaining an EAC, requests for technical assistance, etc. MAOs with D-SNPs will be asked to identify any key EAC changes for CY 2025

## CY 2025 Medicare Advantage Organization, Prescription Drug Plan, Cost Plan, and Medicare-Medicaid Plan Readiness Checklist

### J. Customer Service

- I. Customer Service Call Center Operations – Medicare Advantage Organizations, Part D Sponsors, and MMPs
  - 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 12/01/2023. 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 12/01/2023.
- 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) and applicable final regulations published in the Federal Register, including the final rule (89 FR 30448) issued on April 4, 2024 (<https://www.federalregister.gov/public-inspection/2024-07105/medicareprogram-medicare-advantage-and-the-medicare-prescription-drug-benefit-program-for-contract>).
  - 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), (iii), and (iv). The 2025 MTM program annual cost threshold is \$1,623.
  - 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 05/06/2024 for CY 2025 Medication Therapy Management Program Guidance and Submission Instructions; 42 C.F.R. §§ 423.153(d), 423.2265(b)(13), and 422.111(j).

## CY 2025 Medicare Advantage Organization, Prescription Drug Plan, Cost Plan, and Medicare-Medicaid Plan Readiness Checklist

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

- Resolve Complaints Tracking Module (CTM) complaints designated as “immediate need” within two calendar days of the assignment date, complaints designated as “urgent” within seven days, and complaints designated without an issue level within 30 calendar days. MAOs and Part D sponsors are required to attempt contact with the complainant within seven calendar days of the organization being assigned the complaint in the CTM. (42 C.F.R. § 422.125(b) and 423.129(b))
- 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 memos 05/10/2019, 08/04/2020, 03/21/2022, 9/1/2023, 10/2/2023, and 7/17/2024)

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

- Marketing<sup>2</sup> 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, Part D Sponsors, and MMPs

- Ensure your organization is using the updated CY 2025 required materials on the Marketing Models, Standard Documents, and Educational Material and Part D Model Materials websites. All required materials 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>. (42 C.F.R. §§ 422.2267 and 423.2267, HPMS memo 06/12/2024)
- For MMPs specifically: Ensure your organization is using the updated state-specific CY 2025 model materials. These model materials are posted at: <https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination->

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<sup>2</sup> Regulations at 42 CFR §§ 422.2260 and 423.2260 define marketing communication materials and activities according to intent and content standards.

**CY 2025 Medicare Advantage Organization, Prescription Drug Plan, Cost Plan, and Medicare-Medicaid Plan Readiness Checklist**

[Office/FinancialAlignmentInitiative/MMPInformationandGuidance/MMPMarketingInformationandResources.](#) (Includes HPMS memos 08/29/2024 and 09/03/2024)

- 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))
  - 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))
  - Websites must reflect the most current information within 30 days of any material change. (42 C.F.R. §§ 422.2265(a) and 423.2265(a))
  - The SB, Annual Notice of Change (for renewing plans), 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 your organization’s 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.
  - Provider and Pharmacy Directories are expected to be accurate, in PDF or a printable directory format, searchable by every element required in the model directory, updated within 30 calendar days of receipt of updated or corrected information from the provider/pharmacy, and contain all required data elements (including each provider’s cultural and linguistic capabilities). (42 C.F.R. §§ 422.111(b)(3)(i), 422.111(h)(2)(ii), 423.128(b)(5), 423.128(d)(2)(i), 422.2265(b)(3)-(5), 423.2265(b)(3)-(4), 422.2267(e)(11)(iv)(A), and 423.2267(e)(15)(iv)(A) and the State-specific Marketing Guidance for MMPs)

## CY 2025 Medicare Advantage Organization, Prescription Drug Plan, Cost Plan, and Medicare-Medicaid Plan Readiness Checklist

- MAOs, PDPs, and third-party websites that are used to market their plan products are expected to meet applicable 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 memos 06/28/2024 and 07/18/2024)
- 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).

## L. Enrollment/Disenrollment

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

- 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 4, 2024. Enrollment requests received after December 7, 2024 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 enrollment requests received after the December 7 deadline.

## CY 2025 Medicare Advantage Organization, Prescription Drug Plan, Cost Plan, and Medicare-Medicaid Plan Readiness Checklist

- 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 Advantage and Part D Enrollment and Disenrollment Guidance*, Section 60.2.1.2)
  - 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 Advantage and Part D Enrollment and Disenrollment Guidance*, Section 70.3.5) (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 based on 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) 422.62(d)(1), 422.68(c), and 423.38(c)(26); *Medicare Advantage and Part D Enrollment and Disenrollment Guidance*, Section 30.4)
- III. [Electronic Enrollment Mechanisms - Medicare Advantage Organizations and Part D Sponsors \(Excludes MMPs and PACE\)](#)
- Electronic enrollment mechanisms via a third-party website or non-plan owned electronic device, mechanism, or software are permitted.
  - 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.

## CY 2025 Medicare Advantage Organization, Prescription Drug Plan, Cost Plan, and Medicare-Medicaid Plan Readiness Checklist

- 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 their 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.
- Organizations must notify CMS in a timely manner when security and/or privacy breaches occur.

*Medicare Advantage and Part D Enrollment and Disenrollment Guidance, 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, and PACE)

- 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 Medicaid or LIS eligibility.
  - Full-benefit dual eligible individuals making a one-time-per month election into a fully integrated dual eligible (FIDE) SNP, a highly integrated dual eligible (HIDE) SNP, or an applicable integrated plan (AIP) to facilitate aligned enrollment with a Medicaid managed care organization.
  - Full-benefit dual eligible individuals, partial-benefit dual eligible individuals and other low-income subsidy (LIS) eligible individuals are eligible for a SEP to enroll once per month into a standalone prescription drug plan. This SEP can also be used once per month to switch between standalone prescription drug plans. This SEP does not permit enrollment into MA-PD plans or changes between MA-PD plans.
  - 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, they cannot use the dual/LIS SEP to change plans for as long as they are a potential at-risk or at-risk beneficiary.

*(42 C.F.R. §§ 422.62(b) and 423.38(c); Medicare Advantage and Part D Enrollment and Disenrollment Guidance, Section 30.6)*

## CY 2025 Medicare Advantage Organization, Prescription Drug Plan, Cost Plan, and Medicare-Medicaid Plan Readiness Checklist

- V. [SEP for Enrollments into a 5-Star Plan - Medicare Advantage Organizations and Part D Sponsors \(Excludes MMPs and PACE\)](#)
- Beneficiaries may enroll in a plan awarded an overall 5-star rating for 2025, provided the beneficiary is otherwise eligible for that plan. An individual may use this SEP only one time between December 8, 2024, and November 30, 2025. 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 Advantage and Part D Enrollment and Disenrollment Guidance*, Section 30.6.22)
- VI. [Online Enrollment Center \(OEC\) – Medicare Advantage Organizations and Part D Sponsors \(Excluding MSA, 800-Series-Only, MMPs, and PACE; Optional for SNPs, RFB, and 1876 Cost Plans; Required for PDPs and MA-PDs\)](#)
- 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 2024 and 2025 OEC transactions in separate files, which will be distinguishable by the contract year in the file name. Organizations should ensure both contract years 2024 and 2025 enrollment files are promptly processed. (*Medicare Advantage and Part D Enrollment and Disenrollment Guidance*, Section 40.1.3, and HPMS memo 09/18/2024)
  - Ensure your organization’s ability to conform to and accept the OEC record layout. (HPMS memos 07/17/2024 and 08/28/2024)
    - 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 09/18/2024; *Medicare Advantage and Part D Enrollment and Disenrollment Guidance*, Section 40.1.3; *Medicare Managed Care Manual Chapter 17, Subchapter D Medicare Cost Plan Enrollment and Disenrollment Instructions*, Section 10.1)
- VII. [Retroactive Enrollments – Medicare Advantage Organizations and Part D Sponsors](#)
- Submit enrollments and disenrollments directly to MARx following the “Current Calendar Month” cycle. Organizations can submit enrollments and disenrollments for the current calendar month and for the calendar month prior to the current calendar month, using the User Interface (UI) or in batch submissions. Enrollment into, or disenrollment from, EGWP plans may be submitted via the UI or in batch for the current calendar month minus three months. MMP enrollment transactions must be performed per the three-way contract.

## CY 2025 Medicare Advantage Organization, Prescription Drug Plan, Cost Plan, and Medicare-Medicaid Plan Readiness Checklist

- Prepare systems and processes to support the submission of retroactive enrollment and disenrollment corrections that cannot be accomplished within the Current Calendar Month cycle to the retroactive processing contractor (Reed & Associates). These requests must be made appropriately and timely. For more information, please visit [www.reedassociates.org](http://www.reedassociates.org). 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 Advantage and Part D Enrollment and Disenrollment Guidance*, Section 70.4)

### VIII. 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 20, 60, 70, 80; HPMS memos 01/10/2018 and 08/05/2024)

Note: Beneficiaries with LIS status are not subject to an LEP. *Ibid.* section 30.1.4.

## M. 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>. (Excludes 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 a written EOB directly to enrollees when prescription drug benefits are provided under qualified prescription drug coverage. EOB templates and instructions are available at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Part-D-Model-Materials>. (HPMS memos 05/23/24, 08/22/24)
- 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->

## CY 2025 Medicare Advantage Organization, Prescription Drug Plan, Cost Plan, and Medicare-Medicaid Plan Readiness Checklist

[advantage/medicareadvantageapps?redirect=/medicareadvantageapps/](https://www.cms.gov/medicare/medicare-advantage/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

## CY 2025 Medicare Advantage Organization, Prescription Drug Plan, Cost Plan, and Medicare-Medicaid Plan Readiness Checklist

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

- Section 11201 of the IRA sunsets the Coverage Gap Discount Program and terminates all Coverage Gap Discount Program agreements effective January 1, 2025. Coverage Gap Discount Program agreement responsibilities and duties continue to apply to applicable drugs dispensed prior to January 1, 2025. (42 C.F.R. § 423.2300)
- Section 11201 Section 11201 of the IRA also creates the Manufacturer Discount Program (Discount Program), under which participating manufacturers are required to provide discounts on their applicable drugs in the Initial Coverage and Catastrophic Coverage phases of the Part D benefit, beginning January 1, 2025.
- Sponsors should be familiar with their responsibilities under the Manufacturer Discount Program, including requirements related to discount phase-ins for certain applicable drugs of Specified Manufacturers and Specified Small Manufacturers. (Final Guidance HPMS memorandum 11/17/2023; Frequently Asked Questions (FAQs) HPMS memos 04/19/2024 and 9/06/2024)
- Manufacturer Discount Program Final Guidance, Frequently Asked Questions, Phase-In Eligible National Drug Code 9 (NDC-9) List, Participating Labeler Codes, and other Discount Program information are available on the Part D Information for Pharmaceutical Manufacturers page. (<https://www.cms.gov/medicare/coverage/prescription-drug-coverage/part-d-information-pharmaceutical-manufacturers>)
- The Third Party Administrator (TPA) portal for the Manufacturer Discount Program and Coverage Gap Discount Program is accessed from the TPA's website. (<http://www.tpadministrator.com>). Sponsors should complete the Bank Account Change Form on the TPA website if there have been any changes to the accounts used for sending or receiving payments. Sponsors should also validate any debit blocks and velocity filters which may be in place.
- Sponsors should ensure that your organization's contact information is current and accurate in HPMS ([hpms.cms.gov](http://hpms.cms.gov)).

### 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

## CY 2025 Medicare Advantage Organization, Prescription Drug Plan, Cost Plan, and Medicare-Medicaid Plan Readiness Checklist

42 C.F.R. § 423.120(f). (*Medicare Prescription Drug Benefit Manual Chapter 6 – Part D Drugs and Formulary requirements*, Section 30.3). For instance, for the 2025 formulary:

- Part D sponsors may make immediate substitutions—such as substituting a new generic drug for a brand name drug and/or a new interchangeable biosimilar for a reference product--provided they meet all requirements. These include 42 C.F.R. § 423.120(e)(2)(i) and 42 C.F.R. 423.120(f)(3) and providing advance general notice to current and prospective enrollees that such changes may be made, as required under 42 C.F.R. 423.120(f)(2).
- Permitted midyear formulary changes requiring advance direct notice require 30 days' notice, or when an enrollee requests 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 comply with the processes and requirements under 42 C.F.R. §§ 423.120(b)(1)(i) through (xi).

### 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 reminders: 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.

## CY 2025 Medicare Advantage Organization, Prescription Drug Plan, Cost Plan, and Medicare-Medicaid Plan Readiness Checklist

- 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 Advantage and 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>)

### VII. Medicare Prescription Payment Plan – Part D Sponsors

- Part D sponsors should be familiar with their responsibility to offer all Part D enrollees, including those who receive the low-income subsidy, the option to pay their OOP prescription drug costs in monthly amounts over the course of the plan year and pay \$0 at the point of sale starting January 1, 2025 and meet the requirements outlined in the final part one guidance (available at: <https://www.cms.gov/files/document/medicare-prescription-payment-plan-final-part-one-guidance.pdf>) and final part two guidance (available at: <https://www.cms.gov/files/document/medicare-prescription-payment-plan-final-part-two-guidance.pdf>).
  - CMS does not expect Part D plans that exclusively charge \$0 cost sharing for covered Part D drugs to all plan enrollees to offer enrollees the Medicare Prescription Payment Plan or otherwise comply with the final part one guidance or the final part two guidance. If a Part D plan has any enrollees that could pay any cost sharing, even a nominal amount, under the Part D plan at any point during the year, then the plan must comply with the final part one and final part two guidance.
- Part D sponsors must allow Part D enrollees to elect into the program prior to the plan year (beginning at the start of the AEP) and at any point during the plan year. Part D sponsors must consider Medicare Prescription Payment Plan election requests,

## **CY 2025 Medicare Advantage Organization, Prescription Drug Plan, Cost Plan, and Medicare-Medicaid Plan Readiness Checklist**

regardless of the election mechanism, and process the request within 10 calendar days (if received prior to plan year) or 24 hours (if received during the plan year). Part D sponsors must also have a process to allow a participant who has opted into the program to opt out at any point during the plan year.

- Part D sponsors should be familiar with the requirements related to education, outreach, and communications outlined in the final part one and final part two guidance and be prepared to provide the Medicare Prescription Payment Plan Likely to Benefit Notice to identified enrollees (as outlined in section 30.2.2.1 of the final part two guidance) no later than the end of the AEP for CY 2025 (December 7, 2024).
  - CMS provided final CY 2025 model and standardized documents for the Medicare Prescription Payment Plan to support Part D sponsors in meeting their education, outreach, and communications requirements. See the Medicare Advantage and Prescription Drug Programs: Part C and Part D Medicare Prescription Payment Plan Model Documents (CMS-10882; OMB 0938-New) Information Collection Request (ICR) package for more information.
  - CMS also provided a Medicare Prescription Payment Plan fact sheet and other public-facing resources related to the Medicare Prescription Payment Plan to Part D sponsors on July 12, 2024 and to all interested parties on September 9, 2024. Part D sponsors may use the language and examples in the CMS-developed materials to begin crafting their own educational materials, such as call center scripts, FAQs, and web content.
- Part D sponsors are required to have in place a mechanism to notify the pharmacy when a Part D enrollee who has not already opted into the Medicare Prescription Payment Plan incurs OOP costs with respect to a covered Part D drug that make it likely the Part D enrollee may benefit from the program. As outlined in the final part one guidance, for CY 2025, Part D sponsors must notify a pharmacy when a Part D enrollee incurs OOP costs for a single prescription that equal or exceed \$600.
- Part D sponsors are responsible for correctly calculating monthly caps on program payments based on the statutory formulas outlined in the final part one guidance, determining the amount to be billed (not to exceed the cap), and sending monthly bills to program participants. If an enrollee fails to pay the billed amount by the payment due date, the Part D sponsor must provide individuals with a grace period of at least two months.
- Part D sponsors must pay pharmacies for the final amount the Medicare Prescription Payment Plan participant would have otherwise paid at the point of sale and use an additional Bank Identification Number (BIN)/Processor Control Number (PCN) that is unique to the Medicare Prescription Payment Plan to facilitate electronic processing of supplemental COB transactions for program participants.

## CY 2025 Medicare Advantage Organization, Prescription Drug Plan, Cost Plan, and Medicare-Medicaid Plan Readiness Checklist

- Beginning in 2025, Part D sponsors must submit their Medicare Prescription Payment Plan-specific PCN and BIN data at the plan level through “Set Up Plans” in HPMS. (HPMS memo 09/13/2024)
- Part D sponsors are required to submit claim-level data to CMS through PDE reporting. Beginning in 2025, this includes an indicator for PDEs included in the Medicare Prescription Payment Plan. See the Collection of Prescription Drug Data from MA-PD, PDP and Fallout Plans/Sponsors for Medicare Part D Payments (CMS-10174; OMB: 0938-0982) and the PDE reporting instructions issued on April 15, 2024 in the HPMS memo titled, “Prescription Drug Even Record Reporting Instructions for the Implementation of the Inflation Reduction Act for Contract Year 2025,” for more information.
- Part D sponsors are required to submit beneficiary-level data about participation in the Medicare Prescription Payment Plan to CMS through MARx. See the MARx Medicare Prescription Payment Plan Beneficiary-Level Data Elements (CMS-10887; OMB 0938-1468) Information Collection Request (ICR) and the technical specifications issued on October 7, 2024, for more information.
- Part D sponsors are required to submit PBP-level data to CMS through HPMS. See the Medicare Part D Reporting Requirements (CMS-10185; OMB 0938-0992) ICR and the draft technical specifications issued on August 23, 2024, for more information.

### N. Failure to Collect and Incorrect Collections of Premiums and Cost Sharing

- Effective January 1, 2025, in accordance with 42 C.F.R. § 423.294, Part D sponsors must make a reasonable effort to:
  - Identify all premium and cost sharing amounts incorrectly collected and to pay any other amounts due during the timeframe for coordination of benefits as established at 42 C.F.R. § 423.466(b). A Part D sponsor must issue a refund for an identified enrollee overpayment within the timeframe specified at 42 C.F.R. § 423.466(a)
  - Attempt to collect cost sharing from a beneficiary or to bill cost sharing or premiums to another appropriate party for all amounts other than de minimis amounts (as determined for purposes of 42 C.F.R. § 423.34(c)(2)).

### O. 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

## CY 2025 Medicare Advantage Organization, Prescription Drug Plan, Cost Plan, and Medicare-Medicaid Plan Readiness Checklist

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.
- 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.

### 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 06/28/2024)

## CY 2025 Medicare Advantage Organization, Prescription Drug Plan, Cost Plan, and Medicare-Medicaid Plan Readiness Checklist

- 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)

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

- Ensure your organization follows the CMS guidance per the HPMS memo titled Redetermination of Part D Low-Income Subsidy Eligibility for 2025 issued on 06/28/2024.
- Take appropriate actions in response to CMS deeming. (HPMS memo 06/22/2022)

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

### I. Changes to TrOOP for 2025 – Part D Sponsors

- Sponsors should be aware of the changes to the costs counted toward TrOOP made by the IRA for 2025 and subsequent years. In addition to the third-party arrangements that already count toward TrOOP, the IRA specifically amends the definition of incurred costs that count toward TrOOP for CY 2025 to *include* payments for previously excluded supplemental benefits provided by Part D sponsors and EGWPs and *exclude* payments under the new Discount Program.
- Refer to the *Final 2025 Part D Redesign Program Instructions* for additional guidance.

### II. 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*, Sections 3.5 and 3.7 available at <https://www.cms.gov/data-research/cms-information-technology/access-cms-data-application/mapd-plan-communication-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*.
- Sponsors must prepare for changes in TrOOP eligibility for supplemental payers effective 1/1/25. (Final CY 2025 Part D Redesign Program Instructions and HPMS memo 8/5/24 “Update: Clarification of True Out-of-Pocket (TrOOP) Costs for Calendar Year 2025”)

## CY 2025 Medicare Advantage Organization, Prescription Drug Plan, Cost Plan, and Medicare-Medicaid Plan Readiness Checklist

- III. 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.
  - Sponsors must update their organization's ATBT contact information in HPMS and ensure that your organization has a process in place to maintain current contact information throughout the year. The ATBT contact is the person who the Part D Transaction Facilitator can contact for problem resolution.
- IV. 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 current. 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)
- V. 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)

## CY 2025 Medicare Advantage Organization, Prescription Drug Plan, Cost Plan, and Medicare-Medicaid Plan Readiness Checklist

- 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.

### VI. 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, and 11/14/2023)

### VII. Transition Requirements – Part D Sponsors

- Part D sponsors and applicable MMP contracts 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 newest 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, to ensure that the transition policy has been programmed correctly 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 as described in the annual Formulary Submission Module & Reports Technical Manual 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.

**CY 2025 Medicare Advantage Organization, Prescription Drug Plan, Cost Plan, and Medicare-Medicaid Plan Readiness Checklist**

**Q. 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:

## CY 2025 Medicare Advantage Organization, Prescription Drug Plan, Cost Plan, and Medicare-Medicaid Plan Readiness Checklist

- A current and unrestricted license to practice within the scope of [their] 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 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 MAOs incorporate these courses into their existing in-house training and use the certificate to track course completion 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

## CY 2025 Medicare Advantage Organization, Prescription Drug Plan, Cost Plan, and Medicare-Medicaid Plan Readiness Checklist

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 can 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)

## R. 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 that 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 memos 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.

## S. Public Health Emergencies and Disaster Declarations

### I. Medicare Advantage Organizations and Part D Sponsors

- Develop, maintain, and implement a business continuity plan containing policies and procedures to ensure the restoration of business operations following disruptions to business operations which would include natural or man-made disasters, system failures, emergencies, and other similar circumstances and the threat of such occurrences. MA organizations and Part D sponsors should review or update their business continuity plans to ensure that any necessary planning for business operations disruption due to a cybersecurity attack is included, and implement voluntary

## CY 2025 Medicare Advantage Organization, Prescription Drug Plan, Cost Plan, and Medicare-Medicaid Plan Readiness Checklist

cybersecurity practices to build resiliency. (42 C.F.R. §§ 422. 504(o)(1) and 423.505(p)(1), HPMS memo 03/06/2024, and [HHS Cybersecurity Performance Goals](#))

- 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.

### T. 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, responsibility, and the annual health equity analysis of the use of prior authorization.
- 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.