

# Issue Brief

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## CMS Takes Action on DIR Fees and Restricted Distribution in Part D Proposed Rule

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### Background

CMS's recently released Part D proposed rule, [Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program](#), includes a number of changes that ASHP and other stakeholders sought from the agency.

### *Direct and Indirect Remuneration (DIR) Fees:*

The proposed rule includes policies that would increase transparency around the actual reimbursement amount a Part D pharmacy will receive. CMS proposes that direct and indirect remuneration (DIR) fees, as well as any other pharmacy price concessions, be reflected at the point-of-sale, rather than clawed back at a later date. Additionally, CMS notes that the point-of-sale price should also reflect any incentive payments to the pharmacy (CMS refers to these as "negative DIR") in order to ensure the point-of-sale price accurately reflects total pharmacy reimbursement. CMS has also requested broad feedback from stakeholders regarding how rebates might be shared with beneficiaries to reduce their out-of-pocket costs.

### *Specialty Pharmacies and PBM-Specific Limitations:*

The proposed rule reiterated CMS's longstanding policy that PBMs restrict distribution of Part D drugs to certain specialty pharmacies in contravention of Medicare's convenient access protections. This change likely responds to concerns stakeholders have raised about PBMs restricting distribution of certain Part D drugs to specialty pharmacies in their networks by imposing onerous accreditation or credentialing criteria.

While the proposed rule's changes would be applicable only to Part D medications and transactions, these issues are also occurring in Part B. ASHP is optimistic that CMS will translate similar transparency and access protections to the Part B arena in the coming years. Alex Azar, the nominee for Secretary of the U.S. Department of Health & Human Services, also expressed support during congressional hearings for the implementation of similar provisions in the Part B space. In addition to continuing our advocacy around the issues in Part B, ASHP will submit comments to CMS on the proposed rule by the January 16<sup>th</sup> deadline.