Dark Territory: Lifting The Veil On GPOs And PBMs

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by Robert Burns |

Executive Summary

Based on a new report by the Wharton School, this article tackles criticisms against the intermediaries that connect buyers and sellers, the GPO and PBM. It also analyzes the existential threats facing these intermediaries such as 'safe harbors', threats of disintermediation, and the consolidation of suppliers.

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"Dark Territory" describes a section of railroad track not controlled by any signals. There are safety concerns due to the absence of train detection. There is a lessened ability to detect mis-alignment in track switches, broken rails, or runaway rail cars. It is dark and mysterious.

Health care's version of dark territory consists of intermediaries that connect buyers and sellers. Often, these intermediaries are widely mistrusted and vilified. They seem out of control, lack transparency and federal regulation, act in ways that reportedly threaten patient safety, make a lot of money without making anything, and are viewed with suspicion. During the 1990s, health maintenance organizations (HMOs) constituted the dark territory. The criticisms of HMOs then pale in comparison with the invective leveled over the past two decades at two other intermediaries: group purchasing organizations (GPOs) and pharmacy benefit managers (PBMs).

This article, based on a new report from the Wharton School, takes readers through this dark territory. The allegations against GPOs and PBMs include: monopoly power, anticompetitive behavior, collusion with

manufacturers, exclusive contracts, market foreclosure of small and innovative firms, financial ties with suppliers that mitigate search for the best products at the lowest cost, reduced provider discretion and patient access to needed technologies, conflicts of interest, preoccupation with growing revenues, excessive fees and profits, kickbacks, secret rebates, lack of full disclosure, harms to patient quality, and higher consumer costs. Most of these allegations are mentioned in just one newspaper story.

FTC Launches 'Colonoscopy' Into PBM Practices, Including Focus On Consumer Costs, Access

By Cathy Kelly

08 Jun 2022

Study will examine how the six largest pharmacy benefit managers in the US handle 10 disease categories. Federal Trade Commissioners unanimously support inquiry after its scope was broadened from an earlier version that drew objections from Republicans.

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The article evaluates these claims against several bodies of evidence. These include the historical GPO and PBM chronicle, the agency roles they play on behalf of hospitals and insurers, respectively; the documented tradeoffs made regarding access, cost, and quality while serving their hospital and insurer clients, the difference between static versus allocative efficiency and how intermediaries serve the former but rarely the latter, and the growing concentration in US health care.

The article also analyzes the existential threats facing these intermediaries such as 'safe harbors', threats of disintermediation, and the consolidation of suppliers. The article concludes that GPOs and PBMs are nowhere near the villains that their critics have painted them to be.

Some History Lessons

Critics of GPOs and PBMs rarely bother to examine their history. The narrative has (until now) never been pulled together from archival and eyewitness sources, which requires a lot of homework. As former President Harry Truman said, "the only thing new in the world is the history you don't know." The lessons from this narrative do not support the allegations and conclusions of the critics.

GPOs And PBMs Have Historically Served The Interests Of Local Providers

GPOs were established by local councils and consortia of hospitals as voluntary associations to pursue joint purchasing of commonly needed products, and to reduce their input costs. Many early GPOs were cooperatives organized at the

Biosimilars Forum Welcomes PBM Transparency Act

By Chloe Kent

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community level as efforts to develop mutual leverage (over suppliers) for their joint benefit, i.e. to save money.

The early PBMs similarly began as local cooperatives providing medical and pharmaceutical services to community members through prepaid groups on a capitated basis. They were less health care insurance and more health care assurance providers. They were typically organized around HMOs that provided both medical and pharmacy benefits to cover the total health care needs of their enrollees under an affordable budget. The early PBMs were thus tied to health insurers, just like they are today.

Today, following the decline of HMOs, GPOs and PBMs serve providers of health services but neither supply these services nor charge for them. They are at least one or more degrees of separation from where health care costs and quality are rendered. Efforts by critics to lay the responsibility for rising health care costs or harms to patient quality at their feet are misguided.

Senators Maria Cantwell and Chuck Grassley have introduced a bill which would limit pharmacy benefit managers' ability to engage in "unfair and deceptive" business practices, a move which has been welcomed by the Biosimilars Forum.

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GPO And PBM Leverage Over Product Suppliers

GPOs and PBMs sought to amass purchasing volume to negotiate lower prices from product manufacturers. GPOs aggregated the purchases of independent hospitals; HMO-PBMs combined the prescription orders of scores (and then hundreds) of physicians on their medical staffs. Both routed these orders through a centralized negotiating hub to contract as "one" with manufacturers. The game has always been one of "leverage" over suppliers and exchange of higher buyer volumes for lower unit price. This game became more important for survival and customer service with intensification of input cost pressures and/or reimbursement pressures. When squeezed downstream, GPOs and PBMs sought to squeeze manufacturers upstream.

GPOs And PBMs As Agents Of Providers And Health Plans, Respectively

GPOs and PBMs seek to exert leverage over suppliers, not over their hospital or health plan sponsors. Their actions are thus consistent with being 'agents'. Surveys of hospitals and health plans confirm this agency role via high satisfaction levels and a concordance in their goals and interests. As further evidence of this agency role:

- suppliers have been historically skeptical of intermediaries like GPOs and PBMs, suppliers have sought to render them ineffective,
- GPOs and PBMs believe that supplier competition is always in their interest,
- suppliers do not contract with GPOs and PBMs when they do not have to (due to lack of competition),
- the relationships between suppliers and these intermediaries are characterized as "adversarial", and
- suppliers raise prices unilaterally 'because they can' which the intermediaries seek to counteract.

GPOs And PBMs Subject To Considerable Federal Oversight

Both sets of intermediaries have been subjected to considerable scrutiny by the US Congress (House and Senate hearings), the Congressional Budget Office, and various Federal Agencies such as the Federal Trade Commission (FTC) and the Office of The Inspector General (OIG). Such scrutiny led to the development of 'codes of conduct' for both intermediaries during 2004 to 2005. None of this scrutiny has since resulted in

any subsequent change in legislation or regulatory oversight of either intermediary. This latter point suggests that the codes of conduct may have served their purpose, as some research suggests.

GPOs and PBMs Have Utilized Many of the Same Contracting Tools for Decades

Certain GPO and PBM practices have irritated their critics in the new millennium. For GPOs, these include contract administrative fees (CAFs) paid by manufacturers, sole-source contracts, compliance and committed purchasing contracts, and product bundling. For PBMs, they include drug formularies, CAFs paid by manufacturers, discounts and rebates from manufacturers, narrow pharmacy networks, and spread pricing.

What critics fail to realize is that such contracting tools have long been in place without causing an uproar. That is likely because these tools served the economic interests of their sponsoring organizations downstream (hospitals, health plans), who developed them to deal with competitive and reimbursement pressures. Just like many contracts between buyers and sellers in the private sector, GPO and PBM contracts are never publicly disclosed to encourage price discounting by manufacturers (and inhibit any collusion among them).

GPO And PBM Business Models Have Changed Over Time

Finally, the historical narrative demonstrates that the business models and revenue sources of these two intermediaries have changed over time. GPOs are now concentrating on their professional services (advisory/consulting and analytics) business; PBMs are now heavily focused on the dispensing of specialty drugs. Yet, GPO and PBM critics continue to attack them regarding strategies heavily pursued in the past: CAFs (for GPOs) and manufacturer rebates and pharmacy network management (for PBMs). Although still a sizeable portion of their revenues, such strategies are on the wane.

Static Vs. Allocative Efficiency: Winners And Losers

GPOs and PBMs serve the interests of hospitals and HMOs/health plans, respectively; as noted above, they do not serve large manufacturers. They also do not seek to maximize the welfare of other participants in the institutional or retail supply chains (eg, small medical device makers, independent retail pharmacies) who are their most vocal critics and claim they have been disadvantaged by these intermediaries.

FTC officials note that such "stakeholders frequently attempt to co-opt the government in their battle against rivals … [and are] wary of having the FTC used as a pawn to boost the profitability of certain sectors or insulate them from competition", according to Christine Wilson.

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Tradeoffs: The Name Of The Game

Economics and the entire health care ecosystem are all about tradeoffs. For example, when one examines the different health plans that employers offer workers, one finds that those plans that offer a wider choice of providers (more open-network models such as preferred provider organizations, or PPOs) come with higher premiums - that is, PPOs trade off wider access for higher cost.

The same tradeoffs factor into the strategies employed by GPOs and PBMs. The 'contentious' GPO practices of rebates, compliance, committed contracts, and sole-source contracts all entail tradeoffs between wider product access versus lower product cost. The GPOs have wisely constructed contracts and contract tiers to allow hospitals to select the type of tradeoff they prefer.

PBMs (in partnership with health plans) have similarly developed formulary tiers that allow plan participants to access the drug(s) they prefer at the cost they can afford. GPOs and PBMs do not dictate the choice to their hospital customers and plan enrollees, respectively.

PBM Formulary Exclusions On The Rise, PhRMA Says

By Joseph Haas

26 May 2022

According to a report commissioned by PhRMA, the three largest pharmacy benefit managers continue to exclude more drugs from standard formularies, including those with expedited FDA approval.

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Product quality is, nevertheless, evident in the decisions made by hospitals' product selection committees and health plan pharmacy and therapeutics committees. Such committees are heavily comprised of clinicians (physicians, nurses, pharmacists) who focus primarily on product quality, not on product cost. In other words, these committee mechanisms represent local-level decisions by clinicians on the types of products they want. GPOs and PBMs are not in the business of telling doctors what they can or cannot order or prescribe. To the extent their product choice set is limited, it usually reflects committee (peer) assessments of what are comparable, therapeutically-equivalent products with no evidence-base to differentiate them.

Another area where strategic tradeoffs are evident is national versus local. The GPOs began as local cooperatives and developed contracts for local membership. The proximity and small membership size made it fairly easy to decide upon products and manufacturers to contract with. As they grew, however, the regional and (then) national GPOs faced increasing difficulty in developing contracts that all of their members wanted. The GPOs therefore embarked on several strategies that allowed members to customize contracts to suit local needs and clinician preferences, including regional GPO affiliates, assistance with custom contracting, contracting tiers, etc. The goal was to balance the economic leverage of centralized buying with access to desired products at the local level. PBMs have engaged in similar tradeoffs. They, along with their health plan sponsors, developed national drug formularies than could be tailored or disregarded by health plans at the local level.

Consolidation

GPOs and PBMs have come under fire for being concentrated sectors in which a small number of these intermediaries account for the vast bulk of sales. Such observations are correct. But then critics extrapolate to conclude that these huge oligopolies raise costs, harm their own members, and engage in anti-competitive practices that harm the public's welfare.

The evidence base refutes all of these charges. First, GPOs and PBMs help their hospital and MCO clients by negotiating lower input prices and serve as their agents. Second, there has been no federal antitrust enforcement activity brought against these parties since the early 2000s, there has been a vastly reduced

number of lawsuits filed against them since they adopted codes of conduct in the mid-2000s. Third, the entire health care ecosystem and nearly all the intermediaries in the supply chain have grown more concentrated. For some reason, however, critics do not usually complain about the oligopolies among pharmacies, pharmaceutical wholesalers, and specialty distributors. If one really wants to start pointing fingers at the biggest culprits in consolidation and rising cost, one does not have to look very far: hospital systems.

Existential Threats

Safe Harbors

Despite being large firms in an oligopolistic market, GPOs and PBMs face three existential threats; one from the public sector, and two from the private sector. The first is revocation of their Safe Harbor protection. This issue comes up periodically, gets debated, and then gets beaten back down. Safe harbor protection for GPOs is based in statute, so any change will require some bipartisan effort; safe harbor protection for PBMs rests more on OIG guidance, making it more amenable to change and vulnerable. Indeed, the Biden Administration has taken steps to whittle down the Safe Harbor for manufacturer rebates as part of the November 2021 Infrastructure Investment and Jobs Act; however, that can has been kicked down the road, at least until 2026.

Disintermediation

The second possible threat is possible disintermediation of the intermediaries. In the past, such a threat rested on the possibility of buyers and sellers engaging in direct contracting which did not require an intermediary. To date, direct contracting has been a flop, as witnessed by Medicare's support of provider sponsored organizations in the 1997 Balanced Budget Act and more recently with the Global and Professional Direct Contracting (GPDC) Model for accountable care organizations.

PBM executives also report their concern with aggregated, aggravated, and activated employers - and, thus, employer purchasing coalitions who seek to impose contract terms on the PBM. The employer threat is real in one sense: along with the Federal Government, they are the single largest purchaser of health care products and services. They are also in closer proximity to the patient (their employees and their dependents), see them every day, and have a financial incentive to keep them healthy. This trumps the market position and incentives of every other player in the value chain. At the same time, however, the employer threat is fleeting and transitory. Employers become more heavily engaged in health care spending during upswings in what was once called the "insurance underwriting cycle": the cycle of rises and falls in the percentage increase in health care spending. One could count on employer engagement when health care spending was accelerating; one could also count on employers losing interest when health care spending was decelerating.

The Empire (Always) Strikes Back: Supplier Consolidation, Concentration, And Pricing

The greatest existential threat to intermediaries such as GPOs and PBMs is consolidation and/or concentration among the manufacturers upstream with whom they contract. The immediate impact is a reduction in the number of suppliers available for customers to contract with, and the reduction in the competitive rivalry among these suppliers.

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whom they contract.

In 2009, the top ten medical device firms accounted for 62% of worldwide revenues; by 2017, they accounted for 70% of global revenues. This growing concentration has been driven by mergers and acquisitions of smaller companies, and diversification by large companies into other product segments. GPOs have noticed that there is a dwindling number for suppliers to contract with in several product areas, sometimes as few as two manufacturers. The GPOs' concerns - which, admittedly, are difficult to empirically document and validate - are manifold: threats to supply and possibilities of supply shortage, higher prices, and lower levels of innovation.

A similar threat of consolidation exists in the pharmaceutical sector. Research suggests that pharmaceutical M&A is sometimes motivated by the desire to limit competition. Researchers have found that a company is 5-7% less likely to complete the drug development project in its acquisition's pipeline if those drugs would compete with the acquirer's existing product line (i.e., "killer acquisition"). Other research shows that M&A can result in reduced R&D spending and patenting for several years, while higher competition spurs R&D spending by firms.

However, the threat is not always due to supplier mergers. M&A activity among large pharmaceutical manufacturers has not resulted in a more concentrated sector. In 2006, the top ten firms accounted for 46% of total sales; ten years later they accounted for only 41% of sales.[x] Instead, in recent years, the threat has sometimes come from generic drugs where either market demand is too small to support more than one firm and/or all other suppliers have withdrawn for various reasons. The result is a monopoly and egregious pricing behavior. Two prominent examples are Turing Pharmaceuticals and its drug Daraprim, and Mylan Pharmaceuticals Inc. and its EpiPen - firms which continually hiked their prices because they could.

The threat of supplier concentration particularly resides in the availability of specialty pharmaceuticals, many of which are off patent. There are higher entry barriers in the biologics space due to (among other reasons) uncertainty regarding the regulatory process for biosimilars and the guidelines for 'interchangeability'. The result is fewer competitors and little generic threat to these newer biological products. Biologics as a percentage of drug spending doubled between 2006 and 2016, from 13% to 27%. The wholesale acquisition cost of biologics is a multiple of the cost of small molecules. And the approval of biologic license applications (BLAs) for new biological products has recently overtaken the approval of new molecular entities (NMEs) for traditional drugs. The threat facing payers is containing the cost of these drugs. At the same time, the distribution of specialty pharmaceuticals has become a major revenue driver for the PBMs.

How The Failure Of US PBM Reform Shaped Sanofi's Decision To Exit Diabetes R&D

By Cathy Kelly

31 Dec 2019

And how in contrast, Novo Nordisk is launching its oral GLP-1 agonist for diabetes at a price that may set up 'business as usual' tensions with pharmacy benefit managers and payers.

Read the full article here ›

Moreover, specialty drugs are more buffered from the effects of drug formularies and tiers. Formulary position is driven by competition within the therapeutic area. Such competition is greater in some areas (e.g., metabolic, cardiovascular, central nervous system, gastrointestinal) than in others (oncology, infectious disease, immunology, and respiratory). In the former areas, there is less clinical differentiation among drug classes and more variation in tiering; in the latter areas, there is more clinical differentiation among drug

classes and much less dispersion of formulary drugs across price tiers. This reflects the considerable unmet clinical need and variation in patient response to specialty (eg, oncologic) drugs, making it harder to restrict and/or channel physician choice among products. Finally, drugs that treat widely prevalent conditions (eg, diabetes) and thus incur high aggregate spending are more likely to be targeted by formulary tiers than are specialty drugs that incur lower aggregate spending which are more likely to attract payer strategies, such as step therapy.

Summary

GPOs and PBMs occupy parallel roles in the institutional and retail channels of the health care value chain. There are multiple similarities in their historical origin, product selection bodies, role in the value chain, role as agents for downstream buyers, business model, operating guidelines, transparency, rebates earned, cost management efforts, tradeoffs managed, and directional influence in the supply chain. These similarities are counter-balanced by their differences in channel served, products contracted for, customer served, founding period, owner/sponsor, number of firms, and industry financials.

Finally, the GPOs and PBMs are intermediaries. They do not buy, sell, or price products conveyed through the institutional and retail supply chains, respectively. They are also not providers of health care services. Their impact on the cost and quality of care rendered to patients is thus removed from the parties who play the major roles here. The remarkable finding here is that these intermediaries may nevertheless serve the public's welfare by controlling the rise in health care costs.

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