DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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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, Director
Medicare Drug Benefit and C & D Data Group

SUBJECT: Contract Year (CY) 2023 Final Part D Bidding Instructions

This document contains information on the Part D program, and provides helpful instructions and reminders as Part D sponsors prepare to submit bids for CY 2023.

Formulary Submissions

CY 2023 Formulary Submission Windows

The CY 2023 HPMS formulary submission window will open this year on May 16, 2022 and close at 11:59 p.m. PDT on June 6, 2022. Consistent with 42 C.F.R. § 423.265(b), CMS must be in receipt of a successfully submitted and validated formulary submission by the deadline of June 6, 2022 in order for the formulary to be considered for review. The Part D formulary is part of the plan's complete bid and therefore a 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 https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf). As a reminder, Program 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 2023

formulary submissions, a subsequent limited update window will be provided in August 2022. 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 2023 formulary submission windows will be contained in future HPMS memoranda.

CY 2023 Formulary Reference File

CMS will release the first CY 2023 FRF in March 2022. 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 in April 2022. Sponsors should note that the Part D Bid Review OOPC model released in April will not be modified to incorporate any subsequent FRF updates, as described below. CMS will update the CY 2023 FRF prior to the June 6 formulary submission deadline; however, given the limited timeframe between the May release of the CY 2023 FRF and the June 6 deadline, CMS is unable to accommodate an updated version of the 2023 Part D Bid Review OOPC model to incorporate the new generics that may be added to the May FRF. Therefore, CMS advises plan sponsors that any newly added drugs on the May release of the CY 2023 FRF will not be included in the 2023 Bid Review OOPC model.

Medication Therapy Management (MTM)

For the most recent information regarding Part D MTM programs, see the August 31, 2021 HPMS memorandum, "Correction to Contract Year 2022 Part D Medication Therapy Management Program Guidance and Submission Instructions dated April 30, 2021." A CY 2023 MTM memorandum will be released in mid-April 2022. The memorandum will be available on the CMS.gov MTM page at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/MTM.

CY 2023 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 C.F.R. § 423.153(e)) or PACE organizations. The requirements do apply to Employer Group Waiver Plans (EGWPs).

The CY 2023 HPMS MTM submission window will open on May 9, 2022 and close at 11:59 p.m. PDT on May 23, 2022. The attestation link will be available on May 24, 2022. The CY 2023 MTM program attestation deadline is June 6, 2022 at 11:59 p.m. PDT.

Annual Cost Threshold

Pursuant to 42 C.F.R. § 423.153(d), for 2012 and subsequent years, the annual cost threshold for targeting beneficiaries under 42 C.F.R. § 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 C.F.R. § 423.104(d)(5)(iv). The 2022 MTM program annual cost threshold is $4,696. The 2023 MTM program annual cost threshold will be announced in the CY 2023 MTM memorandum after the release of the CY 2023 Announcement of Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies.

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 2023 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 C.F.R. § 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 C.F.R. § 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 2023 bids. CMS will scrutinize plan benefits that do not meet these parameters pursuant to our negotiation authority under 42 C.F.R. § 423.272(a).

PDP Meaningful Difference

As noted in the January 21, 2022 HPMS email "Release of Updated CY 2022 Part D Baseline OOPC Model," the updated 0.1% sample Part D cohort will be the only enhancement included in the CY 2023 Part D Bid Review OOPC Model to be released in April 2022 for evaluation of CY 2023 plans. The additional enhancement that would have randomly assigned cost sharing for non-formulary (NF) drugs was removed from the reissued CY 2022 Part D Baseline model due to a coding issue that impacted the reproducibility of the Part D OOPC values. We may add this back in future plan year releases but not for the CY 2023 bid review. The values produced from the CY 2023 Part D Bid Review OOPC model will be used in CMS' review of CY 2023 bids for PDP Meaningful Difference. CMS continues to expect that the OOPC value of the basic plan will be higher than that of the OOPC value of the enhanced plan offering(s), as last specified in the CY 2020 Final Call Letter. However, given the updates to the model, CMS will not be using the dollar per month threshold that was used in prior years and based on a different OOPC methodology. Since CY 2023 will be the first year reviewing bids using the updated OOPC

Models, CMS intends to conduct outlier tests to ensure that plan offerings meet the requirements under 42 C.F.R. § 423.272(b)(3)(i). In order to demonstrate that the plan offerings by the sponsor within a service area are substantially different from one another, we expect sponsors to be prepared to provide written justification upon request. As part of our negotiation authority under 42 C.F.R. § 423.272(a), sponsors may be asked to make modifications to their benefit structure or formulary, if the submitted justification is not accepted.

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 C.F.R. § 423.578(a)(6)(iii). As codified in 42 C.F.R. § 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 2023, the specialty-tier cost threshold is maintained at $830, as a 30-day equivalent ingredient cost. Consistent with 42 C.F.R. § 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% if the plan requires the standard deductible, 33% 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 2023 Threshold Values

	CY 2023 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%

	CY 2023 Threshold Values
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	
1-month supply at in-network retail pharmacy	$830

[1] These thresholds are based on the 95th percentile of the CY 2022 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 that for the cost sharing of 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% 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% manufacturer discount for applicable drugs.

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 November 4, 2020 HPMS memorandum, "*Contract Year (CY) 2021 Opioid Safety Edit Reminders and Recommendations*." 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 2023 and future years.

A memorandum providing instructions to Part D sponsors for submitting information about CY 2023 opioid POS safety edit(s) to CMS in HPMS will be released in July 2022. Sponsors should submit opioid safety edits in the HPMS module between August 15, 2022 and 5:00 p.m. EDT on August 22, 2022. 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 September 30, 2021 HPMS memorandum, "Contract Year 2022 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 2023 and future years.

Coordination of Benefits (COB) User Fee

Pursuant to section 1860D-24(a)(3) of the Act and 42 C.F.R. § 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 2023 COB user fee will be collected at a monthly rate of $ 0.1166 for the first 9 months of the coverage year for a total user fee of $1.05 per enrollee per year. Part D sponsors should account for this COB user fee when developing their 2023 bids.

Administrative Information

The policies described in this memorandum will be used in the evaluation of CY 2023 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 applies for CY 2023 (see https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf). The following is a non-exhaustive list of CY 2020 Call Letter policies that apply for CY2023:

- Incomplete and Inaccurate Bid Submissions
- Plan Corrections
- Improving Access to Opioid-Reversal Agents
- Access to Medication-Assisted Treatment
- Part D PBP MRx Enhancements
- Benefit Review
- Tier Composition
- Improving Access to Part D Vaccines
- 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

We are applying the policies mentioned in this memorandum in the same manner for CY 2023 as they were applied in CY 2020-2022. We therefore are not soliciting comments on these policies. Should CMS make any changes to the Benefit Parameters or Tier Thresholds for CY 2024 or beyond, such changes would be made in future rulemaking as necessary.

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.