Pharmacy Benefit Managers (PBMs)

ASCO®
AMERICAN SOCIETY OF CLINICAL ONCOLOGY

POLICY BRIEF

KEY TERMS

Direct and Indirect Remuneration (DIR) Fees – Originally authorized under the Medicare Modernization Act of 2003 in order to help keep drug reimbursement low, the Centers for Medicare & Medicaid Services (CMS) defines DIR as additional compensation received after the point-of-sale that serves to change the final cost of the drug for the payer. Through DIR fees, plan sponsors and PBMs are required to report all "direct" and "indirect" remuneration received from third-parties, including drug manufacturers (sometimes weeks or months after a prescription was filled). Retroactive DIR fees resulted in dispensing pharmacies discovering too late that they did not recoup their costs or even owed additional money to the PBM. The practice of retroactive DIR fees was prohibited by CMS starting in 2024.

Pharmacy Benefit Manager (PBM) – Originally created to serve as third-party administrators of pharmacy claims, PBMs now leverage their market power to obtain lower prices on drugs. Employers and other plan sponsors also use PBMs to outsource the complicated work of designing and maintaining formularies to those with more specialized expertise.

Background

The Center for Medicare and Medicaid Services (CMS) has reported that spending on prescription drugs in America reached $348 billion in 2020.[1] By some estimates, between 85-90% of this market flows through the three largest pharmacy benefit manager (PBM) companies nationwide.[2] Originally designed to help control health insurance program drug spending in newly offered prescription drug benefits, PBMs now work with a vast array of actors in the pharmaceutical supply chain, including manufacturers, wholesalers, pharmacies, and health insurance providers. They primarily serve to negotiate and facilitate payments within this complex system, and largely do not have any direct role in the actual, physical distribution of prescription drugs (though trends toward the integration of PBMs, payers, and specialty pharmacies complicate this assessment).

Leveraging their tremendous market power, PBMs are able to negotiate lower drug prices for the health insurance plans with which they partner. Although this has the potential to generate cost savings for payers and plan sponsors, publicly available studies remain conflicted as to whether those savings necessarily accrue to patients.[3,4]

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[1] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet
[2] National Academy of Sciences, Engineering and Medicine. 2017. Making Medicines Affordable: A National Imperative. Washington, DC: The National Academies Press. Available at https://doi.org/10.17226/24946.
[3] Robert Goldberg, Drug Costs Driven by Rebates, Center for Medicine in the Public Interest. http://bionj.org/wp-content/uploads/2015/11/drug-costs-driven-by-rebates.pdf.
[4] https://www.gao.gov/products/gao-19-498

Concerns for ASCO Members & the Cancer Community

Because PBMs participate in plans that cover so many lives, they have significant influence over the way patients access their medications. In 2018, ASCO released a position statement on PBMs and cancer care, and highlighted numerous areas of concern that could potentially erode access to drugs and impede high quality care.

The role of PBMs in enforcing utilization management (UM) is a key concern. While PBMs are not insurers, they may share the responsibility for enforcing UM policies such as: (i) prior authorization requirements, (ii) restrictive formularies, (iii) step therapy (fail-first) requirements, and (iv) specialty tiers. The potential negative impact of poorly deployed UM policies, and their impact on quality of cancer care, was explored in a 2020 position statement from ASCO. In particular, the inappropriate and excessive use of prior authorization has reached a breaking point, with ASCO joining the American Medical Association and many other medical specialty societies in calling for transparency, streamlined processes, and increased accountability. ASCO has also recently released a new position statement specifically addressing prior authorization practices.

PBMs are increasingly shifting drug dispensing away from physicians and toward pharmacies they own or with which they are affiliated (so-called "patient steering"), which can negatively impact patient care and access.[5] PBMs actively incentivize—and in some cases require—patients to use mail order or specialty pharmacies in lieu of a dispensing physician. Such actions are problematic, as it means PBMs are both competing and determining reimbursement rates for pharmacists. Similarly, the degree to which PBMs are responsible for increases in brown bagging (when a specialty pharmacy ships infusion drugs directly to patients) or white bagging (when a specialty pharmacy ships a patient's infusion drugs to physician offices) is another concern. ASCO has previously stated its concerns about payer policies that require oncologists to administer chemotherapy agents that have been prepared outside the physician's office by an entity under contract with the payer, and for which oncologists assume full liability without having control over chain of custody.

While some concerns such as gag clauses (which prevented pharmacists from informing patients of the lowest cost option to obtain a prescription) have been recently prohibited, other concerns remain. PBMs assert there is no link between drug price growth and the rebates they are receiving.[6] However, the lack of transparency around rebate arrangements prevents the verification of such claims, as well as ascertaining the degree to which patients are benefitting from rebates and discounts. ASCO members have also reported that some patients have had their medication or dosage changed by PBMs without prior approval by the treating physician. Taken together, the impact of such PBM practices on oncology care providers and patient quality of care is increasingly apparent.

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[5] Pharmacy Benefit Managers' Attack on Physician Dispensing and Impact on Patient Care: Case Study of CVS Caremark's Efforts to Restrict Access to Cancer Care Prepared by Frier Levitt, LLC Commissioned by the Community Oncology Alliance, August 2016.

[6] Pharmaceutical Care Management Association. No Correlation Between Increasing Drug Prices and Manufacturer Rebates in Major Drug Categories. https://www.pcmanet.org/wpcontent/uploads/2017/04/Visante-Study-on-Prices-vs.-Rebates-By-Category-FINAL-3.pdf.

Where ASCO Stands on PBMs

Promoting delivery of high value care to every patient with cancer is central to ASCO's mission. ASCO understands and shares concerns about escalating costs and their impact on patients. However, strategies for controlling drug costs must not compromise oncologists' ability to provide the right care, at the right time, for all their cancer patients.

Recommendations in ASCO's 2018 position statement on PBMs included the following items, some of which have now been resolved at the federal level as a result of subsequent or rulemaking from CMS:

- PBMs and the payers with whom they work for should take immediate steps to address quality of care concerns related to the cancer patients they serve, including assuring that changes to prescribed therapy for patients with cancer are made only in the context of prior consultation and approval of their physician.
- Pharmacies should not be prevented from sharing with patients their most cost-effective option for purchasing needed medications (i.e., no gag clauses). To this end, CMS should eliminate contractual requirements that prevent pharmacists from sharing with patients their most cost-effective option for purchasing required medications.
- CMS should leverage its regulatory authority to: 1) require that PBMs provide detailed accounting of DIR fees, and 2) instruct contractors and PBMs to discontinue application of current Star performance ratings and related DIR claw backs on oncology dispensing physicians and practice-based pharmacies, instead relying on measures and standards that are more appropriate to the specialty.
- CMS should enforce its "Any Willing Provider" provision in Medicare Part D, preventing PBMs from excluding qualified in-office dispensing or provider led pharmacies from its networks.
- CMS should consider extending use of the JW modifier to better identify sources and cost of waste related to chemotherapy drugs in both Part B and Part D. Such data should be made public. Private payers should consider similar strategies.
- Pharmacy and Therapeutics committees should include full and meaningful participation by oncology specialists.

For More Information

American Society of Clinical Oncology Position Statement: Pharmacy Benefit Managers and Their Impact on Cancer Care

American Society of Clinical Oncology Position Statement: Copay Accumulators and Copay Maximizers

American Society of Clinical Oncology Position Statement: Prior Authorization

American Society of Clinical Oncology Position Statement: Impact of Utilization Management Policies for Cancer Drug Therapies