

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
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**DATE:** April 5, 2019  
**TO:** Part D Plan Sponsors  
**FROM:** Seema Verma  
**Administrator**  
**SUBJECT:** 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 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 closes on April 8<sup>th</sup>.

If there is a change in the safe harbor rules effective in 2020, CMS will conduct a 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 for plans for which a bid is submitted. 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%. Participation in the two-year demonstration would be voluntary and plans choosing to participate would do so for both years. Under the demonstration, further guidance regarding the application process would be provided at a later date.

We have received questions about how plans should account for the possibility of a change in the safe harbor rules. For CY2020, CMS is specifying 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.