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CENTER FOR MEDICARE

DATE: January 19, 2021

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

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SUBJECT: Contract Year (CY) 2022 Final Part D Bidding Instructions

This guidance document contains information on the Part D program, and provides helpful instructions and reminders as Part D sponsors prepare to submit bids for CY 2022.

Formulary Submissions

CY 2022 Formulary Submission Windows

The CY 2022 HPMS formulary submission window will open this year on May 17, 2021 and close at 11:59 p.m. PDT on June 7, 2021. 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 7, 2021 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 2022 formulary submissions, a subsequent limited update window will be provided in August 2021. 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 2022 formulary submission windows will be contained in future HPMS memorandums.

CY 2022 Formulary Reference File

CMS will release the first CY 2022 FRF in March 2021. The March FRF release will be used in the production of the Bid Review Out-of-Pocket Cost (OOPC) model tool, scheduled to be released in April 2021, in order to assist plan sponsors in satisfying PDP meaningful difference requirements prior to bid submission. Sponsors should note that the 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 2022 FRF prior to the June 7 formulary submission deadline. Since the OOPC model incorporates Medicare Current Beneficiary Survey (MCBS) data from 2016 and 2017, new Part D drugs cannot be included in the Bid Review OOPC model since they would not have appeared in the survey. Further, given the limited timeframe between the May release of the CY 2022 FRF and the June 7 deadline, CMS is unable to accommodate an updated version of the 2022 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 2022 FRF will not be included in the 2022 Bid Review OOPC model.

Medication Therapy Management (MTM)

In the January 19, 2021, Federal Register, CMS published a final rule titled "Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (CMS-4190-F2)" (https://www.federalregister.gov/public-inspection/2021-00538/medicare-and-medicaid-programs-contract-year-2022-policy-and-technical-changes-to-the-medicare) that implements changes to MTM programs for CY 2022 (January 2021 final rule). This rule changes the definition of "targeted beneficiaries" for the purposes of MTM programs to include at-risk beneficiaries in a drug management program (42 C.F.R. § 423.153(d)(2)(ii)), and requires sponsors to provide MTM enrollees with information on the safe disposal of controlled substances (42 C.F.R. § 423.153(d)(1)(vii)(E)).

A memo containing MTM program guidance and submission instructions for CY 2022 will be released in early April. The memo will be available on the CMS.gov MTM page at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/MTM.html.

CY 2022 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 2022 HPMS MTM submission window will open this year on April 26, 2021 and close at 11:59 p.m. PDT on May 10, 2021. As such, the CY 2022 MTM program attestation deadline is May 24, 2021 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 2021 MTM program annual cost threshold is $4,376. The 2022 MTM program annual cost threshold will be the 2021 annual cost threshold adjusted based on the annual percentage increase of 7.31%, as specified in the CY 2022 Announcement of Medicare Advantage Capitation Rates and Part C and Part D Payment Policies. Therefore, the MTM Eligibility Threshold for CY 2022 is $4,696.

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 2022 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, as defined under § 423.265(b)(2), with respect to key characteristics such as beneficiary out-of-pocket costs and formulary structures. Pursuant to § 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 2022 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).

Specialty Tiers

Part D sponsors may exempt formulary tiers in which it places very high-cost Part D drugs from its tiering exceptions process, consistent with 42 C.F.R. § 423.578(a)(6)(iii). In the January 2021 final rule CMS finalized allowing a second, preferred specialty tier beginning January 1, 2022 and several changes to the methodology and calculation of the specialty-tier cost threshold (see 42 C.F.R. § 423.104(d)(2)(iv)). Under the new policy, 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 established by CMS as set forth in the regulation. For CY 2022, the specialty-tier cost threshold is set at $830, as a 30-day equivalent ingredient cost. Consistent with § 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 2022 Threshold Values

Benefit Parameter	CY 2022 Threshold Values
Minimum Meaningful Differences (PDP Cost-Sharing OOPC)[1]	
Enhanced Alternative Plan vs. Basic Plan	$22
Maximum Copay: Pre-ICL and Additional Cost-Sharing Reductions in the Gap (3 or more tiers)	S [2,3]
Preferred Generic Tier	<$20 [4]
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[5]	$11
Vaccine Tier	$0
Maximum Coinsurance: Pre-ICL (3 or more tiers)	S [2,3]
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[5]	15%
Vaccine Tier	0%
Maximum Coinsurance: Additional Cost-Sharing Reductions in the Gap for Applicable Beneficiaries (all tier designs)	S [6]
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[5]	50%
Vaccine Tier	0%
Minimum Specialty Tier Eligibility	
1-month supply at in-network retail pharmacy	$830

[1] CMS is currently working on technical enhancements to the OOPC model, but is mindful of a common stakeholder request for stability in the meaningful difference threshold. As such, the Enhanced Alternative Plan to Basic Plan meaningful difference minimum threshold will be maintained at the level from CY 2019.

[2] These thresholds are 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.

[3] "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.
[4] 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.
5 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.
[6] 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, 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 HPMS memo, "*Contract Year (CY) 2021 Opioid Safety Edit Reminders and Recommendations*" released on November 4, 2020. Comprehensive guidance for sponsors and educational materials for providers, beneficiaries, and other partners (pharmacies, professional organizations, advocacy groups, etc.) is 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 2022 and future years.

Drug Management Programs

The January 2021 final rule implements changes to Part D drug management programs (DMPs) for 2022. This rule requires all Part D plan sponsors to have a DMP by January 1, 2022 (consistent with section 1860D-4(c)(1)(F)), revises the criteria used to identify potential at-risk beneficiaries (42 C.F.R. § 423.153(f)(16)), and makes other technical changes to these programs (42 C.F.R. § 423.153(f)(15)(ii)(D); 42 C.F.R. § 423.100). Policy and technical guidance 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 2022 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 2022 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 2022 bids.

Administrative Information

The policies described in this memo will be used in the evaluation of CY 2022 bids submitted by Part D sponsors in accordance with our negotiation authority under section1860D-11(d)(2) of the Act. Unless otherwise noted in this document or adopted in the January 2021 final rule, the guidance issued in the Final CY 2020 Call Letter applies for CY 2022 (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 CY2022:

- 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 memo in the same manner for CY 2022 as they were applied in CY 2020. We therefore are not soliciting comments on these policies. Should CMS make any changes to the Benefit Parameters or Tier Thresholds for CY 2023 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 drug management programs, please email PartD_OM@cms.hhs.gov.

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