



DATE: February 1, 2024

TO: All Prescription Drug Plans, Medicare Advantage-Prescription Drug Plans,
Section 1876 Cost Plans, Medicare-Medicaid Plans, and PACE plans

FROM: Vanessa S. Duran
Acting Director, Medicare Drug Benefit and C & D Data Group

SUBJECT: Contract Year (CY) 2025 Final Part D Bidding Instructions

The purpose of this memorandum is to provide Part D sponsors with instructions as they prepare to submit bids for CY 2025. This memorandum includes annual programmatic updates and serves to supplement the forthcoming Final CY 2025 Part D Redesign Program Instructions document¹ which will include program instructions for 2025 for the implementation of provisions enacted in the Inflation Reduction Act (IRA, P.L. [117-169](#)), on August 16, 2022.

Implementation of Part D IRA Provisions

In order to implement applicable Part D provisions of the IRA, CMS has previously issued program instruction via the Health Plan Management System (HPMS) for both CY 2023 and CY 2024. Except as updated for CY 2025 in the forthcoming Final CY 2025 Part D Redesign Program Instructions, the previous instructions set forth still apply:

- [CY 2023 Program Guidance Related to Inflation Reduction Act Changes to Part D Coverage of Vaccines and Insulin](#)
- [REVISION – Contract Year 2023 Program Guidance Related to Inflation Reduction Act Changes to Part D Coverage of Vaccines](#)
- [Final Contract Year \(CY\) 2024 Part D Bidding Instructions](#)

Annual Programmatic Updates

Formulary Submissions

¹ CMS released the Draft CY 2025 Part D Redesign Program Instructions on January 31, 2024 and is voluntarily soliciting comment on these draft program instructions. CMS will consider comments received by March 1, 2024. Please see <https://www.cms.gov/files/document/draft-cy-2025-part-d-redesign-program-instruction.pdf>.

CY 2025 Formulary Submission Windows

The CY 2025 HPMS formulary submission window will open this year on May 13, 2024 and close at 11:59 p.m. PDT on June 3, 2024. Consistent with 42 CFR § 423.265(b), CMS must be in receipt of a successfully submitted and validated formulary submission by the deadline of June 3, 2024 in order for the formulary to be considered for review. The Part D formulary is part of the plan's complete bid. Therefore, failure to submit and link a formulary to each plan that uses a formulary by the statutory deadline of the first Monday in June as required by section 1860D-11(b) of the Social Security Act (the Act), may result in denial of that bid submission (please refer to the section "Incomplete and Inaccurate Bid Submissions" in the [CY 2020 Final Call Letter](#)). As a reminder, Programs of All-Inclusive Care for the Elderly (PACE) organizations that intend to implement a formulary drug list or utilization management requirements for Part D drugs must also submit a formulary to CMS as outlined above.

Following the review and approval of initial CY 2025 formulary submissions, a subsequent limited update window will be provided in August 2024. We do not expect sponsors to make significant enhancements or significant negative changes to existing formulary drugs during this window, since the formulary version that was initially submitted to CMS for review was considered in the bid and Part D benefits review. Details regarding subsequent CY 2025 formulary submission windows will be provided in future HPMS memoranda.

CY 2025 Formulary Reference File (FRF)

CMS will release the first CY 2025 FRF in March 2024. The March FRF release will be used in the production of the Part D Bid Review Out-of-Pocket Cost (OOPC) model tool, scheduled to be released prior to the bid deadline. Consistent with the process for CY 2024, CMS intends to release a refreshed version of the Part D Bid Review OOPC model to account for changes in the May FRF. Given the limited timeframe between the May release of the CY 2025 FRF and the June 3, 2024 bid submission deadline, a refreshed Part D Bid Review OOPC model will be provided as quickly as possible, at least one week prior to the bid submission deadline. We note that the only change to the posted model package will be slight changes in the input files to reflect the anticipated small number of changes between the March and May FRFs. This will include both FRF additions and deletions, both of which are expected to have a neutral impact or reduction in Part D OOPC estimates.

Medication Therapy Management (MTM)

All Part D sponsors are required to have an MTM program designed to ensure, with respect to targeted beneficiaries, that covered Part D drugs are appropriately used to optimize therapeutic outcomes through improved medication use, and to reduce the risk of adverse events, including adverse drug interactions. MTM program requirements are codified at 42 CFR § 423.153(d). For the most recent information regarding Part D MTM programs, see the April 21, 2023 HPMS memorandum, "*Contract Year 2024 Medication Therapy Management Program Information and Submission Instructions.*"

CMS proposed various changes to MTM program requirements in the “Medicare Program; Contract Year (CY) 2024 Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications” proposed rule (the CY 2024 proposed rule) (87 FR 79542), which appeared in the December 27, 2022 issue of the Federal Register. Until such time as a final regulation addressing these proposals becomes effective, CMS will continue to apply policies related to the MTM program requirements at 42 CFR § 423.153(d) in the same manner as they were applied for CY 2024.

A CY 2025 MTM memorandum will be released in April or May 2024. The memorandum will be available on the CMS.gov MTM page at: <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/MTM>.

CY 2025 MTM Submissions and Attestations

Annually, sponsors submit an MTM program description to CMS through the HPMS for review and approval. CMS evaluates each program description to verify that it meets the current minimum requirements for the program year. These requirements do not apply to MA Private Fee for Service (MA-PFFS) organizations (see 42 CFR § 423.153(e)) or PACE organizations. The requirements do apply to Employer Group Waiver Plans (EGWPs). The CY 2025 HPMS MTM submission window will open on May 22, 2024 and close at 11:59 p.m. PDT on June 5, 2024. The attestation link will be available on June 6, 2024. The CY 2025 MTM program attestation deadline is June 20, 2024 at 11:59 p.m. PDT.

Annual Cost Threshold

Pursuant to 42 CFR § 423.153(d), for 2012 and subsequent years, the annual cost threshold for targeting beneficiaries under 42 CFR § 423.153(d)(2)(iii)(B) is specified as costs for covered Part D drugs in an amount greater than or equal to \$3,000 increased by the annual percentage specified in 42 CFR § 423.104(d)(5)(iv). The 2024 MTM program annual cost threshold is \$5,330. In the CY 2024 proposed rule (87 FR 79542-79548), CMS proposed changes to MTM eligibility criteria, including revising the methodology for calculating the cost threshold to be commensurate with the average annual cost of five generic drugs (\$1,004 in 2020). Until such time as a final regulation addressing these proposals becomes effective, CMS will continue to apply policies related to the MTM eligibility criteria at 423 CFR § 423.153(d) in the same manner as they were applied for CY 2024. The 2025 MTM program annual cost threshold will be included in the CY 2025 MTM memorandum to be released in April or May 2024.

Part D Benefit Parameters for Non-Defined Standard Plans

Part D sponsors can offer Non-Defined Standard Plans under which they can modify certain benefit parameters, including tiered cost sharing. The CY 2025 Part D benefit parameters for Non-Defined Standard Plans are set forth in the table below, addressing three key areas: Standalone Prescription Drug Plan (PDP) meaningful difference, tiered cost sharing, and the specialty tier threshold.

Pursuant to 42 CFR § 423.272(b)(3)(i), CMS will only approve a bid submitted by a Part D sponsor if its plan benefit package or plan cost structure is substantially different from those of other plan offerings by the sponsor in the service area, with respect to key characteristics such as beneficiary out-of-pocket costs and formulary structures. Pursuant to 42 CFR § 423.104(d)(2)(iii), tiered cost sharing for non-defined standard benefit designs may not exceed levels annually determined by CMS to be discriminatory. CMS will use the values included in the chart below as part of our benefit and formulary review and negotiation of CY 2025 bids. CMS will scrutinize plan benefits that do not meet these parameters pursuant to our negotiation authority under 42 CFR § 423.272(a).

PDP Meaningful Difference

Please refer to the forthcoming Final CY 2025 Part D Redesign Program Instructions document for meaningful difference requirements for CY 2025.

CMS released the Draft CY 2025 Part D Redesign Program Instructions on January 31, 2024² and is voluntarily soliciting comment on these draft program instructions. As noted in the draft document, please send comments regarding these draft program instructions to PartDRedesignPI@cms.hhs.gov with the subject line “Draft CY 2025 Part D Redesign Program Instructions.” CMS will consider comments received by 6:00 PM Eastern Time Friday, March 1, 2024. CMS will issue final program instructions for 2025 after considering the public comments received in response to these draft program instructions. In the final program instructions, CMS may change any policies, including policies on which CMS has not expressly solicited comment, based on the agency’s further consideration of the relevant issues. Policies established in the final program instructions for 2025 are subject to change in subsequent years.

Cost-Sharing Thresholds

The Non-Defined Standard cost-sharing thresholds remain unchanged for CY 2025, as detailed below in the Benefit Parameters for CY 2025 Threshold Values chart. Following the enactment of the IRA and resulting changes to the Part D program, CMS solicited feedback from interested stakeholders regarding these cost-sharing thresholds, as well as the current Part D Tier Models. We appreciate the feedback we received. Given the significant work involved in implementing the Part D Redesign and new Medicare Prescription Payment Plan for CY 2025, CMS has deferred any potential changes related to cost sharing thresholds and Tier Models for CY 2025 but will continue to carefully consider the feedback we received for future years.

Specialty Tiers

Part D sponsors may exempt formulary tiers in which they place very high-cost Part D drugs from their tiering exceptions process, consistent with 42 CFR § 423.578(a)(6)(iii). As codified in 42 CFR § 423.104(d)(2)(iv), in order for a Part D sponsor to place a Part D drug on a specialty tier, a Part D drug’s 30-day equivalent ingredient cost must exceed a dollar-per-month threshold

² The Draft CY 2025 Part D Redesign Program Instructions are available at <https://www.cms.gov/files/document/draft-cy-2025-part-d-redesign-program-instruction.pdf>.

annually reviewed and established by CMS. For CY 2025, the specialty-tier cost threshold will remain the same as for CY 2024, at \$950 for a 30-day equivalent ingredient cost. Consistent with 42 CFR § 423.104(d)(2)(iv)(D), CMS sets the maximum allowable cost sharing for a single specialty tier, or, in the case of a plan with two specialty tiers, the higher cost-sharing specialty tier, at 25 percent if the plan requires the standard deductible, 33 percent cost sharing if no deductible is required, or some percentage in between dependent on a decreased deductible. Therefore, for plans that offer two specialty tiers, the cost sharing for the lower cost sharing, preferred specialty tier must be anything less than that of the higher cost-sharing specialty tier.

Benefit Parameters for CY 2025 Threshold Values

	CY 2025 Threshold Values
Minimum Meaningful Differences (PDP Cost-Sharing OOPC)	
Enhanced Alternative Plan vs. Basic Plan	Refer to CY 2025 Part D Redesign Program Instructions
Maximum Copay: Initial Coverage Phase (3 or more tiers)	\$ ^{1,2}
Preferred Generic Tier	<\$20 ³
Generic Tier	\$20
Preferred Brand/Brand Tier	\$47
Non-Preferred Drug Tier	\$100
Non-Preferred Brand Tier	\$100
Injectable Tier	\$100
Select Care/Diabetic Tiers ⁴	\$11
Vaccine Tier	\$0
Maximum Coinsurance: Initial Coverage Phase (3 or more tiers)	\$ ^{1,2}
Preferred Generic Tier	25%
Generic Tier	25%
Preferred Brand/Brand Tier	25%
Non-Preferred Drug Tier	50%
Non-Preferred Brand Tier	50%
Injectable Tier	33%
Select Care/Diabetic Tiers ⁴	15%
Vaccine Tier	0%
Minimum Specialty Tier Eligibility	
30-day equivalent ingredient cost	\$950

¹ These thresholds are based on the 95th percentile of the CY 2024 Bid Data, which are unchanged from the thresholds based on the 95th percentile of the CY 2020 Bid Data. We will separately evaluate plans with atypical tiering structures, such as a two-tier formulary.

² “S” in the above chart refers to “standard retail cost sharing” at a network pharmacy. Standard retail cost sharing

(S) is cost sharing other than preferred retail cost sharing offered at a network pharmacy.

³ There is no separate maximum cost-share threshold for the Preferred Generic tier. Cost sharing for the Preferred Generic tier that is lower than cost sharing for the Generic tier will not be subject to additional scrutiny. Equivalent cost sharing for the Preferred Generic and Generic tiers will be accepted only in cases where the sponsor buys down the cost sharing to \$0 for both generic tiers.

⁴ The Select Care Drug and Select Diabetic Drug Tiers provide a meaningful benefit offering when they have low or \$0 beneficiary cost sharing for drugs targeting specific conditions (e.g., \$0 tier for drugs related to diabetes and/or smoking cessation).

Improving Drug Utilization Review Controls in Medicare Part D

Opioid Safety Edits

For the most recent information regarding Part D opioid point-of-sale (POS) safety edit(s), see the December 19, 2022 HPMS memorandum, “*Medicare Part D Opioid Safety Edit Reminders and Recommendations and Frequently Asked Questions (FAQs)*.” Guidance for sponsors and educational materials for providers and beneficiaries are available on the Improving Drug Utilization Review Controls in Part D webpage: <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html>. CMS will continue to update this page, including the FAQs, to provide additional guidance as needed for CY 2025 and future years.

A memorandum providing instructions to Part D sponsors for submitting information about CY 2025 opioid POS safety edits to CMS in HPMS will be released in July 2024. Sponsors should submit opioid safety edits in the HPMS module between August 13, 2024 and 5:00 p.m. EDT on August 20, 2024. For CY 2025, CMS requests that all PACE organizations submit opioid safety edit information in HPMS regardless of whether they adjudicate claims at POS.

Drug Management Programs (DMPs)

All Part D sponsors are required to have a DMP. DMP requirements are codified at 42 CFR § 423.153(f). See the April 20, 2023 HPMS memorandum, “CORRECTION - *Contract Year 2023 Part D Drug Management Program Guidance*,” for the most recent information regarding Part D DMPs.

CMS proposed various changes to DMP requirements in the “Medicare Program; Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications” proposed rule (the CY 2025 proposed rule) (88 FR 78476), which appeared in the November 15, 2023 issue of the Federal Register. Until such time as a final regulation addressing these proposals becomes effective, CMS will continue to apply policies related to the DMP requirements in 42 CFR § 423.153(f) in the same manner as they were applied for CY 2024.

Guidance, technical documents, notices, and FAQs for DMPs are available on the Improving Drug Utilization Review Controls in Part D webpage: <https://www.cms.gov/Medicare/>

[Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html](#). CMS will continue to update this page to provide additional guidance as needed for CY 2025 and future years.

Coordination of Benefits (COB) User Fee

Pursuant to section 1860D-24(a)(3) of the Act and 42 CFR § 423.464(c), CMS is authorized to impose user fees on Part D sponsors for the transmittal of information necessary for benefit coordination between sponsors and other entities providing prescription drug coverage. We review and update this user fee annually to reflect the costs associated with COB activities for the specific year. The 2025 COB user fee will be collected at a monthly rate of \$0.078 for the first 9 months of the coverage year, for a total user fee of \$0.70 per enrollee per year. Part D sponsors should account for this COB user fee when developing their 2025 bids.

Administrative Information

The programmatic policies described in this memorandum will be used in the evaluation of CY 2025 bids submitted by Part D sponsors in accordance with our negotiation authority under section 1860D-11(d)(2) of the Act. Unless otherwise noted in this document or the forthcoming Final CY 2025 Part D Redesign Program Instructions document, the guidance issued in the Final CY 2020 Call Letter still applies for CY 2025 (see [CY 2020 Final Call Letter](#)). The following is a non-exhaustive list of CY 2020 Call Letter policies that apply for CY 2025:

- Incomplete and Inaccurate Bid Submissions
- Plan Corrections
- Improving Access to Opioid-Reversal Agents
- Access to Medication-Assisted Treatment
- Benefit Review
- Tier Composition
- Improving Access to Generic and Biosimilar Medicines*
- PDP Crosswalk Policy*
- Low Enrollment Plans (Standalone PDPs only)
- PDP Non-Renewal Policy Clarifications*
- Part D Mail Order Auto-Ship Modifications*

*Denotes policies included in the CY 2024 proposed rule, which appeared in the December 27, 2022 issue of the Federal Register. Until such time as a final regulation addressing these proposals becomes effective, CMS will continue to apply policies in the same manner as they were applied for CY 2024.

For questions related to Part D Benefits, please email PartDBenefits@cms.hhs.gov.

For questions related to Part D Policy, please email PartDPolicy@cms.hhs.gov.

For questions related to Part D Formularies, please email PartDFormularies@cms.hhs.gov.

For questions related to Part D MTM Programs, please email PartD_MTM@cms.hhs.gov.

For questions related to Part D opioid safety edits or DMPs, please email

PartD_OM@cms.hhs.gov.

For questions related to the Part D Bid Pricing Tools, please email actuarial-bids@cms.hhs.gov.

For questions related to Part D Payment Policy, please email PartDPaymentPolicy@cms.hhs.gov.