DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid
Services
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TO: All Medicare Advantage organizations, Medicare Advantage Prescription Drug Plans, Medicare Prescription Drug Plans, 1876 Cost Plans, and Programs for All Inclusive Care for the Elderly

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SUBJECT: Contract Year 2026 Readiness Checklist for Medicare Advantage Organizations, Prescription Drug Plan Sponsors, 1876 Cost 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, 2026.

The Contract Year (CY) 2026 Readiness Checklist is a tool for organizations to use in preparation for the upcoming year. It does not supersede requirements established in statutes or regulations as they relate to Medicare Advantage (MA) organizations, Medicare Advantage Prescription Drug Plans (MA-PD) plans, Medicare Prescription Drug Plans (PDPs), 1876 Cost Plans and Programs for All Inclusive Care for the Elderly (PACE). CMS recommends that organizations review this checklist and take the necessary steps to fulfill requirements for CY 2026. 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 the Appendix.

Notes:

- Unless otherwise indicated, items that apply to MA organizations also apply to 1876 Cost Plans. “Part D sponsors” refers to all organizations offering Part D prescription drug coverage.

- PACE organizations should also review requirements found at 42 C.F.R. 460 and additional resources at https://www.cms.gov/medicare/medicaid-coordination/pace
- MA organizations, Part D sponsors, and PACE plans should stay up to date on CMS guidance by reviewing HPMS memos regularly at https://hpms.cms.gov/app/ng/home/
- Medicare Managed Care Manual Chapters are found at https://www.cms.gov/regulations-and-guidance/guidance/manuals/internet-only-manuals-ioms-items/cms019326
- Prescription Drug Benefit Manual Chapters are found at https://www.cms.gov/medicare/coverage/prescription-drug-coverage-contracting/prescription-drug-benefit-manual

Center for Medicare CY 2026 Medicare Advantage Organization, Prescription Drug Plan, Cost Plan, and PACE Readiness Checklist

Center for Medicare CY 2026 Medicare Advantage Organization, Prescription Drug Plan, Cost Plan, and PACE Readiness Checklist

A. Inflation Reduction Act (IRA)

- The Inflation Reduction Act of 2022 (IRA, P.L. 117-169) was signed into law August 16, 2022. The IRA made significant changes to the Medicare Part D program, including:
    - Sections 11001 and 11002 - Medicare Drug Price Negotiation Program, which provides Medicare the ability to directly negotiate the prices of certain high expenditure, single source drugs and biological products. CMS selected ten drugs covered under Medicare Part D for the first cycle of negotiations that now have maximum fair prices (MFP), that will go into effect beginning January 1, 2026, based on negotiations and agreements reached between CMS and participating drug companies in 2024. Part D plan payment for a selected drug during its price applicability period must not exceed the applicable MFP, plus any dispensing fees.
    - Section 11201 – Medicare Part D Benefit Redesign, which includes reducing the annual out-of-pocket threshold to $2,000 in 2025 and adjusting it thereafter based on the annual percentage increase in average expenditures for covered Part D drugs in the U.S. for Part D eligible individuals in the previous year, eliminating the coverage gap phase of the benefit, sunsetting the Coverage Gap Discount Program, and replacing the Coverage Gap Discount Program with the Manufacturer Discount Program, which began on January 1, 2025. The redesign also involved 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
        - Establishment of the of the Selected Drug Subsidy
    - 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.
- CMS also issued several important Health Plan Management System (HPMS) memos related to IRA changes, including the following:
    - April 1, 2024, *Final CY 2025 Part D Redesign Program Instructions*
    - April 25, 2024, *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*
    - September 6, 2024, *Medicare Part D Manufacturer Discount Program: Frequently Asked Questions*

  - September 13, 2024, *Reporting Routing Values for the Medicare Prescription Payment Plan*
  - December 20, 2024, *Revised Medicare Part D Manufacturer Discount Program Final Guidance*
  - December 20, 2024*, Updates to the Drug Data Processing System (DDPS) Month End Reports*
  - January 10, 2025*, Calendar Year (CY) 2026 Advance Notice and Draft CY 2026 Part D Redesign Program Instructions*
  - January 14, 2025*, 2025 Prescription Drug Event Participant Guide*
  - January 17, 2025*, Prescription Drug Event (PDE) Analysis Website for CMS Data Quality Review Outliers, Withheld and Invoiced Outliers, and Reviews of Invoiced Data Disputed by Manufacturers*
  - April 7, 2025*, Calendar Year (CY) 2026 Rate Announcement and Final CY 2026 Part D Redesign Program Instructions*
  - April 15, 2025*, Prescription Drug Event Record Reporting Instructions for the Implementation of the Inflation Reduction Act for Contract Year 2026*
  - July 31, 2025*, Contract Year 2026 Technical Guidance and Prescription Drug Event Record Reporting Examples for D-SNPs utilizing State-Only Funded Wrap Coverage to Buy Down the Nominal LIS Copayment*
- Additional guidance implementing the IRA will be released on a rolling basis and HPMS should be reviewed regularly.

B. Access to Services and Information

I. MA Organizations and Part D Sponsors

- 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 12/05/24)
- 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) 2026 model materials into Spanish, Chinese, Korean and Vietnamese. (HPMS memo 09/30/2025)
  - 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.

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

I. MA 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.
- MA organizations 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)

D. Precluded Providers and Prescribers

I. MA Organizations and Part D Sponsors

- Provide beneficiary notices about precluded providers and prescribers.
- A MA organization 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; https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/Preclusion-List.

E. Systems, Data, & Connectivity

I. HPMS – MA Organizations and Part D Sponsors

- Ensure key staff members register for the Plan Connectivity Module within HPMS by e-mailing hpms_access@cms.hhs.gov. (HPMS memo 06/10/2025)
- 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, such as Part D payment reconciliation, 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 – MA 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 – MA Organizations and Part D Sponsors

- Have controls in place to ensure downloaded applications are processed in the plan's system and submitted to MARx timely.
- Review and implement guidance regarding software improvements to the enrollment and payment systems.
- Ensure familiarity with the requirements and processes that MA organizations and Part D sponsors 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 10/31/2025)
- 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*)

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 2026 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.
    - Confirm drug pricing and pharmacy network data files for MPF are complete, correct, and accurate, and that only pharmacies under contract for 2026 are included in the submission. Incorrect data may result in suppression from the MPF and/or applicable compliance actions. (HPMS memo 05/27/2025)
    - 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 05/27/2025)
- 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 2026 drug pricing and pharmacy network data which was previously a known exception in 2025, 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 05/27/2025)

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 (https://partd.programinfo.us/PatientSafety). 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. (HPMS memo 04/24/2025)

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, after case management and notification, to limit at-risk beneficiaries' access to coverage of frequently abused drugs (opioids and benzodiazepines) to a selected prescriber(s) and/or network pharmacy(ies) or implement beneficiary-specific claim edits for such drugs.
- Ensure your organization can effectively support the activities needed to have a DMP, including systems processes (e.g., MARx – See Section D.III.), required case management and beneficiary notices, call center scripts and triage processes for enrollees submitting information to the plan or requesting appeals, claims system edits to operationalize coverage limitations for frequently abused drugs, and outreach and education (e.g., communications to network prescribers and pharmacies).
- 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 *Medicare Advantage Prescription Drug (MAPD) Plan Communications User Guide available at* https://www.cms.gov/data-research/cms-information-technology/access-cms-data-application/mapd-plan-communication-user-guide)
- 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/PatientSafety 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 edits 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 2026 opioid safety edits may be revised by sending an email to PartD_OM@cms.hhs.gov with the subject line "Opioid Safety Edit Request to Revise – [applicable contract ID number(s)]." Include in the email the following information:
  - The contract ID(s) associated with the change.
  - The intended revisions to the opioid safety edit(s).
  - The proposed implementation date of the revision.
  - A justification for the mid-year change of the opioid safety edit.

  See 42 C.F.R. § 423.153(c)(2), Calendar Year (CY) 2018, 2019 and 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, HPMS memos 10/23/2018, 12/19/2022, and 07/03/202535, 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) – MA Organizations and PACE

- MA organization 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), and 422.310(g). Successful submission means that your file was sent, received, had all errors and rejections corrected, and was accepted by the system prior to the risk adjustment data submission deadline.
- MA organizations should reference the April 15, 2022 HPMS memo, *Reminder of Existing Obligation to Submit Accurate Risk Adjustment Data*, for information regarding the existing statutory, regulatory, and contractual obligations, including 42 CFR 422.503(b)(4)(vi) and 422.504(h), to submit accurate risk adjustment data, and correct their risk adjustment data based on their best knowledge, information, and belief.

- MA organizations are required to execute the annual risk adjustment data certification in the form provided in the regulations at 42 CFR 422.504(l) and in their contract with CMS. MA organizations cannot alter or caveat the certification in any way, including through separate communications with CMS.
- To receive proper payment, MA organizations must be certified to submit data through the EDS and, if applicable, RAPS.
- Information about becoming certified to submit data, guidance regarding data submission to CMS, and other resources can be found on the Customer Service Support Center (CSSC) website, https://www.csscoperations.com/. Payment year information regarding the risk adjustment data submission deadlines discussed in 422.310(g) are released annually via HPMS memo.
    - Risk adjustment data submitted after the deadline for an initial risk score run but prior to the deadline for the mid-year run will be included in the mid-year run. Risk adjustment data submitted after the deadline for a mid-year run but prior to the deadline for final reconciliation run will be included in the final reconciliation run.
    - It is important to note that while data must be updated and corrected by organizations before and after the final risk adjustment data submission deadline, CMS will not make additional payments for diagnoses received after the final risk adjustment data submission deadline (42 CFR 422.310(g)).
    - We strongly encourage organizations to submit their data throughout the data collection period and well in advance of the risk adjustment data submission deadlines to ensure ample time to resolve any data submission issues, such as validation errors, data rejections, or inaccuracies in submitted files by the relevant deadline (initial, mid-year, or final). We expect plans to take particular care before the final deadline, since per 422.310(g)(2), CMS does not include diagnoses submitted after this deadline, and will only process deletes submitted after this deadline, in later risk score runs.
- 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.
- For PACE organizations, both RAPS and encounter data will be included in the calculation of risk scores for CY 2026. As noted in the January 29, 2024 HPMS memo, *PACE Organization Risk Adjustment Submissions to the Encounter Data System*, PACE organizations should be transitioning their submission of data to EDS rather than RAPS. Once a PACE organization has fully transitioned to submitting data to EDS, they are no longer required to submit data to RAPS. However, RAPS will remain available for the correction of data for prior years.
- 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 provide submitting organizations with details on how to successfully submit encounter data records (EDRs) for supplemental services. Answers to frequently asked questions about submission of supplemental services can be found in the November 12, 2024, HPMS memo, *Submission of Supplemental Benefits Data on Medicare Advantage Encounter Data Records – Reminders, Other Supplemental Service Updates, and Frequently Asked Questions (FAQs)*. Supplemental dental services can be submitted starting in September 2024 and CMS released 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 and further clarified on August 15, 2025 " Medicare Advantage Encounter Data Dental Submissions Clarifications Update"*). 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 (NOTE: Plans should note that 837D submissions do not require the use of specific PWK segment identifiers.)
- Submitting organizations can register for the Risk Adjustment for EDS and RAPS User Group sessions announced via HPMS memo.
- Assistance with data submission can be obtained by emailing csscoperations@palmettogba.com, or by calling 1-877-534-2772.
- The 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 memos on risk adjustment and encounter data topics including:
    - Submission Requirement Updates.
    - Edit Changes.
    - Submission Deadlines.
  - Request access to the Risk Adjustment/Encounter Data Module in HPMS by contacting HPMS_Access@cms.hhs.gov to download reports designed to improve the completeness of encounter data reporting including:

- Encounter Data Report Cards: The report cards are intended to provide MA organizations with information on encounter data submissions in order to drive self-assessment and improvement by MA organizations. (HPMS memo 10/04/2019)
- Submission Performance Reports: The reports provide contract level performance measures and thresholds. (HPMS memo 08/20/2018)

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 CSSC website, https://www.csscoperations.com/, as well as memos available on HPMS. Assistance with data submission can be obtained by emailing csscoperations@palmettogba.com or by calling 1-877-534-2772.
- 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. (two HPMS memos released 01/17/2025).
- Submit initial PDE records for selected drugs (as described at section 1192(c) of the Social Security Act) within seven calendar days from the date the Part D sponsor (or its contracted first tier, downstream, or related entity) receives the claim. (42 C.F.R. § 423.325(b))
- Submit initial PDE records for non-selected drugs within 30 calendar days from the date the Part D sponsor (or its contracted first tier, downstream, or related entity) receives the claim. (42 C.F.R. § 423.325(a)(1))
- Submit adjustment or deletion PDE records within 90 calendar days of the Part D sponsor (or its contracted first tier, downstream, or related entity) discovering or receiving notification of an issue that requires a change to the previously submitted PDE record. (42 C.F.R. § 423.325(a)(2))

- Submit revised PDE records to resolve CMS rejected records within 90 calendar days of the rejection. (42 C.F.R. § 423.325(a)(3))
- Establish procedures for analyzing recurring reports to ensure that PDE data maintained by CMS, which serve as the basis for Part D payment reconciliation, align with the organization's internal records. CMS reports include the following:
    - Drug Data Processing System (DDPS) Cumulative Beneficiary Summary
    - P2P Accounting Report
    - P2P (Plan to Plan) Reports
    - Coverage Gap Invoice Report for years prior to 2025
    - Manufacturer Discount Program Invoice Reports (See generally, HPMS memo 1212/20/2024)
    - 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 2026.
    - Additional Guidance on the Impact of Supplemental Payments on Manufacturer Discount Program Calculations and True Out-of-Pocket (TrOOP) Cost Accumulation (HPMS memo 11/26/2024)
    - Prescription Drug Event Record Reporting Instructions for the Implementation of the Inflation Reduction Act for Contract Year 2026 (HPMS memo 4/15/2025)
    - Contract Year 2026 Technical Guidance and Prescription Drug Event Record Reporting Examples for D-SNPs utilizing State-Only Funded Wrap Coverage to Buy Down the Nominal LIS Copayment (HPMS memo 7/31/2025)
    - See also the 2025 Prescription Drug Event Participant Guide available on the Customer Service and Support Center (CSSC) Operations website (https://www.csscoperations.com/internet/csscw3.nsf/DID/BXZ6BMHXNL)
- 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 04/21/2025)
    - 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 04/21/2025)

  - Each year prior to the Part D payment reconciliation, Part D sponsors must certify their Part D cost data by electronically signing attestations in HPMS. (HPMS memo 8/29/2025)
- 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,* and *May 9, 2022 final rule (CMS 4192-F*)

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

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

F. Reporting

I. Healthcare Effectiveness Data and Information Set (HEDIS®), Health Outcomes Survey (HOS), and Consumer Assessment of Healthcare Providers and Systems (CAHPS®) – MA Organizations and Part D Sponsors

- Prepare to submit HEDIS®, HOS, and CAHPS® measures to the appropriate entity by the specified due date. (HPMS memo 06/09/2025)
- Prepare to sign up for the 2026 HOS or HOS-M if the MA organization is planning on sponsoring a fully integrated dual eligible special needs plan (FIDE SNP) in 2027 in order to be considered for 2027 frailty payment.

II. Part C and Part D Reporting Requirements - MA Organizations and Part D Sponsors

- MA organizations 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 (https://PartD.ProgramInfo.us/). (HPMS memo 06/24/2025)
- MA organizations and Part D sponsors must collect and report data in accordance with the applicable Part C and Part D Reporting Requirements; select a contractor to conduct

independent data validation; and submit information to CMS according to the requirements and established deadlines. (42 C.F.R. §§ 422.516(a) and (g); §§ 423.514(a) and (j), https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/ReportingRequirements; https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_ReportingOversight)

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

III. Reporting and Returning Sponsor Identified Overpayments – MA Organizations and Part D Sponsors

- Consistent with section 1128J(d) of the Social Security Act, 42 CFR §§ 422.326, and 423.360, every MA organization and Part D sponsor is required to report and return to CMS any overpayment it received no later than 60 days after the date on which the organization or sponsor identified the overpayment.
- Refer to the HPMS memos below:
    - Risk Adjustment Related Overpayments:
        - April 15, 2022, *Reminder of Existing Obligation to Submit Accurate Risk Adjustment Data*
        - March 15, 2024, *Support for Use of Encounter Data in Overpayment Reruns*
        - May 21, 2024, *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, *Reopening Process and Updates to the PDE/DIR-related Overpayment Reporting*. See also, 89 FR 30448, 30460 (April 23, 2024)
- For additional information regarding risk adjustment related overpayments, refer to the following resources:
    - "Use of Encounter Data in Overpayment Reruns User Group – May 1, 2024" slide deck on the CSSC Operations website

- "Risk Adjustment Overpayment Reporting Computer-Based Training" on the CSSC Operations website (https://csscoperations.com/)
- "Quick Reference Guide: Risk Adjustment Overpayment Reporting" on the Risk Adjustment Overpayment Reporting (RAOR) module in HPMS

IV. Fiscal Soundness – MA Organizations and Part D Sponsors

- MA organizations 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.

V. 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)(iii)(B)). 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. https://www.cms.gov/regulations-and-guidance/guidance/manuals/internet-only-manuals-ioms-items/cms019326

G. 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 – MA 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 – MA Organizations and Part D Sponsors

1. Notify your account manager at least 60 days prior to the effective date of a new contract.
2. 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.
3. 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. Enrollment in the Medicare Transaction Facilitator Data Module for the Medicare Drug Price Negotiation Program

- Effective January 1, 2026, pursuant to Medicare Transaction Facilitator requirements for network pharmacy agreements provision finalized in the April 4, 2025 final rule (CMS-4208-F), any contract between the sponsor and a pharmacy, or between a first tier, downstream, or related entity and a pharmacy on the sponsor's behalf, for participation in one or more of the Part D sponsor's networks must include a provision requiring the pharmacy to be enrolled in the Medicare Transaction Facilitator Data Module (MTF DM) (or any successor to the MTF DM) in a form and manner determined by CMS. (42 C.F.R. § 423.505(q))
- Such provision must also require the pharmacy to maintain and certify up-to-date, complete, and accurate enrollment information with the MTF DM, in accordance with applicable terms and conditions of participation with the MTF DM, including but not limited to contact, third-party support entity or entities, and banking information, in a form and manner determined by CMS. (42 C.F.R. § 423.505(q))

V. State Medicaid Agency Contracts – MA Organizations offering D-SNPs

- MA organizations 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, 2026. (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).

- MA organizations 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).
- MA organizations 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 underserved enrollee populations.

H. Customer Service

I. Customer Service Call Center Operations – MA Organizations, Part D Sponsors

- Ensure compliance with standards found at 42 C.F.R. §§ 422.111(h)(1) and 422.112(a)(8), 423.128(d)(1), and the call center monitoring HPMS memo dated 12/05/2024. 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.

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 12/05/2024.

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.
- 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 2026 MTM program annual cost threshold is $1,276.
- 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 05/06/2025 for CY 2026 Medication Therapy Management Program Guidance and Submission Instructions; 42 C.F.R. §§ 422.111(j), 423.153(d), and 423.2265(b)(13).

IV. Complaints Tracking Module - MA Organizations and Part D Sponsors

- Address and resolve the complaints received by CMS against them in the Complaints Tracking Module (CTM) (42 C.F.R. §§ 422.504(a)(15) and 423.505(b)(22)).
- Display a link to the Medicare.gov online complaint on the plan's main Web page. (42 C.F.R. §§ 422.2265(b)(8) and 423.2265(b)(8))
- Adhere to the timelines to resolve complaints. 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. MA organizations 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*, review all complaints at intake, including verifying the contract assignment and issue level. If necessary, submit any Plan Requests as soon as possible. (HPMS memos 08/04/2020, 03/21/2022, 9/1/2023, 10/2/2023, 07/17/2024, and 01/06/2025)

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

I. Required Materials – MA Organizations, Part D Sponsors

- Ensure your organization is using the updated CY 2026 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 06/16/2025, 07/28/25)

II. Referencing Star Ratings in Marketing Materials – MA Organizations and Part D Sponsors

- Provide the overall Star Ratings information to beneficiaries through the CMS standardized Star Ratings document, which must be provided to all prospective enrollees when an enrollment form is provided. For online enrollment, the Star Ratings 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 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 423.2263(c))
- MA organizations and Part D sponsors are not permitted to display or release their Star Ratings information until CMS releases the Star Ratings on Medicare Plan Finder. (42 C.F.R. §§ 422.2267(e)(13) and 423.2267(e)(17))
- MA organizations and Part D sponsors must clearly identify which contract year their Star Ratings reference. (42 C.F.R. §§ 422.2263(c) and 423.2263(c))

III. Websites – MA 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 Summary of Benefits, 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 (LIS) 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))
- 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, 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)
- MA organizations, Part D sponsors, 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). 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 - MA Organizations and Part D Sponsors

- Implement agent/broker compensation rates, submissions, and training and testing requirements. (HPMS memos 06/15/2025)

VI. Beneficiary Opioid Education – Part D Sponsors

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

J. Enrollment/Disenrollment

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

- The AEP period begins October 15 and ends on December 7. An AEP enrollment/disenrollment election type cannot be used after the end of the AEP. For enrollment requests received after December 7, 2025, beneficiaries must be eligible for a valid election period such as an Initial Election Period (IEP) or a Special Enrollment Period (SEP).
- Plans may submit enrollments that have a January 1, 2026, enrollment effective date no earlier than October 4, 2025.
- 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, https://www.cms.gov/medicare/enrollment-renewal/managed-care-eligibility-enrollment)
- 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, https://www.cms.gov/medicare/enrollment-renewal/managed-care-eligibility-enrollment
- 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.

II. MA Open Enrollment – MA 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, https://www.cms.gov/medicare/enrollment-renewal/managed-care-eligibility-enrollment)

III. Electronic Enrollment Mechanisms - MA Organizations and Part D Sponsors (Excludes 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.
- 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 – MA Organizations and Part D Sponsors (Excludes 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 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 monthly dual/LIS SEP to change Part D 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, https://www.cms.gov/medicare/enrollment-renewal/managed-care-eligibility-enrollment)

V. SEP for Enrollments into a 5-Star Plan - MA Organizations and Part D Sponsors (Excludes PACE)

- Beneficiaries may enroll in a plan awarded an overall 5-star rating for 2026, provided the beneficiary is otherwise eligible for that plan. An individual may use this SEP only one time between December 8, 2025, and November 30, 2026. 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, https://www.cms.gov/medicare/enrollment-renewal/managed-care-eligibility-enrollment)

VI. Online Enrollment Center (OEC) – MA Organizations and Part D Sponsors (Excluding MSA, 800-Series-Only, 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 regularly 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 2025 and 2026 OEC transactions in separate files, which will be

distinguishable by the contract year in the file name. Organizations should ensure both contract years 2025 and 2026 enrollment files are promptly processed. (*Medicare Advantage and Part D Enrollment and Disenrollment Guidance,* Section 40.1.3, and HPMS memo 08/01/2025)

- Ensure your organization's ability to conform to and accept the OEC record layout. (HPMS memos 7/11/2025, 09/05/2025, and 09/15/2025)
    - Have controls in place to ensure downloaded applications are appropriately processed in the plan's system and submitted to MARx timely.
    - The OEC uses Coordinated Universal Time (UTC) which is four hours earlier than Eastern Daylight Time. Calculate the application date on enrollments received via the OEC to be 11 hours earlier than the time and date CMS "stamps" on the request. Use the adjusted application date to determine eligibility for election periods and proper effective date for coverage. (HPMS memo 08/01/2025; *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, https://www.cms.gov/medicare/enrollment-renewal/managed-care-eligibility-enrollment)

VII. Retroactive Enrollments – MA 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. 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.

  (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

- 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. (*Chapter 4 - Creditable Coverage Period Determinations and the Late Enrollment Penalty Guidance*, Sections 20, 30.1.4

60, 70, 80, https://www.cms.gov/medicare/enrollment-renewal/part-d-plans/creditable-coverage-and-late-enrollment-penalty; HPMS memos 01/10/2018 and 08/05/2024, 7/22/2025)

Note: Beneficiaries with LIS status are not subject to an LEP.

K. Benefits Administration and Beneficiary Protections - Applicable organization types noted below

I. Explanation of Benefits

- MA organizations, as specified in 42 C.F.R. § 422.111(k), must 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 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 06/16/25 and 07/28/25)

II. Network Adequacy and Access

- Ensure on an ongoing basis that MA organization provider networks meet network adequacy requirements. (42 C.F.R. §§ 422.112(a)(1) and 422.116; *Medicare Advantage and Section 1876 Cost Plan Network Adequacy Guidance*, available at https://www.cms.gov/medicare/medicare-advantage/medicareadvantageapps?redirect=/medicareadvantageapps/)
- 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, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf)
- 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.

III. Billing and Anti-Discrimination Requirements Applicable to Dually Eligible Enrollees – MA Organizations

- Adopt measures to protect dually eligible enrollees from improper billing and educate network providers about applicable billing requirements. All MA organizations 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) Medicaid eligibility group, 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 at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf* and *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf*)

  For further information about plan obligations to protect members from improper billing, see 10/31/2024 HPMS memo titled *QMB_Billing_hpms_CLEAN.pdf* [QMB Billing HPMS Memo] at https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly/hpms-memos-wk-5-october-28-31.

- For PACE organizations specifically, all enrollees -- regardless of whether they have QMB status or not – have zero Medicare A/B coinsurance, copayments, and deductibles.
- To reinforce billing requirements, simplify compliance, and prevent improper billing, CMS strongly encourages organizations to affirmatively inform providers if member cost-sharing liability is zero. MA organizations can provide real-time information and indicators through automated eligibility-verification systems, online provider portals and phone query mechanisms and clearly indicate members owe $0 directly on the Explanations of Payment statements for providers and on member identification cards. For CMS resources available to plans to identify QMB status, see 10/31/2024 QMB Billing HPMS Memo. 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)

IV. Manufacturer Discount Program / Coverage Gap Discount Program – Part D Sponsors

- Section 11201 of the IRA sunset the Coverage Gap Discount Program and terminated 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 of the IRA also established the Manufacturer 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, that began on January 1, 2025.
- Part D 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. (Revised Final Guidance HPMS memo 12/20/2024; Frequently Asked Questions (FAQs) HPMS memo 09/06/2024)
- Manufacturer Discount Program Revised Final Guidance, Frequently Asked Questions, Phase-In Eligible National Drug Code 9 (NDC-9) List, Participating Labeler Codes, and other Manufacturer 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). Part D 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. Part D sponsors should also validate any debit blocks and velocity filters which may be in place.
- Part D sponsors should ensure that your organization's contact information is current and accurate in HPMS (hpms.cms.gov).

V. Selected Drug Subsidy Program – Part D Sponsors

- Section 11201 of the IRA added section 1860D-14D to the Act, creating a new selected drug subsidy program, which begins in CY 2026. Under the program, the Secretary must, periodically and on a timely basis, provide Part D plan sponsors with a subsidy for selected drugs equal to 10 percent of the drug's negotiated price. Sponsors should be familiar with the 2026 PDE reporting guidance including their responsibilities under the selected drug subsidy program. September 30, 2025, HPMS memo *Applicability of the Selected Drug Subsidy for Certain Claims for 2026* and April 15, 2025, HPMS memo *Prescription Drug Event Record Reporting Instructions for the Implementation of the Inflation Reduction Act for Contract Year 2026*)

VI. Formulary – Part D Sponsors

- Ensure that your organization complies with policies governing midyear formulary changes, including the provision of notice to beneficiaries and other entities outlined in 42 C.F.R. § 423.120(f). (*Medicare Prescription Drug Benefit Manual Chapter 6 – Part D Drugs and Formulary requirements*, Section 30.3) For instance, for the 2026 formulary:

  - Part D sponsors may make immediate substitutions—such as substituting a new generic drug for a brand name drug, a new interchangeable biosimilar for a reference product, and/or an unbranded biological product marketed under the same biologics license application (BLA) as a brand name biological 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).
- Medicare Part D plans must include each covered Part D drug that is a selected drug under section 1192 of the Social Security Act on their Part D formularies during CY 2026 if an MFP is in effect for that drug.
  - Part D plan sponsors may immediately substitute a selected drug that is a brand name drug with a generic drug of the brand name drug, and a selected drug that is a reference product with an interchangeable biological product of the reference product, provided such substitution is in accordance with 42 C.F.R. §§ 423.120(e)(2)(i) and 423.120(f)(2), (3), and (4), as implemented in the Final CY 2026 Part D Redesign Program Instructions.

VII. 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, https://www.cms.gov/medicare/health-plans/medicareadvtgspecratestats/downloads/advance2017.pdf*)
- 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.
- 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

VIII. Quality Improvement (QI) Program, Chronic Care Improvement Program (CCIP) – MA Organizations (Excludes non-network PFFS/MSA, Cost Plans, PACE)

- Ensure that your MA organization'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)

IX. 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. Part D sponsors must meet the requirements outlined at 42 C.F.R. § 423.137 and in all applicable guidance.
    - 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 requirements at 42 C.F.R. § 423.137 and all applicable 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 42 C.F.R. § 423.137 and all applicable 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, 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 and process voluntary termination requests within three calendar days.
- Beginning with the CY 2026 plan year, Part D sponsors are required to automatically renew Medicare Prescription Payment Plan participation for enrollees remaining in the same PBP in the upcoming year. Part D sponsors must send an automatic renewal notice to enrollees participating in the Medicare Prescription Payment Plan after the end of AEP but prior to the beginning of the plan year. These requirements, as outlined at 42 C.F.R. § 423.137, take effect for the CY 2026 plan year; Part D sponsors are required to automatically renew Medicare Prescription Payment Plan participation for enrollees participating in the program in 2025.
- Part D sponsors should be familiar with the requirements related to education, outreach, and communications outlined at 42 C.F.R. § 423.137 and in all applicable guidance and be prepared to provide the Medicare Prescription Payment Plan Likely to Benefit Notice to identified enrollees no later than the end of the AEP for CY 2026, December 7, 2025.
- CMS provided an update on the CY 2026 model and standardized documents (see September 30, 2025 HPMS message *Medicare Prescription Payment Plan: Update on 2026 Model Documents*) 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 0938-1475) Information Collection Request (ICR) package for more information.
    - CMS also released updated versions of the Medicare Prescription Payment Plan fact sheet and other public-facing resources related to the Medicare Prescription Payment Plan, which are available on Medicare.gov.
    - Part D sponsors may use the language and examples in the CMS-developed materials to craft 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 at 42 C.F.R. § 423.137 and in all

applicable guidance, for CY 2026, Part D sponsors must notify a pharmacy when a Part D enrollee incurs OOP costs for a single prescription that equals or exceeds $600.

- Part D sponsors are responsible for correctly calculating monthly caps on program payments based on the statutory formulas outlined at 42 C.F.R. § 423.137 and in all applicable 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.
- 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. Additional instructions were issued in the August 22, 2025, HPMS memo titled *Announcement of the MARx Software Release*.
- 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 Part D Reporting Requirements technical specifications for more information.

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

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

- In order to establish the correct premium, cost sharing, and deductible levels with the correct effective dates for current, prior, and prospective enrollees, Part D sponsors should refer to the Weekly/Monthly Transaction Reply Report (TRR). Part D sponsors will receive data indicating new or modified LIS eligibility status for former, current, and

prospective members of their Part D plan via the weekly TRR. (*Medicare Prescription Drug Benefit Manual Chapter 13 – Premium and Cost-Sharing Subsidies for Low-Income Individuals*, Section 70.1. https://www.cms.gov/medicare/coverage/prescription-drug-coverage-contracting/prescription-drug-benefit-manual)

- 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 LIS 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)

- Sponsors should make reasonable attempts to notify affected members within 30 days of CMS's notification of status changes to advise affected members 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 *LIS Redetermination of Part D Low-Income Subsidy Eligibility for 2026* issued on 06/23/2025.

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

I. Changes to TrOOP – 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 and subsequent years 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* and *Final 2026 Part D Redesign Program Instructions* for additional guidance. Refer to the *Final 2025 Part D Redesign Program Instructions* and *Final 2026 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 (https://www.cms.gov/medicare/coverage/prescription-drug-coverage-contracting/prescription-drug-benefit-manual).*

- Sponsors should refer to the *Final CY 2025 Part D Redesign Program Instructions* and *Final CY 2026 Part D Redesign Program Instructions* for guidance on incurred costs that count toward TrOOP.

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 (https://www.cms.gov/medicare/coverage/prescription-drug-coverage-contracting/prescription-drug-benefit-manual) 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

- Sponsors must ensure their 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. Refer to the HPMS email "Request for Updated Plan Contact Information for Hospice Coordinator" dated 01/26/2018 on the pathway for updating.
- Part D sponsors and hospice organizations are strongly encouraged to utilize the standard PA form from the HPMS Email re: *Request for Updated Plan Contact Information for Hospice Coordinator* dated 03/24/2015 to facilitate coordination between Part D sponsors, hospices, and prescribers who serve beneficiaries enrolled in hospice. It can be found at: https://www.cms.gov/medicare/payment/fee-for-service-providers/hospicehttps://www.cms.gov/medicare/payment/fee-for-service-providers/hospice
- 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) (see the HPMS memo *Update on Part D Payment Responsibility for Drugs for Beneficiaries Enrolled in Medicare* dated 11/15/2016).
- Part D sponsors and hospice organizations are encouraged to use the alternative Hospice N transaction method for receiving Notice of Election (NOE) information discussed in the HPMS Memo *Alternative Method for Part D Plan Sponsors to Receive Hospice Notice of Election (NOE) Information* dated 8/15/2025.

V. End-Stage Renal Disease (ESRD) - Part D Sponsors

- 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).
- Sponsors should review the HPMS memo titled *Clarification of Exclusion from Part D Payment for Drugs and Biological Products Included in the End-Stage Renal Disease Prospective Payment System* and dated July 14, 2025. This memo consolidated existing Part D ESRD guidance and clarified the payment determination questions about excluding Part D payment for drugs and biological products that are included in the ESRD PPS for Medicare beneficiaries with ESRD on renal dialysis.
    - Part D plan sponsors may either place prior authorization (PA) requirements on the identified categories of "always drugs" in Table 1 in the July 14, 2025 memorandum or should have other mechanisms in place to ensure payment under Part D is made only when appropriate.
    - With respect to the identified categories of "may be drugs" in Table 2 in the July 14, 2025 memorandum, sponsors are not expected to 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 drug or biological product has been inappropriately billed to Part D, the sponsor and the ESRD facility should negotiate repayment.
    - Sponsors should 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 – MA Organizations and Part D Sponsors

- MA organizations must coordinate all benefits administered by the plan, including drugs for which payment may be available under Part A or Part B. (42 C.F.R. § 422.112(b)(7))
- 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 memo 11/14/2024)

VII. Transition Requirements – Part D Sponsors

- Part D sponsors should re-review the guidance in Chapter 6 of the Medicare Prescription Drug Benefit Manual related to the transition requirements at 42 C.F.R. § 423.120(b)(3) in preparation for each new contract year. These requirements are especially important at the start of a contract year when a plan receives the 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.

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

I. Timeframes for Adjudicating Requests – MA Organizations and Part D Sponsors

- MA organizations 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. 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.
- Part D Sponsors must adjudicate requests in accordance with the rules at 42 C.F.R. §§ 423.568, 423.570, 423.572, 423.584, and 423.590 and effectuate favorable decisions in accordance with the rules at §§ 423.636 and 423.638.

II. Staffing Requirements Related to Initial Coverage/Organization Determinations and Appeals – MA Organizations and Part D Sponsors

- Organizations must employ a medical director who is responsible for the clinical accuracy of all initial coverage decisions/organization determinations 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 Part D Sponsor 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))

  - A person or persons who were not involved in making the organization determination must conduct the reconsideration/redetermination and when the initial determination was based on a lack of medical necessity, the reconsideration or redetermination must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue. (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 decision based on medical necessity (or any substantively equivalent term used to describe the concept of medical necessity) on the initial review of the request, the integrated organization determination or integrated reconsideration must be reviewed by a physician or other appropriate health care professional. Any physician or other health care professional who reviews an integrated organization determination must have:
    - A current and unrestricted license to practice within the scope of [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 – MA 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), and 423.566(a) and (d))

IV. Online Appeals Training Courses – MA 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 MA organizations 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 – MA Organizations including Applicable Integrated Plans and Part D Sponsors

- Enrollees of MA organizations 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) and 423.562(b)
- Part D sponsors must ensure that their organization provides immediate access to the coverage determination and redetermination processes via a toll-free telephone number and website and provides access to model forms for making coverage and appeal requests. 42 C.F.R. § 423.128(b)(7)(i) and (ii)

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

- Applicable Integrated Plans 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)
- 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)

O. Compliance Programs

I. MA Organizations and Part D Sponsors

- MA organizations 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 MA organizations and Part D sponsors routinely review and share information throughout the organization from the CMS Part C and Part D Compliance and Audits webpage and HPMS memos. 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.

- Materials regarding the Annual Part C Utilization Management ("UM") data submission, which will begin in 2026.
- Part C and Part D Program Audit and Enforcement Reports.
- Information pertaining to compliance and enforcement actions.

P. Public Health Emergencies and Disaster Declarations

I. MA 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 cybersecurity practices to build resiliency. (42 C.F.R. §§ 422. 504(o)(1) and 423.505(p)(1), HPMS memo *Addressing Impacts Related to the Cyberattack on Change* Healthcare dated 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.

Q. Utilization Management Committee

I. MA Organizations

- MA organizations 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 42 C.F.R. § 422.137, including requirements for committee composition, responsibility, and the use of prior authorization.
- Note that CMS has suspended enforcement of requirements at 42 C.F.R §§ 422.137(c)(5), and 422.137 (d)(6) and (7) until further notice.
- 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.