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The Ripple Effects of Pharmaceutical Reform:

PBMs and Direct-to-Patient Models

Whitepaper

June 2026

Recent upsets in pharmaceutical contracting and sales processes are poised to fundamentally alter how the industry's market operates.

Pharmacy Benefit Manager (PBM) reform—a mix of federal policy and litigation outcomes aimed at reducing the differential between list and net prices for pharmaceuticals—and Direct-to-Patient sales models aimed at offering patients close-to-net price transparency at the point of sale, are couched as tactics for lowering patient costs, increasing transparency, and cutting out the middlemen. But third-party payers will have steep revenue consequences, and as a result, prices for patients may rise.

From landmark federal lawsuits like the Federal Trade Commission's (FTC) recent settlement with Express Scripts, to the rise of Direct-to-Patient startups, the traditional "list-to-net" pricing system has been flipped upside down. Manufacturers must prepare for downstream effects of these sweeping policies.

The FTC, PBMs, and Rising Premiums

The FTC's landmark litigation against three major PBMs has resulted in one settlement with Express Scripts. This settlement is a major step toward delinking rebates and eliminating what many consider bad-faith pricing practices. The broader goal is to shift the market from a hidden gross-to-net strategy to transparent, net-based pricing.

Patient out-of-pocket costs have historically been based almost exclusively on list price. If drug pricing trends continue to shift toward lowering out-of-pocket patient costs (which a coinsurance model based on net price would support), the insurer will be paying more for each patient that fills a prescription. For the insurer to offset those costs, patient premiums will almost certainly increase. Negative public perception of premium increases is likely to follow, as was observed in the past open enrollment period for ACA exchange plans, with some patients paying over $1,000 a month in premiums to maintain their coverage.

Completely upsetting this system carries significant downstream risks. Historically, insurers and Managed Care Organizations (MCOs) have relied heavily on PBM rebate revenue to offset their overall costs. With some patients already facing massive premium hikes, critical questions remain: Is radical drug price transparency worth the drastically higher monthly premiums for patients? Do the benefits outweigh the costs in disrupting this channel?

The Complications of the Direct-to-Patient (DTP) Model

There are many commercial scenarios in which DTP is not a viable pricing and commercialization strategy and does not result in patient savings. For specialty drugs, but also specialty-lite and even high-priced retail drugs, DTP results in a cash price that is more expensive for patients than their insured price would be. For example, a discounted rate of $200 in the DTP model would be more unaffordable in both the short and long term than a $50 branded drug insurance copay. Many manufacturers cannot afford to offer cash prices low enough for individual patients to mediate the difference in price.

However, the value of the DTP model in certain channels is clear, and it has radically reduced prices for some drugs with extraordinary economic benefits across population health.

DTP is very beneficial in the following specific niches:

- **Lifestyle & Access-Challenged Drugs:** Middle to upper-middle-class patients that are willing to pay cash for therapies like GLP-1s or fertility medications can completely avoid insurance hurdles and prior authorizations.

- **On-Demand or Acute Therapy Needs:** Patients who need refills or small amounts of medication immediately (like an acute migraine medication), and cannot wait for their traditional insurance to approve it, would benefit from DTP models.

- **Late-to-Market Manufacturers:** An 8th-to-market drug could heavily discount its cash price in the DTP model and win some market share if it cannot successfully compete in traditional channels.

Navigating the Market Disruptions

Many factions are trying to address the latest market upset including companies like our own, the life sciences industry as a whole, the FTC, the legal system, and others.

Net first policies are complicated. Less coinsurance will be received by payers who will in turn need to make up the loss or risk going out of business as recently observed in the Part D market. Negative public perception of the Affordable Care Act premium increases is likely to follow a net first global market pricing strategy for the U.S.

Whether it's PBM reform or the uncertainty of DTP savings, there is no perfect system for drug pricing and in each strategy, there are trade-offs for patients and manufacturers alike. With such a deeply interconnected ecosystem of manufacturing, pricing, insurance, and patient needs, major disruption in one sphere has rippling effects in all the others.

A radical market takeover of DTP with patient premium increases would create chaos, but in certain channels with certain patient types, a net first strategy can be extremely beneficial to patients.

There is deep complexity with recent pharmaceutical reforms and the market will continue to react to them over the next few years.

To get a deeper analysis of what manufacturers should be considering to solve these problems for themselves, check out our white paper on our website - *The Policy-Driven PMA Pivot Series*

Navigating disruption from pricing negotiations and newly introduced models requires a customized strategy. There is no one-size fits all approach. Contact Triangle Insights Group to discuss how these emerging channels and policy shifts will impact your specific asset's lifecycle.

Reach out to Triangle Insights Group today

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