Proposed Drug Rebate and PBM Service Fee Regulations Abandoned by Administration

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by Alissa Smith and Laura B. Morgan

As reported here in February, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) released two new significant proposed regulations that would have had a transformative effect on the drug discount and rebate arrangements that are commonplace between pharmaceutical manufacturers and Medicare Part D Plans and Medicaid Managed Care Organizations (and the pharmacy benefit managers (PBMs) acting on their behalf). The Administration's goal with these proposed regulations was to reduce prescription drug prices. However, in July, the Administration abandoned these proposed regulations (as shown on the Office of Management and Budget website) out of concern that they would actually have the opposite effect and result in increased drug prices. President Trump reportedly became concerned after the proposals received significant support from the pharmaceutical companies.

The proposals would have eliminated the current federal anti-kickback statute (AKS) safe harbor protection relied upon by manufacturers and PBMs for the rebates paid by manufacturers to PBMs for certain drugs. In its place, the OIG proposed a much more narrow safe harbor that would have only applied if the reduced price from the manufacturer was fixed in advance and disclosed to the plan, the full value of the price reduction was disclosed to the pharmacy through a chargeback to ensure that the total payment to the pharmacy for the drug was no less than what the health plan (or PBM on its behalf) paid to the manufacturer for the drug, and the reduction in the drug's price was completely applied to the price charged to the patient at the point of sale.

At the same time, the OIG also proposed a new PBM service fee AKS safe harbor that would

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have protected payments by manufacturers to PBMs for certain services provided by PBMs, but with strict requirements for the manufacturer and PBM to have a written agreement for the services which set the compensation for the services in advance at a rate that is consistent with fair market value and not based on the volume or value of any referrals or other business generated between the parties or the health plan. The proposed service fee safe harbor would have also required the PBM to annually disclose such arrangements, services and compensation to the health plans and to the Secretary of HHS upon request.

The Administration has been vocal about its goal of reducing drug prices for patients. So, we expect alternative action in the future which could take the form of legislation rather than the rule-making process.

We are continuing to closely monitor changes in the area.