A new White Paper by the law firm of Frier Levitt, LLC examines the ongoing practice by Pharmacy Benefit Managers (PBMs) to increase corporate profits through murky “direct and indirect remuneration” fees—commonly known as “DIR Fees”—charged to community oncology practices, as well as retail and specialty pharmacies (“Pharmacy Providers”).

DIR Fees, which have no basis in regulation or law, artificially inflate the costs paid by Medicare beneficiaries for prescription drugs, pushing them into the Medicare Part D “donut hole” faster, fueling rising drug prices, and ultimately adding to the burden on taxpayers.

**PBMs must report all discounts given after the drugs are sold to CMS. These are called “Direct and Indirect Remuneration” or “DIR.”** PBMs often receive additional discounts from manufacturers after the initial sale of drugs to patients. These include such things as manufacturers’ rebates and co-pay assistance programs. Discounts change the final cost of the drugs and CMS wants to be able to calculate reimbursement on the final, lowest price paid. DIR is a legitimate concept that helps CMS improve transparency in the Medicare Part D program.

**PBMs have twisted this into a made-up term broadly known as “DIR Fees” which only serve to generate profits.** These include a variety of different fees with different names including “performance fee” or “PNR” fees. DIR Fees are calculated as a percentage—up to 9% of the list price of cancer drugs and other expensive therapies—under the guise of metrics made up by the PBM to assess “performance” or “quality.” They are charged several months after the drugs have been dispensed to patients and Pharmacy Providers reimbursed. DIR Fees only serve to increase PBM profits and have no basis in regulation or law.

Patients are forced to pay a higher price for drugs because of DIR Fees while PBMs profit at their expense. Because of DIR Fees, patients are forced to pay for drugs at a higher list price, while PBMs profit at their expense. The higher initial drug costs push patients into the “donut hole” faster, which means patients and Medicare pay more.
DIR Fees Unfairly Accelerate the Triggering of Medicare Part D’s “Donut Hole.” Assume a Medicare patient pays $290 per month for a drug at the point-of-sale. After twelve $290 fills, the patient will be in the “donut hole” and will be responsible for a higher cost sharing amount for all prescriptions until they exit the “donut hole.” However, if the point-of-sale price did not include the 5.5% DIR Fee that is subsequently clawed back by the PBM, the patient would have never reached the “donut hole” to begin with.

CMS estimates that more than 25% of all Part D participants in the “donut hole” will discontinue prescription their drug regimens because of the much higher out-of-pocket costs they face. This disruption of treatment translates into poorer health care and outcomes, costing Medicare even more money in the form of more frequent doctor visits and expensive hospital admissions.

**DIR Fees have no legitimate basis in regulation or law.** The only purpose they serve is to create additional profit for the PBMs. There is little evidence that retroactive DIR Fees are ever reported to Medicare, which further disguises actual drug costs. CMS is unable to determine the full extent of DIR Fees and their impact on the health care system. Percentage-based DIR Fees are fueling rising drug prices because PBMs have a vested interest to drive up drug prices by extracting higher rebates from pharmaceutical manufacturers.

**Legislative and regulatory action on DIR Fees is needed by CMS and Congress.** PBM imposed DIR Fees have a drastic financial impact on patients, the Medicare Part D program, and Pharmacy Providers. PBMs have exceeded their administrative authority by implementing DIR Fees. Action is needed, both by CMS, under the Trump Administration, and Congress.


**About the Community Oncology Alliance:** The Community Oncology Alliance (COA) is a non-profit organization dedicated solely to preserving and protecting access to community cancer care, where the majority of Americans with cancer are treated. COA leads community cancer clinics in navigating an increasingly challenging environment to provide efficiencies, patient advocacy, and proactive solutions to Congress and policy makers. To learn more about COA visit [www.CommunityOncology.org](http://www.CommunityOncology.org).