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DATE: April 4, 2023

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

FROM: Amy Larrick Chavez-Valdez
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SUBJECT: Final Contract Year (CY) 2024 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 2024. This memorandum includes both annual programmatic updates and program instruction for the implementation of provisions effective in 2024 enacted in the Inflation Reduction Act (IRA, P.L. [117-169](#)), on August 16, 2022.

Program Instructions for Implementation of Part D IRA Provisions Effective 2024

In order to implement applicable provisions of the IRA, CMS issued program instruction via the Health Plan Management System (HPMS) memorandum dated September 26, 2022 titled “Contract Year 2023 Program Guidance Related to Inflation Reduction Act Changes to Part D Coverage of Vaccines and Insulin.” Except as updated for CY 2024 below, the instructions set forth in the September 26, 2022 memorandum still apply.

CMS solicited feedback on the IRA policies included in the “Draft Contract Year (CY) 2024 Part D Bidding Instructions” released January 30, 2023. The comments we received were operational in nature and pertained largely to questions on prescription drug event (PDE) reporting and the submission of plan benefit packages (PBPs) and/or bid pricing tools (BPTs). Clarification, where necessary, is provided in the corresponding sections of this memorandum. PDE guidance for CY 2024 will be provided separately.

Cost Sharing for Catastrophic Coverage

Section 11201 of the IRA amends section 1860D-2(b)(4) of the Act by eliminating enrollee cost sharing in the catastrophic phase of the Part D benefit beginning in CY 2024. Specifically, beginning in CY 2024 and for each succeeding year, enrollee cost sharing after an enrollee has incurred costs for covered Part D drugs in a year equal to the annual out-of-pocket threshold will be \$0 for all covered Part D drugs. This requirement does not apply to excluded category drugs that are covered under enhanced alternative plans.

Basic Part D Benefits: ACIP-recommended Adult Vaccines and Covered Insulin Products

Section 11401 of the IRA amended section 1860D-2(b) of the Act by adding paragraph (b)(8) to the requirements for standard prescription drug coverage. Section 1860D-2(b)(8) of the Act

specifies that no deductible or cost sharing be applied with respect to adult vaccines recommended by the Advisory Committee on Immunization Practices (ACIP).

Section 11406 of the IRA amended section 1860D-2(b) of the Act by adding paragraph (b)(9) to the requirements for standard prescription drug coverage. In part, section 1860D-2(b)(9) of the Act specifies that for 2024 such coverage provides benefits for any covered insulin product with cost sharing for a month's supply that *does not exceed* the applicable copayment amount. The "applicable copay amount" in 2024 is \$35. The statute prohibits cost sharing that exceeds the applicable copayment amount, but does not require that cost sharing be equal to the applicable copayment amount. Accordingly, the standard prescription drug coverage requirement includes the value of the Part D plan's coverage of covered insulin products (regardless of whether cost sharing under the plan is equal to the IRA maximum of \$35 per month supply or a lower amount), which will always be reflected in the plan bid as a basic benefit. Therefore, insulin cost sharing under Defined Standard (DS), Actuarially Equivalent (AE), Basic Alternative (BA), and Enhanced Alternative (EA) plans always reflects basic coverage and not enhanced coverage subject to an additional premium.

In addition, section 1860D-2(b)(9) of the Act specifies that for plan year 2023 and subsequent plan years, no deductible shall apply with respect to any covered insulin product. For CY 2024, CMS will require Part D sponsors to apply consistent enrollee cost sharing for covered insulin products starting with first dollar coverage (i.e., no deductible applies) through to the catastrophic phase of the benefit. In other words, the enrollee cost sharing for covered insulin products that a Part D sponsor specifies in its bid submission will apply from the start of the benefit, regardless of the deductible for other Part D drugs on the formulary tier, and must be continued through the coverage gap phase of the benefit (see additional details below).

The IRA changes to the standard prescription drug coverage, through the addition of paragraphs (b)(8) and (b)(9), are considered separate from, but in addition to, the requirements under section 1860D-2(b)(2)(A)(i) and (ii) that apply a 25 percent coinsurance (or actuarially equivalent design) for all other covered drugs in the initial coverage phase. As such, covered insulin products and ACIP-recommended adult vaccine costs will be considered separately for purposes of actuarial equivalence testing. Final BPTs and bid instructions will be released by CMS's Office of the Actuary; in the interim, plan sponsors can refer to the "Instructions for Completing the Prescription Drug Plan Bid Pricing Tool for Contract Year 2024" for further details, available in the BPT 2024 Beta Testing Version zip file accessed via the [HPMS Landing Page](#) under Documentation.

Tier Placement and Cost Sharing for Covered Insulin Products

Part D sponsors may place covered insulin products on any tier, and apply utilization management strategies (e.g., prior authorization and step therapy), insofar as such tier placement or utilization management strategy is consistent with the requirements of CMS's formulary review and approval process under 42 CFR § 423.120(b). However, regardless of a covered insulin product's tier placement or applicable utilization management strategy, the statutory cost-sharing limits under section 1860D-2(b)(9) and (c)(6) of the Act still apply.

For bid submission purposes, sponsors will enter cost sharing for each formulary tier as usual. However, the CY 2024 PBP will allow sponsors to identify which formulary tiers contain insulin products and enter specific insulin copay values for each of those tiers, and for each pharmacy network. The copay for insulin cannot exceed the copay (if applicable) that is entered for all

other drugs on the tier, and both data fields must be completed even if the covered insulin products have the same copay as the other drugs on the tier. If submitting a coinsurance structure for non-insulin drugs on a tier, plan sponsors will need to submit a separate copay for insulins placed on the tier, up to a maximum of \$35 for a one-month supply. While the DS plan design does not allow for a tiered formulary benefit, the CY 2024 PBP is designed to require a separate copay entry for insulin products, while maintaining the DS 25 percent coinsurance structure in the initial coverage and coverage gap phases for all other formulary drugs (with the other exception being ACIP-recommended adult vaccines, as noted below). The plan-specific copay for insulin products is the cost sharing that will apply for covered insulin products, even for DS plans.

Examples of PBP data entry for various scenarios are included in the table below. Please note that Part D sponsors will have the option of entering an insulin copay for a tier that does not include insulin products on initial submission, in the event they want to add a covered insulin product to that tier midyear. Sponsors may add insulin products midyear to a formulary tier if the plan had established an insulin copay for that tier during the initial bid submission. If an insulin copay was not submitted during the initial bid submission for a given tier, sponsors may not add insulin products midyear to that formulary tier. Once a cost-sharing amount has been submitted and approved, Part D sponsors will not be permitted to make midyear changes to cost-sharing amounts. When identifying the formulary exception tier(s) in the PBP, sponsors are reminded to enter an insulin copay (even if no insulins are included on the tier) that will apply to approved formulary exception requests for non-formulary insulins. The insulin copay entered for any tier identified as an exceptions tier will apply to approved formulary exceptions requests, formulary insulins (if applicable) and any insulins added to that tier midyear and may be no greater than \$35 for a one-month supply.

CY 2024 PBP Data Entry Examples for Insulin Cost Sharing*

| Intent | Non-insulin Cost Sharing | Insulin Cost Sharing** | PBP Data Entry |
|---|--------------------------|------------------------|---|
| Copay Formulary Tier where copay is the same for insulin and non-insulin drugs | \$20 | \$20 | Enter \$20 in both the non-insulin copay field and the insulin copay field. |
| Copay Formulary Tier where copay is different for insulin and non-insulin drugs | \$20 | \$15 | Enter \$20 in the non-insulin copay field. Enter \$15 in the insulin copay field. |
| Coinsurance Formulary Tier with copay entry for insulin | 25% | \$35 | Enter 25% in the non-insulin coinsurance field. Enter \$35 in the insulin copay field. |
| Defined Standard plan with copay entry for insulins | N/A | \$20 | There is no data entry for the non-insulin cost sharing. Enter \$20 in the insulin copay field. |

*Submitted insulin copays apply from first dollar coverage up to the out-of-pocket threshold (inclusive of the coverage gap phase).

**The CY 2024 PBP cost-sharing fields for insulin will accept copay amounts only.

Given the time constraints to make system changes ahead of CY 2024 formulary and bid submissions, CMS is unable to accommodate Part D Tier Model changes at this time, including changes to add tier model options. We are interested, however, in additional feedback on what options CMS should consider to optimize IRA implementation for CY 2025 and beyond. We encourage this feedback to be shared with CMS as detailed in the “Administrative Information” section of this memorandum.

Tier Placement and Cost Sharing for Adult Vaccines

In the September 2022 guidance, we stated “the term “adult vaccine recommended by [ACIP]” means a covered Part D drug that is a vaccine licensed by the US Food and Drug Administration (FDA) under section 351 of the Public Health Service Act (PHSA) for use by adult populations and administered in accordance with recommendations of ACIP.” We also stated that “recommended” by ACIP for use in adults means all categories of ACIP recommendations, including those that are specified as based on shared clinical decision-making and ACIP recommendations for use in limited populations and circumstances for vaccines that are not on the CDC/ACIP Adult Immunization Schedule for routine immunization. We further clarify that in order for an adult use of a vaccine to be considered “ACIP recommended,” such use must be approved by the CDC Director and published in the CDC’s Morbidity and Mortality Weekly Report (MMWR).

Consistent with previous years, Part D sponsors may place ACIP-recommended adult vaccines on any tier, including a vaccine tier, and apply utilization management strategies (e.g., prior authorization and step therapy), insofar as such tier placement or utilization management strategy is consistent with the requirements of CMS’s formulary review and approval process under 42 CFR § 423.120(b). However, regardless of an ACIP-recommended adult vaccine’s tier placement or applicable utilization management strategies, the statutory cost-sharing limits required under sections 1860D-2(b)(8) and (c)(5) of the Act still apply. For bid submission purposes, Part D sponsors will be required to attest that they are charging \$0 for ACIP-recommended adult vaccines.

Annual Programmatic Updates

Formulary Submissions

CY 2024 Formulary Submission Windows

The CY 2024 HPMS formulary submission window will open this year on May 15, 2023 and close at 11:59 p.m. PDT on June 5, 2023. 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 5, 2023 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 at [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 2024 formulary submissions, a subsequent limited update window will be provided in August 2023. 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 2024 formulary submission windows will be provided in future HPMS memoranda.

CY 2024 Formulary Reference File

CMS will release the first CY 2024 Formulary Reference File (FRF) in March 2023. 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. As proposed in the November 25, 2022 [HPMS memorandum](#) titled “Proposed Part D Out-of-Pocket Cost Model Updates,” CMS intends to release a refreshed version for the Bid Review OOPC model to account for changes in the May FRF. Given the limited timeframe between the May release of the CY 2024 FRF and the June 5 deadline, a refreshed Bid Review OOPC model would be provided as quickly as possible. We note that the only change to the model would be the input files to reflect the anticipated small number of changes between the March and May FRFs. This would include both FRF additions and deletions, both of which are expected to have a neutral impact or reduction in OOPC estimates.

Medication Therapy Management (MTM)

For the most recent information regarding Part D MTM programs, see the April 15, 2022 HPMS memorandum, “Contract Year 2023 Medication Therapy Management Program Information and Submission Instructions.” CMS proposed various changes to MTM program requirements in the “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 on these proposals is published, CMS will continue to apply policies in the same manner as they were applied for CY 2023.

A CY 2024 MTM memorandum will be released in April or May 2023. The memorandum will be available on the CMS.gov MTM page at: <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/MTM>.

CY 2024 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 2024 HPMS MTM submission window will open on May 24, 2023 and close at 11:59 p.m. PDT on June 7, 2023. The attestation link will be available on June 8, 2023. The CY 2024 MTM program attestation deadline is June 21, 2023 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 2023 MTM program annual cost threshold is \$4,935. 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 on these proposals is published, CMS will continue to apply policies in the same manner as they were applied for CY 2023. The 2024 MTM program annual cost threshold will be included in the CY 2024 MTM memorandum to be released in April or May 2023.

Part D Benefit Parameters for Non-Defined Standard Plans

Part D sponsors have the ability to offer Non-Defined Standard Plans under which they can modify certain benefit parameters, including tiered cost sharing. The CY 2024 Part D benefit parameters for Non-Defined Standard Plans are set forth in the table below, addressing three key areas: PDP meaningful difference, tiered cost sharing, and the specialty tier threshold. Pursuant to 42 CFR § 423.272(b)(3)(i), CMS will approve a bid submitted by a Part D sponsor only 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 2024 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

As noted in the November 25, 2022 HPMS memorandum “Proposed Part D Out-of-Pocket Cost Model Updates,” the Part D OOPC model is being enhanced in two ways. One enhancement will account for potential therapeutic alternatives and formulary exceptions within the model. The second enhancement will be an annual release of a refreshed OOPC model that incorporates changes from the May FRF prior to the bid submission deadline. CMS will continue to release the initial Bid Review OOPC model ahead of the bid submission deadline and, in addition, intends to publish a refreshed model that includes changes from the May FRF. The comments that we received on these enhancements were largely supportive. Stakeholders did express concern over the timing of the refreshed OOPC model in May; CMS will make every effort to release this refresh as soon as practicable.

The values produced from the CY 2024 Part D Bid Review OOPC model will be used in CMS’s review of CY 2024 PDP bids for meaningful difference. In CY 2023, CMS updated the Part D Bid Review OOPC Model to utilize a 0.1 percent sample Part D cohort. With this cohort change to the OOPC methodology in CY 2023, an outlier test was used instead of the dollar per month threshold that was used in prior years.

Given the additional updates to the OOPC model, CMS will continue to use an outlier approach for CY 2024 to ensure that plan offerings meet the requirements under 42 CFR § 423.272(b)(3)(i). CMS expects sponsors to be prepared to provide written justification, upon

request, that demonstrates that the plan offerings within a service area are substantially different from one another. As part of our negotiation authority under 42 CFR § 423.272(a), sponsors may be asked to make modifications to their benefit structure or formulary, if the submitted justification is not accepted. While some stakeholders have previously reported that an outlier analysis poses a challenge since plans do not have a target when preparing their bids, given the aforementioned changes to the OOPC model, CMS will be repeating an outlier test for at least one more year. We encourage sponsors to prepare their bids with a good faith effort at achieving a meaningful difference between their basic and enhanced plans. At a minimum, CMS continues to expect that the OOPC value of the basic plan will be higher than the OOPC value of the enhanced plan offering(s), as specified in the [CY 2020 Final Call Letter](#). We will continue to contemplate how to evaluate meaningful difference in light of the IRA Part D Redesign and OOPC model enhancements. We are interested in feedback on this topic for CY 2025 and beyond. We encourage this feedback to be shared with CMS as detailed in the “Administrative Information” section of this memorandum.

Cost-Sharing Thresholds

The CY 2024 cost-sharing thresholds remain unchanged, as detailed below in the Benefit Parameters for CY 2024 Threshold Values chart. In light of the IRA Part D Redesign, we are interested in feedback on this topic for CY 2025 and beyond. We encourage this feedback to be shared with CMS as detailed in the “Administrative Information” section of this memorandum.

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 annually reviewed and established by CMS, as set forth in the regulation. For CY 2024, the specialty-tier cost threshold will increase from \$830 to \$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 2024 Threshold Values

| | CY 2024 Threshold Values |
|--|--------------------------|
| Minimum Meaningful Differences (PDP Cost-Sharing OOPC) | |
| Enhanced Alternative Plan vs. Basic Plan | Outlier Analysis |
| Maximum Copay: Pre-ICL and Additional Cost-Sharing Reductions in the Gap (3 or more tiers) | S ^{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: Pre-ICL (3 or more tiers) | S ^{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% |
| Maximum Coinsurance: Additional Cost-Sharing Reductions in the Gap for Applicable Beneficiaries (all tier designs) | S ⁵ |
| Preferred Generic Tier | 15% |
| Generic Tier | 15% |
| Preferred Brand/Brand Tier | 50% |
| Non-Preferred Drug Tier | 50% |
| Non-Preferred Brand Tier | 50% |
| Injectable Tier | 50% |
| Select Care/Diabetic Tiers ⁴ | 50% |
| 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 2023 Bid Data, which are unchanged from the thresholds based on the 95th percentile of the CY 2020 Bid Data. As in previous years, we will also set similar thresholds for 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 in the case when a 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). We continue to expect cost sharing for the Vaccine tier, or Select Care/Select Diabetes tiers that contain vaccines, to be \$0.

⁵ Additional gap cost-sharing reductions for applicable beneficiaries are communicated in the PBP at the tier level and sponsors may elect to provide this benefit for all drugs on a tier (full tier coverage) or a subset of drugs on a tier (partial tier coverage). If the additional gap cost-sharing reduction benefit for a brand labeled tier applies to only non-applicable (i.e., generic) drugs or both generic and applicable drugs on that tier, then the generic drug beneficiary coinsurance maximum of 15 percent applies. Injectable, Specialty, Select Care and Select Diabetic Drug labeled tiers for which additional gap coverage is offered, if any, will be analyzed in the same manner as brand labeled tiers with respect to beneficiary coinsurance maximums. Note that the beneficiary coinsurance maximums for the coverage gap reflect the plan liability but exclude the 70 percent manufacturer discount for applicable drugs. For CY 2024 insulin product coverage, any cost-sharing amount specified during bid submission will apply during both the initial coverage and coverage gap phases of the benefit.

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 2024 and future years.

A memorandum providing instructions to Part D sponsors for submitting information about CY 2024 opioid POS safety edits to CMS in HPMS will be released in July 2023. Sponsors should submit opioid safety edits in the HPMS module between August 14, 2023 and 5:00 p.m. EDT on August 21, 2023. As a reminder, PACE organizations only need to submit opioid safety edit information if adjudicating 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 November 28, 2022 HPMS memorandum, “Contract Year 2023 Part D Drug Management Program Guidance,” for the most recent information regarding Part D DMPs.

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 2024 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 2024 COB user fee will be collected at a monthly rate of \$ 0.0833 for the first 9 months of the coverage year for a total user fee of \$0.75 per enrollee per year. Part D sponsors should account for this COB user fee when developing their 2024 bids.

Administrative Information

The programmatic policies described in this memorandum will be used in the evaluation of CY 2024 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, the guidance issued in the Final CY 2020 Call Letter still applies for CY 2024 (see [CY 2020 Final Call Letter](#)). The following is a non-exhaustive list of CY 2020 Call Letter policies that apply for CY2024:

- 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 on these proposals is published, CMS will continue to apply policies in the same manner as they were applied for CY 2023.

Feedback Requested

Given the impact of the IRA Part D redesign and associated policies, CMS continues to encourage Part D sponsors to provide feedback on several annual programmatic policies for CY 2025 and beyond. These areas include, but are not limited to, how CMS should: (1) define PDP meaningful difference to ensure a substantial difference exists between basic and enhanced benefit plans offered by a parent organization in a PDP region; (2) set non-defined standard cost-sharing thresholds; and (3) define parameters for an enhanced benefit plan under the Part D redesign. Please send comments related to these policies to PartDBenefits@cms.hhs.gov with the subject line “CY 2025 Part D Redesign.” Given time constraints related to systems and policy changes, comments received after **June 5, 2023** may not be able to be fully considered for CY 2025.

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.