Direct and Indirect Remuneration Fees: The Controversy Continues

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Abstract

The Centers for Medicare and Medicaid Services (CMS) initially created direct and indirect remuneration (DIR) fees with the enactment of Medicare Part D in order to track rebates and other price adjustments made to pharmacy benefit managers (PBMs). PBMs have expanded the use of these fees to “claw back” money from pharmacies on already dispensed medications. Community and specialty pharmacies claim these fees are not transparent, hurt patients and taxpayers, and negatively impact their fiscal bottom line, while PBMs assert that these fees actually reduce premiums for patients. Congress has stepped into the dispute by introducing legislation that would halt retroactive DIR fees.

Keywords

legal aspects, pharmacists, education, managed care

The Centers for Medicare and Medicaid Services (CMS) initially developed the concept of direct and indirect remuneration (DIR) fees upon the enactment of the Medicare Modernization Act of 2003.^{1,2} This Act created the Medicare Part D prescription drug benefit.³ CMS contracts with various plan sponsors (eg, UnitedHealth Group, Humana, etc) to administer Part D plans for enrollees. These plan sponsors subsequently contract with pharmacy benefit managers (PBMs) to manage the drug benefit of Part D. PBMs, such as Express Scripts or CVS Caremark, contract with pharmacy providers, negotiate reimbursement rates, and process medication claims. As part of these functions, PBMs negotiate rebates from pharmaceutical manufacturers or establish other price adjustments to prescription drugs that ultimately lower the overall drug costs for Medicare Part D plans.^{2,4} DIR fees were originally intended as a way for CMS to track the annual amount of these rebates and price adjustments so that it can appropriately and legally base reimbursement on the lowest price. However, over time, the original meaning of DIR fee has expanded considerably.

Today, a DIR fee has essentially become a “catch all” term used by PBMs that encompasses many different fees including costs for pharmacies to participate in a Part D preferred network, price reconciliations based on contractual rates, compliance fees for contract-based performance metrics, or a combination of these fees.^{1,5} The actual amount of these fees may range from \$2 to as high as \$12 per claim or may even be a percentage amount per claim.⁵ This expansion of DIR fees has resulted in controversy. Community and specialty pharmacies argue that these fees are really a means for PBMs to contractually “claw back” millions of dollars from pharmacies on medications that are already dispensed. Often, pharmacies

note that DIR fees are charged back to them months after the point-of-sale and that a lack of transparency in contract wording makes pharmacies unable to accurately estimate how much money will be owed to the PBM. In addition, the National Community Pharmacists Association and the Community Oncology Alliance argue that the new DIR fees negatively impact patients and taxpayers.^{1,2} These organizations argue that PBM DIR fees result in increased out-of-pocket costs by driving patients more rapidly into the Medicare Part D “donut hole” where they become responsible for a greater portion of prescription costs.⁶ In addition, this could eventually lead to taxpayers being on the hook for a significant portion of a patient’s health care costs if expenses mount and a patient is pushed beyond the donut hole into Medicare’s catastrophic coverage phase. PBMs obviously have a different take on these fees, stating that PBMs and DIR fees improve patient care by reducing premiums and that eliminating these fees is only a ploy to increase profits for community and specialty pharmacies.⁷

The controversy surrounding DIR fees has even caught the attention of Congress. In early 2017, bipartisan legislation was introduced in both the House and the Senate that aims to halt retroactive DIR fees on prescription drug claims.^{8–10} The “Improving Transparency and Accuracy in Medicare Part D Spending Act” states that PBMs “may not retroactively reduce payment on such claim directly or indirectly through

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aggregated effective rate or otherwise except in the case such claim is found to not be a clean claim.” Despite the Act’s introduction in both Houses of Congress, forward progress has been slow and there is no specific timeline for when the bill may be officially considered.

In summary, DIR fees were initially created by CMS with the enactment of Medicare Part D to track rebates and other price adjustments made to PBMs. More recently, PBMs have expanded the use of these fees to “claw back” money from pharmacies on already dispensed medications. Community and specialty pharmacies claim these fees negatively impact their finances, are not transparent, and hurt patients and taxpayers while PBMs assert that these fees actually reduce premiums for patients. Congress has stepped into the dispute by introducing legislation that would halt retroactive DIR fees. However, until movement on this legislation occurs, pharmacies should perform due diligence when evaluating PBM contracts and make sure that they understand all of the potential fees to minimize disruption to their business.¹

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