DEPARTMENT OF HEALTH & HUMAN SERVICES
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TO: Part D Plan Sponsors

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SUBJECT: Additional Guidance Regarding Part D Bids

On February 6, 2019, the Department of Health and Human Services published a proposed rule that would expressly exclude from safe harbor protection under the Anti-Kickback Statute (AKS) rebates on prescription drugs paid by manufacturers to Part D plan sponsors, Medicaid managed care organizations, and pharmacy benefit managers under contract with them. The rule also proposed the creation of two new safe harbors. The comment period for the proposed rule closed on April 8th.

On April 5, 2019 we announced that if there is a change in the AKS rules effective in 2020, CMS will conduct a voluntary two-year demonstration that would test an efficient transition for beneficiaries and plans to such a change in the Part D program. The demonstration would consist of a modification to the Part D risk corridors. We announced that for CY2020, under the demonstration, the government would bear or retain 95% of the deviation between the target amount, as defined in section 1860D-15(e)(3)(B) of the Social Security Act (the Act) and the actual incurred costs, as defined in section 1860D-15(e)(1) of the Act, beyond the first 0.5%.

At that time we also provided guidance regarding bids for CY2020. In particular, we specified the following practice and procedure with respect to the submission of bids: plan sponsors will submit bids for CY2020 in a form and manner that is consistent with the Anti-Kickback Statute law and regulations in effect as of the bid submission deadline, including, for the purposes of bid development, the treatment of manufacturer rebates per our existing rules and guidance related to Direct and Indirect Remuneration.

Since releasing this guidance on April 5, 2019, we answered questions during an industry call with more than 1,000 participants on April 8, 2019, and have received additional inquiries requesting clarification to our guidance. The attachment to this memo provides a series of questions and answers in response to the questions we have received pertaining to the April 5 guidance. Thank you.

Attachment: 2020 Part D Bidding Guidance

Questions and Answers

Q1: What did CMS announce on April 5 concerning the Anti-Kickback Statute (AKS) proposed rule?

A: In conjunction with the annual bidding instructions, CMS announced the availability of a potential voluntary Part D risk sharing demonstration project, conducted under Section 402 demonstration authority, to test whether alternative payment methods could increase the efficiency and economy of the Part D program without adversely affecting quality. Specifically, if a final rule eliminating safe harbor protection for drug manufacturer rebates were to be finalized and in effect in 2020, CMS would test and evaluate the use of narrowed risk corridors to provide for an efficient transition for beneficiaries and plans to significant changes in the Part D program.

Q2: What potential change in AKS rules are you referring to?

A: On February 6, 2019, the Department of Health and Human Services issued a proposed rule in the Federal Register that if finalized as proposed, effective January 1, 2020, would expressly exclude from safe harbor protection under the AKS rebates on prescription drugs paid by manufacturers to Part D plans, Medicaid managed care organizations, and pharmacy benefit managers under contract with them. The comment period for the proposed rule closed on April 8, 2019.

Q3: How do Part D risk corridors operate today?

A: If a plan's actual drug costs are up to five percent higher or lower than their bid projection, the plan is at full risk for those unanticipated losses or savings. If their drug costs exceed bid projections by more than that threshold, the government shares some of the risk through a risk corridor reconciliation that occurs after the year is over. For a plan sponsor's costs that are 5-10% in excess of the bid, risk is split 50/50 between government and plan, and for costs in excess of 10% of the bid, the government pays 80% and the plan pays 20%. Savings are also split symmetrically along this schedule if costs are below the bid.

Q4: Is CMS modifying how the target amount and allowable risk corridor costs are calculated for purposes of risk corridor reconciliation in any way under the demonstration?

A: No. CMS will calculate the target amount and allowable risk corridor costs exactly as per the existing methodology. In regards to the allowable risk corridor costs, specifically, CMS will continue to include all incurred costs related to the basic Part D benefit for Part D drugs.

Q5: Would this demonstration be voluntary or mandatory?

A: Participation in the two-year demonstration would be voluntary. Plans choosing to participate would be required to do so for both CY2020 and CY2021.

Q6: If a Part D plan (PBP) participates in the first year of the demonstration (i.e., CY2020), can it opt out of the second year of the demonstration (i.e., CY2021)?

A: No. Plans that choose to participate in this two-year demonstration, if it is effectuated, would do so for both years. This is true even if the plan's (PBP's) benefits change in year two.

Q7: How should plans account for the possibility of a change in the AKS rules in their bids? Does the specification regarding how to bid apply to non-participants?

A: For CY2020, all plan sponsors that currently submit Part D bids, regardless of planned demonstration participation, should submit bids in a form and manner that is consistent with the AKS law and regulations in effect as of the bid submission deadline, including, for the purposes of bid development, the treatment of rebates per our existing rules and guidance related to Direct and Indirect Remuneration. In other words, demo participants and non-participants should, for CY2020, submit bids that reflect AKS rules in effect as of the bid submission deadline.

Q8: When are Part D bids due for CY2020?

A: June 3, 2019.

Q9: What does CMS mean by the following phrase from the April 5 memo: "form and manner that is consistent with the AKS law and regulations in effect as of the bid submission deadline"? How should plans bid if an AKS change is finalized before the bid deadline?

A: The changes to the discount safe harbor proposed in the AKS rule, if finalized, would not take effect prior to January 1, 2020. No changes to the current AKS rules will be finalized prior to June 4, 2019. Therefore, CMS is specifying that CY2020 plan bids should be submitted in a form and manner that is consistent with the *already existing* AKS law and regulations, i.e., that they not reflect the changes to the AKS rules proposed in the February 6, 2019 NPRM.

Q10: Will the demonstration be effectuated if the AKS rule is not effective in 2020? What if the finalized rule is only effective for part of the 2020 calendar year?

A: The demonstration would only be effectuated if the changes to the AKS rules proposed in the February 6, 2019 NPRM are finalized, as determined by the Secretary, to go into effect for any part of CY2020.

Q11: Are plans allowed to have a 2020 Part D benefit structure that includes flat co-pay tiers?

A: Nothing in CMS regulations precludes a 2020 Part D benefit structure that includes flat co-pay tiers. In addition, we note the Notice of Proposed Rulemaking, "Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees," published in the Federal Register (Vol. 84, No. 25) on February 6, 2019, expressly contemplated continuation of the co-pay tier structure. Specifically, the Notice of Proposed Rulemaking stated on page 2353: "With a reduced price charged by the pharmacy, patients with coinsurance or deductible plans will likely experience reductions in cost-sharing for rebated brand-name [drugs] at the point of sale. Patients with fixed co-payments may not see changes in their cost-sharing at the point of sale outside of the deductible, coverage gap, or catastrophic phases of their

benefits. These effects will accrue to some beneficiaries through lower out-of-pocket costs and to all beneficiaries through more transparent pricing."

Q12: When and how would a Part D plan sponsor apply for the demonstration? At what level of the organization is participation determined, i.e., plan benefit package, contract, parent organization?

A: If CMS proceeds with the demonstration after publication of a final AKS rule, CMS will provide instructions on when and how a Part D plan sponsor will notify CMS that they wish to participate in the demonstration. The decision to participate will need to be made at the plan benefit package (PBP) level.

Q13: Part D risk corridors do not apply to EGWPs. Will EGWPs be able to participate if CMS proceeds with implementing the demonstration program?

A: No, EGWPs are not eligible to participate in the demonstration, if CMS proceeds with it. They will continue to be paid under the existing methodology.

Q14: Will private fee-for-service plans be able to participate in the demonstration?

A: No, private fee-for-service plans are not eligible to participate in the demonstration, if CMS proceeds with it. They will continue to be paid under the existing methodology.

Q15: Will PACE organizations be able to participate in the demonstration?

A. Yes. PACE organizations are currently subject to risk corridor reconciliation and would be eligible to participate in the demonstration, if CMS proceeds with it.

Q16: Will Section 1876 Cost Plans be able to participate in the demonstration?

A. Yes. 1876 Cost Plans are currently subject to risk corridor reconciliation and would be eligible to participate in the demonstration, if CMS proceeds with it.

Q17: Will Medicare-Medicaid Plans (MMPs) be able to participate in the demonstration?

A: Yes. MMPs are currently subject to risk corridor reconciliation and would be eligible to participate in the demonstration, if CMS proceeds with it.

Q18: For plans that participate in the demonstration, will bid, formulary, and benefit information submission requirements and reviews be modified from established policy and guidance provided in the CY2020 Final Call Letter? Will the deadlines included in the Call Letter be modified? Will there be any changes to the total beneficiary cost or meaningful difference requirements?

A. No. The bid, formulary, and benefit information submissions and reviews will be conducted in accordance with the policies and guidance specified in the CY2020 Final Call Letter. All deadlines included in the Call Letter are still applicable. The total beneficiary cost requirements for CY2020 will also remain unchanged.

Q19: Will CMS be increasing the Part D de minimis amount for CY2020?

A: CMS will determine the de minimis amount based on the bids submitted and will announce the policy per our normal timeline, in the summer prior to the beginning of the contract year.