DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop 00-00-00
Baltimore, Maryland 21244-1850

CENTER FOR MEDICARE

DATE: February 6, 2020

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) 2021 Final Part D Bidding Instructions

This memorandum contains information on the Part D program, and provides helpful instructions and reminders as Part D sponsors prepare to submit bids for CY 2021.

Formulary Submissions

CY 2021 Formulary Submission Windows

The CY 2021 HPMS formulary submission window will open this year on May 11, 2020 and close at 11:59 p.m. PDT on June 1, 2020. CMS must be in receipt of a successfully submitted and validated formulary submission by the deadline of June 1, 2020 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 1860D- 11(b) of the Social Security 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, 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 2021 formulary submissions, a subsequent limited update window will be provided in August 2020. During this window, Part D sponsors may add drugs that are new to the Formulary Reference File (FRF), and may also make negative changes to existing formulary drugs, only if the affected drug is replaced by an equivalent generic or therapeutically similar drug (at the same or more enhanced formulary placement). 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 2021 formulary submission windows will be contained in future HPMS memorandums.

CY 2021 Formulary Reference File

CMS will release the first CY 2021 FRF in March 2020. 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 2020, 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 2021 FRF prior to the June 1 formulary submission deadline. Since the OOPC model incorporates Medicare Current Beneficiary Survey (MCBS) data from 2015 and 2016, 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 2021 FRF and the June 1 deadline, CMS is unable to accommodate an updated version of the 2021 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 2021 FRF will not be included in the 2021 Bid Review OOPC model.

Medication Therapy Management (MTM)

Annual Eligibility Threshold

Per 1860D-4(c)(2)(a)(ii), targeted beneficiaries for a Part D plan's MTM program, in general, are enrollees who meet all of the following criteria: have multiple chronic diseases, are taking multiple Part D drugs, and are likely to incur annual Part D drug costs that meet or exceed a certain threshold. Per 42 C.F.R. §423.153(d), for 2012 and subsequent years, the annual cost threshold for targeting beneficiaries 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 2020 MTM program annual cost threshold is $4,255. The 2021 MTM program annual cost threshold will be the 2020 annual cost threshold adjusted based on the annual percentage increase, which will be finalized in the CY 2021 Announcement of Medicare Advantage Capitation Rates and Part C and Part D Payment Policies. Therefore, the MTM Eligibility Threshold for CY2021 will be announced at the time of the release of the CY 2021 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 2021 Part D benefit parameters for Non-Defined Standard Plans are set forth in the table below, addressing two key areas: PDP meaningful difference and tiered cost-sharing. 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 (other than defined standard) 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 cost-sharing, formulary structure, or benefits offered. 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 2021 bids.

Benefit Parameters for CY 2021 Threshold Values

	CY 2021 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	

	CY 2021 Threshold Values
1-month supply at in-network retail pharmacy	TBD[7]

[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 that was established for 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] A separate maximum cost-share threshold for the Preferred Generic tier has not been established. Cost-sharing for the Preferred Generic tier need only be lower than that for the cost-sharing of the Generic tier. Equivalent cost-sharing for the Preferred Generic and Generic tiers will not be accepted, except 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 must provide a meaningful benefit offering with 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.

[7] CMS is proposing to codify the specialty tier cost threshold methodology and calculation in the proposed 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-P), February 5, 2020, https://www.federalregister.gov/public-inspection/current. If finalized as proposed, the final threshold would be published in the corresponding final rule.

Improving Drug Utilization Review Controls in Medicare Part D

Opioid Safety Edits

Information regarding helpful reminders and recommendations as Part D sponsors prepare to implement opioid point-of-sale (POS) safety edit(s) for CY 2021, see the HPMS memo, "*Contract Year (CY) 2020 Opioid Safety Edit Reminders and Recommendations*" released on December 9, 2019. CMS released comprehensive guidance for sponsors and educational materials for providers, beneficiaries, and other partners (pharmacies, professional organizations, advocacy groups, etc.), 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 website, including the FAQs, to provide additional guidance as needed for CY2021 and future years.

Drug Management Programs

CMS codified these programs in the CY 2019 Final Rule (https://www.gpo.gov/fdsys/pkg/FR-2018-04-16/pdf/2018-07179.pdf). CMS recently proposed changes to these programs in the proposed 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-P), February 5, 2020, https://www.federalregister.gov/public-inspection/current. Any further updates to the policy for such programs, including OMS criteria, will be made in future rulemaking as necessary. Additional guidance documents 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 website to provide additional guidance as needed for CY2021 and future years.

Coordination of Benefits (COB) User Fee

Pursuant to Section 1860D-24(a)(3) of the Social Security 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 2021 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 2021 bids.

Administrative Information

The policies described in this memo will be used in the evaluation of CY 2021 bids submitted by Part D sponsors in accordance with our negotiation authority under 1860D-11(d)(2) of the Social Security Act. Unless otherwise noted in this document or proposed in the in the proposed 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-P), February 5, 2020, the guidance issued in the Final CY 2020 Call Letter applies for CY 2021 (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 CY2021:

- 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 (Stand-alone 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 2021 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 2022 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.