

EFFORTS TO ENHANCE PRESCRIPTION DRUG PRICING TRANSPARENCY GAINING TRACTION: IMPLICATIONS FOR PHARMACY STAKEHOLDERS

Driven in part by retroactive fees imposed upon pharmacies by pharmacy benefit managers ("PBMs") and compounded by recent high profile cases of significant price increases for relatively common drugs,¹ both retail and institutional pharmacies have continued to push for enhanced prescription drug pricing transparency. Recent state and federal legislation, as well as lawsuits filed by coalitions of pharmacy providers and their representative affinity groups, suggests growing and significant inertia moving toward this goal. Not only should pharmacy stakeholders closely monitor these developments, they should carefully consider the underlying issues and their potential impact when contracting for pharmacy benefits coverage.

One of the most prominent examples of these developments is the legislation that was recently introduced in the U.S. Senate and House of Representatives that would prohibit Medicare Part D plans and their contracted PBMs from retroactively reducing payments to pharmacies for clean claims submitted at the point of sale. These retroactive fees are implemented via what are commonly referred to as direct and indirect remuneration ("DIR") fees. Additionally, approximately 31 states now have laws requiring transparency surrounding maximum allowable cost ("MAC") pricing caps commonly utilized in PBM contracts with more in development. These examples, in addition to increased scrutiny of PBM practices by various state and federal agencies, serve as a reminder to pharmacy network participants to carefully consider the terms of their PBM contracts since enhanced price transparency protections, while beneficial, may not sufficiently protect the interests of participating pharmacies.

This article discusses pending state and federal legislation impacting pharmacy claims payment and addresses how pharmacy network participants of all types - including pharmacies, PBMs and individual consumers - may be affected by upcoming changes in the law.

BACKGROUND & DISCUSSION

DIR and Increased Transparency for Pharmacies

With the implementation of Medicare Part D, the Centers for Medicare & Medicaid Services ("CMS") coined the term DIR to refer to price concessions and fees impacting the price of a drug that are not captured at the point of sale. These include any number of fees charged to pharmacies by prescription benefit plans and PBMs after the point of sale, such as fees for network participation, periodic reimbursement reconciliations and to incentivize compliance with certain quality measures. Each year, CMS requires Part D plan sponsors to report drug costs and DIR associated with the Medicare prescription drug benefit, though the wide ranging nature of DIR fees often results in ambiguity about the detail behind the components of DIR charges to pharmacies. This has served to obscure true reimbursement amounts for drugs and to create uncertainty regarding anticipated reimbursement for pharmacies during the payor contracting process.

To counteract this uncertainty that can make it difficult for pharmacies to prepare reliable budget assumptions in conjunction with the commencement of a new plan or PBM contract, CMS and Congress have indicated a willingness to bring about more transparency related to DIR via statutory mandates. These efforts were in part initiated as a result of the fact that in 2014 CMS proposed guidance that would have required Part D sponsors to publish all DIR fees that could reasonably be determined at the point of sale for the contract year 2016. However, despite support from Congress and network pharmacies, CMS ultimately decided not to finalize the guidance.

In part due to CMS's decision not to require enhanced reporting of DIR fees, bipartisan support in both the Senate and the House of Representatives in September of this year resulted in parallel bills ([S. 3308](#) and [H.R. 5951](#)) that would prohibit Medicare Part D plan sponsors and PBMs from retroactively reducing claim payments submitted by pharmacies under Medicare Part D. More specifically, this legislation would require contracts between a Part D sponsor (or the sponsor's agent or PBM) and a pharmacy to include language prohibiting the Part D plan sponsor or agent from retroactively reducing payments to the pharmacy (either directly or indirectly) for clean pharmacy claims. Retroactive *increases* in payment to a pharmacy by a sponsor (or the sponsor's agent) would be permitted. Beyond the obvious benefits to participating network pharmacies, the [National Community Pharmacists Association](#) has stated that it believes that the proposed legislation would also serve to lower cost-sharing for consumers since the DIR fees would be reported to CMS as pharmacy price concessions at the point of sale.

Perhaps lending additional inertia to legislative efforts to mandate DIR fee transparency, the recently released **2017 Office of Inspector General ("OIG") Work Plan** notes that prices for the most commonly used brand-name drugs have risen substantially since 2002. OIG announces in the Work Plan that it will evaluate the extent to which corresponding pharmacy reimbursement for brand-name drugs under Part D changed between 2011 and 2015 in light of the rate of inflation for the same period.

Increased Transparency from PBMs

PBMs provide various pharmacy benefit management services to payors. These include claims processing, pharmacy network development and maintenance, drug formulary development and manufacturer discount and rebate agreement development. Since PBMs manage prescription drug benefits for the majority of Americans, this serves to aggregate their bargaining power.

While this consolidated approach has resulted in enhanced bargaining power for PBMs generally, it has also invited scrutiny from consumers, legislators, insurers and pharmacies seeking to understand the exact nature of the relationships cultivated by PBMs and virtually every participant in the pharmaceutical supply chain. For example, Express Scripts, the largest PBM in the United States, recently received subpoenas from U.S. Attorney's Offices in New York and Massachusetts. In New York, the government requested information about Express Scripts' relationships with pharmaceutical manufacturers and prescription drug plan clients, including payments made to and from those entities. In Massachusetts, the government sought information about the relationships between Express Scripts, pharmaceutical manufacturers, independent 501(c)(3) charities providing cost-sharing assistance to federal health care program beneficiaries and specialty pharmacies. These examples further illustrate the increased national focus on transparency in prescription drug pricing and the critical role that PBMs play in such arrangements. As key players in policy-making and law enforcement seek reasons behind spiking drug prices and introduce more transparency into the system, PBMs like Express Scripts can expect heightened scrutiny from legislators and investigators.

MAC Legislation

The MAC refers to the maximum amount that a health plan will reimburse a pharmacy for a given strength and dosage of a generic drug or brand name drug that has a generic version available. Currently, there is no singular standard regarding the inclusion of drugs on a PBM or plan's MAC list or for the methodology as to how exactly a PBM or plan will determine or update the MAC for a particular drug. As a result, PBMs and plans have historically enjoyed discretion in determining pricing for drugs on a MAC list. This latitude resulted in frustration that in turn led to relatively widespread state and federal legislative and regulatory efforts to increase MAC transparency.

At the federal level, CMS issued a **Final Rule** in 2014 that functionally requires disclosure by Part D plan sponsors of various pricing standards, including MAC standards and other publicly or non-publicly available costs. The Final Rule requires Part D plan sponsors to "[u]pdate any prescription drug pricing standard . . . based on the cost of the drug used for reimbursement of network pharmacies by the Part D sponsor on January 1 of each contract year and not less frequently than once every 7 days thereafter." Additionally, Part D plan sponsors must indicate the sources used for making any updates to their prescription drug pricing standard.²

At the state level, approximately 31 states passed MAC laws requiring PBMs to disclose and update their MAC sources and pricing information. For example, Wisconsin now requires PBMs to update MAC pricing information at least every 7 business days, reimburse for prescribed drugs or devices subject to this updated MAC information, and eliminate drugs from the MAC list or modify MAC in a timely fashion consistent with prescribed drug or device availability and pricing changes in the marketplace.³ Furthermore, laws in states like Minnesota include additional provisions requiring contracts between PBMs and pharmacies to include appeal, investigation and dispute resolution provisions related to MAC pricing.⁴

PRACTICAL TAKEAWAYS

Recent legislative and investigatory actions on both the state and federal levels reflect an increasing desire for transparency in prescription drug pricing. Therefore, health care entities such as pharmaceutical manufacturers, PBMs, pharmacies, payors and other health care providers responsible for or affected by drug pricing should carefully design, implement and monitor their contracts, programs and policies to acknowledge pricing transparency trends and to ensure compliance with the changing environment. This should include efforts to ensure careful attention is paid to contract terms and to ensure both state and federal legislators consider the practical implications of any proposed changes in the law. Given the increased state and federal legislative interest in DIR fees and MAC transparency, for example, pharmacy stakeholders should consider reaching out to their legislative advocacy teams to monitor updates or changes in laws affecting topics such as DIR fees, MAC pricing standards and pharmacy appeal rights and deadlines (among others). Additionally, stakeholders should work with their contracting teams to ensure that applicable laws are appropriately incorporated into their pharmacy, PBM and payor agreements.

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