Pharmacy Benefit Management: Are Reporting Requirements Pro- or Anticompetitive?

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ABSTRACT The market-based US healthcare system relies on pharmacy benefit managers (PBMs) to control pharmaceutical costs, in contrast to most other countries that regulate drug prices and access. Optimal structuring and regulation of PBM contracts pose significant agency challenges for private and public payers. However, recent reporting requirements for PBMs may be counterproductive and reflect the interests of competitors rather than customers.

Key Words: Pharmaceuticals; Pharmacy Benefit Management; Insurance; Transparency; Regulation.

JEL classifications: D4; I13; I18; L8.

1. Introduction

Insurance coverage for drugs provides consumer protection but also reduces consumer demand elasticity. This creates both consumer moral hazard (use of low benefit care) and producer moral hazard (producers charge higher prices). US insurers/payers manage pharmacy benefits to restrain these effects, using formularies of covered drugs and patient cost-sharing, negotiating prices charged by drug manufacturers and pharmacies, and processing claims. Selfinsured employers and many smaller health plans contract out these functions to specialized pharmacy benefit managers (PBMs), while some large health plans have developed in-house PBMs.

In response to concerns of whether payers have the information necessary to contract efficiently for these services, recent legislation has increased data reporting requirements for PBMs. Reporting of cost data to the government was required for prescription drug plans (PDPs) that perform PBM functions for Medicare Part D, and the Affordable Care Act requires data reporting by PBMs serving health plans in insurance exchanges. Similar requirements have been proposed for data reporting to self-insured employers.

Previous literature on PBM data reporting requirements has questioned the need for data reporting and recognized that in the context of oligopoly,

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Exhibit 1089 IPR2017-00807 ARGENTUM transparency of competitor prices may facilitate collusion.¹ This article contributes to this literature by reviewing empirical evidence on concentration in this industry, with the two largest PBMs accounting for 59% of industry revenues in 2013, and the limited extent of competitive entry over the last decade. It also reviews recent survey evidence of employer contracting with PBMs. Competitive dynamics in this industry are complex, because the independent PBMs are both suppliers to large health plans and sometimes competitors with their in-house PBMs. Similarly, because large PBMs operate mail-order pharmacies, they are both customers of retail pharmacies and competitors. Any mandates for data reporting should evaluate the demand from employer customers and also consider potential anticompetitive effects in the market for PBM services and pharmacy services.

In this article, Section 2 outlines the basic business model of PBMs, including their roles as suppliers to health plans and competitors, and as both purchasers from retail pharmacies and competitors, through PBMs' operation of mail-order pharmacies. Section 3 describes the industry structure and evidence on competitive entry. Section 4 discusses survey evidence from PBM customers. Section 5 evaluates proposals for data reporting and concludes.

2. The PBM Business Model

PBMs use a range of strategies to manage and administer pharmacy benefits on behalf of payers/sponsors.² These strategies include management of drug utilization and negotiation of rebates on drug prices, by means of formularies with tiered patient cost-sharing and access controls; negotiation with retail pharmacies for discounts on drug prices and dispensing fees, in return for participation in the preferred pharmacy network; claims processing and reimbursement of retail pharmacy claims; and operation of mail-order pharmacy. The basic principle is that PBMs can drive discounts on drug prices and pharmacy fees by restricting patients' choice of drugs or pharmacies, thereby increasing volume for preferred suppliers that accept the discounted prices. Thus, more restrictive drug formularies or pharmacy networks generally obtain larger discounts.

2.1. Strategies

2.1.1 Formulary Structure

PBMs (sometimes in conjunction with a health plan's Pharmacy and Therapeutics Committee) structure a formulary of covered drugs and associated patient cost-sharing. Most formularies now have three or four tiers. The lowest tier covers generics, with average co-pay of \$11; the second tier includes preferred brands, with average co-pay of \$30; the third tier includes nonpreferred and off-patent brands, with average co-pay of \$56 (PBMI 2013). Many plans also have a fourth tier for expensive specialty drugs, often with a co-insurance of 20–30% of drug price. Utilization of nonpreferred and specialty drugs may be further managed through requirements that physicians obtain prior authorization and/or that patients first try less costly alternatives ("step edits"). Large self-insured employers may structure their own formulary, but smaller self-insured employers usually choose one of several standard formularies offered by their PBM or health plan.

2.1.2 Negotiating Drug Rebates with Pharmaceutical Manufacturers

Restrictive formulary structures enable PBMs to "shift market share" to preferred drugs with relatively low patient cost-sharing and possibly other access controls. PBMs may enhance share shifting by encouraging pharmacies to call the patient's doctor to authorize switching to preferred drugs.³ PBMs' ability to shift share enables them to negotiate discounts/rebates off list prices from branded drug manufacturers, in return for preferred placement and increased market share for their drugs. PBMs' ability to shift share and thereby negotiate rebates is greatest in therapeutic classes with several drugs of very similar efficacy, such that physicians and patients accept restrictions on their choice and are sensitive to modest cost-sharing differentials. Drug price rebates are typically paid by electronic transfer from the drug manufacturer to the PBM, on evidence of preferred formulary status and/or increased drug utilization. The pass-through of the drug rebates by PBMs to plan sponsors has been a contentious issue, but recent evidence suggests that most sponsors capture most of the rebates (see below).

2.1.3 Contracting for Discounted Pharmacy Costs

When pharmacies dispense drugs to patients, they add a mark-up to the exwholesaler price at which they purchased the drugs, to cover their inventory and other costs, and a dispensing fee for their time. An important source of PBMs' cost savings for payers is the negotiation of discounts on pharmacy mark-ups and dispensing fees. Under pressure from retail pharmacy associations, many states have enacted Any Willing Provider laws that require PBMs to contract with any pharmacy willing to accept their fees.⁴ Theory and evidence suggest that such laws lead to higher costs to consumers, by limiting PBMs' ability to contract selectively in return for discounted fees (FTC 2014).

2.1.4 Processing Pharmacy Claims

PBMs provide convenience for pharmacies and patients by providing IT services that enable pharmacies to verify at point-of-sale whether a drug is covered by the patient's plan and their co-payment. The pharmacy then collects the co-pay from the patient and bills the PBM for the remaining drug cost and dispensing fee, at agreed rates.

2.1.5 Mail-Order Pharmacy Dispensing

All major PBMs operate their own mail-order pharmacies that dispense medications through the mail. PBMs offer patients lower cost-sharing on drugs dispensed through the mail, to encourage acceptance of mail dispensing.

2.1.6 Other Functions

In addition to these basic services, large PBMs offer a range of other services, including drug utilization review, compliance and therapy management, and specialty pharmacy services such as home infusion.

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Figure 1 shows the flow of money and goods in pharmacy benefit management. Pharmaceutical manufacturers typically sell their drugs to wholesalers that distribute the drugs to pharmacies, including PBMs' mail pharmacies. PBMs contract with and collect rebates from drug manufacturers, contract with and reimburse retail pharmacies, and dispense drugs through their mail pharmacies.

2.2. How PBMs Make Money

Although the survival and growth of PBMs suggests that on balance they offer net savings to plan sponsors on essential claims processing, management of drug utilization and prices and management of pharmacy dispensing costs, nevertheless concerns have been raised over how far PBMs pass through the savings realized and whether sponsors have the information needed for informed contracting. In particular, the following components of PBM revenues are at issue:

2.2.1. Spreads on Retail Pharmacy-Dispensed Drugs. PBMs capture the spread between the prices at which they are reimbursed by sponsors and the prices they pay to pharmacies for dispensed drugs. These contractually agreed prices are typically expressed as a percentage of a widely available list price benchmark, most commonly average wholesale price (AWP). For example, the PBM may reimburse pharmacies for drugs at AWP minus 18% plus a \$1 dispensing fee. The PBM contracts for reimbursement from the sponsor at a somewhat smaller discount off AWP, say AWP minus 16% plus a \$2 administration fee per script. The difference between the sponsor's payment to the PBM and the PBM's payment to the pharmacy (the "retail spread") is a significant source of PBMs' net revenue.

These payment rates from PBMs to pharmacies and from pharmacies to wholesalers are complex and not generally known to plan sponsors.



Figure 1. The flow of money and goods in pharmacy benefit management.

Manufacturers of on-patent brand drugs typically sell their drugs to wholesalers at the manufacturer's list price or wholesale acquisition cost (WAC), net of any discounts for prompt payment and so on. Manufacturers also supply their list price(s) to third party database companies such as Medi-Span that calculate and publish the AWP. AWP is generally based on the standard formula (WAC + 20%), but if manufacturers also list a suggested wholesale price (SWP), Medi-Span sets AWP at the manufacturer's SWP.⁵ Thus, for on-patent brand drugs AWP is a list price that is usually higher than and roughly but not strictly proportional to the price the wholesaler actually paid. Wholesalers distribute drugs to pharmacies, adding their own margin, and retail pharmacies add their own mark-up to the drug price plus a dispensing fee. In a cash transaction to a self-pay patient, this marked-up retail price would be charged in full to the patient. PBMs reduce costs for sponsors by negotiating discounts on the pharmacies' customary drug mark-ups and dispensing fees.

2.2.2. Generics. Managing generics has been a major source of PBM savings for payers. Under most state substitution laws, pharmacies are authorized to substitute any bio-equivalent generic for the brand, even if the physician prescribes the brand, unless the physician explicitly notes "brand required." PBMs incentivize patients to accept generic substitution, by offering much lower cost-sharing on generics. PBMs also incentivize pharmacies to substitute low priced generics by reimbursing pharmacies for generics using a maximum allowable cost (MAC). The MAC is the same for all generic versions of a drug, and is based on the PBM's estimate of generic acquisition cost to pharmacies. MAC reimbursement incentivizes pharmacies to use the lowest cost generic available as the pharmacy captures the spread between the MAC and its acquisition cost. MAC reimbursement thus also incentivizes generic suppliers to offer price discounts to pharmacies. Over time, PBMs revise down their MAC, based on actual pharmacy acquisition cost for generics, thereby capturing (some of) the savings from competitive discounting by generic manufacturers to pharmacies. Unlike AWP, which is a list price schedule set by third party database companies, each PBM sets its own MAC reimbursement prices for pharmacies (Eberle and Van Amber 2008). The majority of PBM contracts with plan sponsors (75%) bill for generics based on MAC pricing, and the remainder bill for generics using discounted AWP (PBMI 2013). PBMs earn a spread on generics dispensed through retail pharmacies, as they do on brand drugs. However, retail pharmacies retain significant discounts on generics.⁶

2.2.3. Mail-Order Pharmacy Business. Mail dispensing substitutes the PBM's own dispensing costs for those of retail pharmacies. Mail dispensing may also enhance a PBM's ability to ensure patient adherence and formulary compliance, because the PBM can ensure that their in-house pharmacist calls physicians to switch patients to preferred drugs and contacts patients with reminders for prescription renewal. PBMs' enhanced ability to influence

utilization through mail dispensing may enable them to capture larger rebates on branded drugs.

The PBM's mail-order pharmacy also captures the discounts from generic manufacturers that would normally accrue to the retail pharmacy. Discounts on generics have become an increasingly important source of revenue for both PBMs and retail pharmacies, as the generic share of prescriptions has grown to >80% in the USA (Zirkelbach 2014). PBMs typically incentivize enrollees to use mail dispensing by offering a 90-day mail co-pay that is only roughly two times rather than three times the 30-day retail co-pay (PBMI 2013). Unsurprisingly, mail dispensing has been strongly opposed by retail pharmacies, leading to pressure for restrictive legislation in some states.

2.2.4. *Manufacturer Rebates.* Sponsor–PBM contracts usually specify the percentage of brand manufacturer rebates to be passed through to the sponsor. Although competition among PBMs should in theory assure rebate pass-through to plan sponsors, in practice this is a contentious issue because the magnitude of rebates is confidential, which is arguably necessary to encourage discounting by manufacturers and effort by PBMs. The amounts involved are unobservable because rebates are transmitted electronically to PBMs, which book their share as a reduction to the cost of revenues.⁷

The available evidence suggests that rebates have declined absolutely and as a share of PBMs' profits. In 2003, Medco retained \$1.59 billion in rebates (>50% of total rebates) on \$1.52 billion of gross profit, whereas in 2011, Medco retained only \$757 million in rebates (12.1% of total rebates) on \$4.62 billion of gross profit.⁸ This decline in retained rebates reflects several factors. First, the opportunity to capture brand rebates has declined following the patent expiries and generic erosion of many blockbuster brand drugs. In 2004, generics accounted for 57% of prescriptions in the USA; by 2013, the generic share of prescriptions was 86% (IMS Health 2014). Second, an increasing share of drug expenditures is for specialty drugs, which are typically differentiated. Strong doctor/patient preferences between differentiated drugs undermine PBMs' ability to shift share and negotiate rebates for specialty drugs. Third, in 2006, the establishment of Medicare Part D coverage of outpatient drugs for seniors included requirements for transparency and pass-through of manufacturer rebates.⁹ A 2011 study found that on average, PBMs administering Part D plans retained <1% of negotiated rebates (Department of Health and Human Services, Office of Inspector General 2011). These practices on Part D programs may have spilled over to private plans. Fourth, the threat of litigation may have reduced PBMs' capture of rebates.¹⁰

Recent survey evidence (PBMI 2013) shows that contracts with plan sponsors include a variety of different mechanisms for rebate pass-through, which complicates comparison across plans. In 2013, only 6% of large employers reported capturing no rebates, compared to 25% of small employers. However, conclusions from such evidence are tentative because contracts with greater PBM rebate retention may have offsetting decreases in other types of PBM compensation. That retained rebates are less important to overall PBM profitability is underscored in Medco's FY2004 SEC 10-K filing, which states, "the impact on profitability from the increase in generic utilization, particularly in mail order, more than offsets the impact from lower rebate retention on brand name prescriptions." Similarly, Express Scripts' investor presentations state that while rebates drove earnings growth in the 1990s, increases in generic utilization accounted for the majority of earnings growth in the 2000s (Express Scripts 2014).

3. PBM Market Structure and Competition

Employer plan sponsors have three options for managing pharmacy benefits. First, the sponsor may "carve in" these functions to the health plan that administers the sponsor's medical benefit, which would typically either operate its own in-house PBMs or contract with an independent PBM. Second, the sponsor may "carve out" the pharmacy management directly to an independent PBM. Third, very large employers may conduct some of the core formulary-related PBM services in-house, outsourcing to a PBM only the claims processing that requires specialized IT (Bisping 2010). In practice, 66% of small employers contract for their PBM through a health plan administrator, and only 30% contract with a PBM directly, whereas 30% of large employers contract through a health plan, and 65% contract directly with a PBM (PBMI 2013). The efficient performance of the PBM industry for plan sponsors relies on competition. As one indicator of competition, this section provides evidence on industry structure and entry.

3.1. PBM Market Shares

Defining PBM market shares is problematic because some PBMs outsource claims processing to other PBMs, which leads to significant duplication in shares measured as covered lives or total claims processed. Market shares based on 2013 PBM total revenue are shown in Table 1 (Lofberg 2012).

Market shares based on claims processed are shown in Table 2 (Atlantic Information Services (AIS); Casey 2013). This measure shows a larger role of companies such as Argus Health Systems that process claims for other PBMs and plan sponsors, but capture a small share of total revenue.¹¹

The large PBMs also play a major role as PDPs that administer the Medicare Part D program. Table 3 shows the top eight PDP sponsors by total PDP lives.¹²

BM Market share by 2013 PBM	
Express Scripts	34%
CVS Caremark	26%
OptumRx (United)	12%
Prime Therapeutics (BC)	5%
Catamaran	5%
Humana	5%
MedImpact	3%
Cigna	3%

Table 1. PBM market shares, by 2013 revenue

Note: Shares do not sum to 100 due to All Other residual.

Source: http://media.corporate-ir.net/media_files/irol/99/99533/dec2012/CVS_Caremark_2012_Analyst_Day-Per_Lofberg_Presentation.pdf

PBM	Expected market share by 2014 claims processed
Express Scripts	27%
CVS Caremark	19%
OptumRx (United)	12%
Argus Health Systems	11%
Catamaran	10%

Table 2. PBM market shares, by claims processed

Source: Atlantic Information Systems (AIS); Casey (2013).

Part D plan parent	Market share
UnitedHealth Group	21.8%
Humana	16.4%
CVS Caremark	11.4%
Express Scripts	7.3%
Aetna	6.3%
CIGNA	4.6%
WellCare Health Plans	4.4%
WellPoint	2.9%

Table 3.PDP market shares, by PDP lives

Source: https://kaiserfamilyfoundation.files.wordpress.com/2014/08/8621-exhibit-1–6.png, based on Georgetown/NORC analysis of CMS Enrollment files, 2006–2014. Includes PDP and MA-PD plans.

Based on annual revenue shares (Table 1), the two and four largest independent PBMs account for almost 60% and 76% of the market, respectively. Concentration has increased over the last decade through mergers and acquisitions. Express Scripts acquired Wellpoint's wholly owned NextRx PBM in 2009 (Wellpoint 2009) and then merged with Medco in 2012 (Express Scripts 2012). CVS and its PBM, PharmaCare, merged with Caremark Rx in 2006 (CVS Caremark 2007) to become CVS Caremark and later acquired Longs Drug Stores' PBM, RxAmerica, in 2008 (CVS Caremark 2008). Catamaran was created by SXC Health Solution's 2012 acquisition of Catalyst (Catalyst Health Solutions 2012), which had previously purchased Walgreens Health Initiatives in 2011 (Catalyst Health Solutions 2011). Catamaran was acquired by United in May 2015.

Several large health plans have attempted to develop their own PBMs to compete with the large independent PBMs. OptumRx is wholly owned by United Healthcare and primarily provides PBM services to United's clients. Prime Therapeutics is co-owned by 13 nonprofit Blue Cross Blue Shield Licensees and serves primarily these health plans. Large health insurers Humana, Cigna, and Aetna all operate their own captive PBMs, but outsource some services to third party PBMs. Catamaran has grown quickly since the 2012 SXC/Catalyst merger. This evidence indicates significant consolidation over time in the PBM industry. Competitive entry by full service PBMs has been limited and has occurred mainly through large health plans insourcing their own pharmacy management. Some of these health plan–owned PBMs

continue to rely partly on external PBMs for claims processing; for example, Wellpoint sold its in-house PBM to Express Scripts and Humana and Cigna contract with external claims processors. This evidence suggests that scale economies are significant, particularly in claims processing, which may preclude entry by new operators other than related health plan businesses with existing large-scale operations.

The limited public evidence on contracting strategies also sheds light on competitive dynamics in this industry. Catamaran has grown by offering fixed fee per transaction pricing with clarity on rebates and other fees.¹³ MedImpact offers clients full disclosure on rebate administration.¹⁴ Large employer members of the HR Policy Association have negotiated an exclusive agreement with Prime Therapeutics, including clear pass through pricing with no undisclosed PBM mark-ups, 100% pass through of pharmaceutical rebates, and the option for additional savings through narrowing the pharmacy network.¹⁵ However, as Morningstar points out, "Express Scripts' operating income accounts for well less than 1% of its clients' overall health-care costs. If Express Scripts can lower its clients' health-care costs by even a few percentage points more than the competition, it will justify the company's margins and facilitate market share gains" (Morningstar 2012). This underscores the agency challenge facing sponsors: focusing solely on driving down a PBM's operating income could be counterproductive, if this leads the PBM to skimp on efforts to constrain drug costs.

4. Survey Evidence on Employer Contracting with PBMs

Employers seeking to contract for PBM services may request proposals from several PBMs, possibly using a third party benefits consultant. A basic PBM proposal typically includes, among other terms: any per claim fees, for example for claim processing, dispensing, prior authorization, and so on; the reimbursement rate to be paid to the PBM for brand and generic drugs, at retail and mail order, usually expressed as a % of AWP for brands and % of MAC for generics; and the share of drug rebates to be passed through to the employer.

The PBMI (2013) study provides survey evidence on the PBM contracting experience of large (>5,000 employees) and small firms (≤5,000 employees). This study surveyed a broad sample of employers, including most size classes, geographies, and industries. However, it was not a random sample of employers, and not all employers responded to all questions, so findings may not be generalizable. Nevertheless, this survey provides the best available evidence on employer contracting with PBMs.

Consider first the PBM charges for drugs dispensed through their own mail order versus retail pharmacies. The average reimbursement level is AWP minus 16% for branded 30-day retail drugs and AWP minus 22% for branded mail-order drugs. The median dispensing fee for 30-day retail prescriptions is \$1.50 and \$0 for mail-order prescriptions. These data indicate that PBMs typically pass on some savings from mail dispensing, and incentivize sponsors and patients to use mail service. MAC pricing for generics is used by 75% of employers for 30-day retail prescriptions and 70% of employers for mail-order prescriptions. In other cases, the average reimbursement level for generics is AWP minus 65% for 30-day retail and AWP minus 61% for mail order, but this differential is not statistically significant. The evidence confirms that the majority of employers receive a share of manufacturer drug rebates through various mechanisms, including a specified percentage of actual rebates, a guaranteed flat minimum level of rebates per prescription or per rebateable drug (preferred tier brands). Different ways of calculating rebates complicate comparison across contracts. The mean and median employer shares of drug rebates were 60% and 80% for retail dispensed drugs, for employers with a rebate share arrangement that responded to this question (PBMI 2013).

The PBMI study also highlights some differences in negotiated pricing between large and small employers. Large employers received higher retail discounts on branded and generic drugs, paid lower dispensing fees, and were more likely to receive manufacturer rebates than were smaller employers. All of these differences were found to be statistically significant. There were no significant differences by employer size for mail or specialty discounts.

PBM spreads are not transparent to sponsors, because most PBMs do not disclose either the price that they pay to retail pharmacies or drug acquisition costs for their mail operations. However, given the common use of AWP minus x% pricing for reimbursement by the sponsor to the PBM for branded drugs, this enables sponsors to compare their costs for branded drugs meaningfully across PBM proposals. Although comparison of generic prices across proposals is less precise because PBMs' MAC prices may differ, in practice these differences are unlikely to be systematically materially large, given that these MAC prices must be sufficient to attract pharmacies to participate in the PBM's network.

PBMs also sometimes take risk by guaranteeing a certain level of savings on drug costs compared to the sponsor's expenditures in the previous year. However, the frequency of such arrangements is unclear.¹⁶ It is also unclear whether such arrangements would benefit sponsors, if spending less on pharmaceuticals increases other medical costs or reduces benefits to consumers.

4.1. Allegations of Conflict of Interest

Various sources of conflict of interest have been alleged against PBMs. First, allegations related to PBM ownership of mail pharmacies and self-dealing prompted the FTC to obtain proprietary data on PBM contracts and claims paid from 2002–2003. The FTC concluded, "These data provide strong evidence that ... PBMs' ownership of mail-order pharmacies generally did not disadvantage plan sponsors ... these allegations [of self-dealing arrangements] are without merit" (FTC 2005). The evidence above suggests that PBMs do typically share with plan sponsors the savings realized on mail dispensing.

Second, retention of rebates by PBMs has led to the allegation that a PBM has incentives to encourage members to take a drug with a higher net cost to the plan sponsor if the PBM receives a larger rebate than on a drug with lower net cost to the plan sponsor. For example, litigation in 2004 accused Medco of switching patients from lower cost drugs to similar drugs that cost the sponsor more but paid higher rebates. The resulting out-of-court settlements with the Department of Justice and state Attorneys General deemed it illegal for a PBM

to incentivize a patient to switch to a drug with higher net cost to the plan sponsor (Freudenheim 2004). However, the decline in opportunity for brand rebates and the growth in generics availability have resulted in better alignment between the PBMs' incentives and those of sponsors, to encourage generic substitution whenever possible. The pass-through of generic discounts has so far not emerged as a major issue. On a related point, Abrams (2007) argues that PBMs keep retail pharmacy reimbursements for generic drugs artificially high in order to protect margins in their mail-order business. In theory, competition on other contract terms could enforce a competitive passthrough of generic discounts while preserving the PBM's incentives for effort in squeezing retail pharmacy margins and obtaining generic discounts for their mail-order pharmacy. In practice, the limited evidence provides little support for the allegation. FTC (2005) found that employers pay lower prices on mail order and, overall, rejected the allegation that PBMs' ownership of mail-order pharmacy harms their customers.

Third, the fact that the PBM's retail spread is usually a fixed percentage of the drug's list price in theory implies that PBMs have little incentive to control the rate of increase in drug prices or to prefer drugs with lower list prices. This potentially perverse incentive may be mitigated if competition is effective in forcing PBMs to compete on their ability to control drug spending and its growth for sponsors. However, this presupposes that sponsors are able to evaluate the effectiveness of PBMs at managing drug expenditures while preserving cost-effective levels of access and health outcomes. In fact, PBMs do not generally take financial risk for the rate of growth of total drug spending, which would eliminate this potential conflict of interest, possibly because such risk sharing could also lead to excessive controls on patient access.¹⁷ More generally, in any PBM carve-out situation, the health plan or sponsor foregoes the ability to coordinate pharmacy and other healthcare cost management optimally. Obtaining transparency on PBM costs and margins alone would be a blunt and ineffective tool to achieve optimal cost-quality coordination across pharmacy and other services.

5. PBM Reporting Requirements: Pro- or Anticompetitive?

The Affordable Care Act (ACA) requires specific disclosures by PBMs participating in qualified health plans in federal or state insurance exchanges and by PDPs administering Medicare Part D plans, including:¹⁸

The aggregate amount of all price concessions including rebates earned on behalf of the patient from drug manufacturers, wholesalers, or pharmacies;

The aggregate amount of price concessions passed onto the health plan sponsors;

The aggregate amount of the difference between the amount the health plan pays the PBM and the amount the PBM pays retail and mail pharmacies.

These required aggregate disclosures do not require the PBM to divulge information on specific manufacturer contracts or pricing for specific customers or products. The required PBM disclosures are to CMS, in the case of PDPs, and to the qualified health plan, for health plans sold on exchanges. Under the law, the disclosed information is confidential. In addition, several states require more detailed information disclosure.¹⁹ Reporting requirements have also been proposed for PBMs serving ERISA-regulated self-insured employers.

5.1. Potential Benefits of Reporting Requirements for Employer-Sponsored Plans

The proposed reporting requirements by PBMs to employer sponsors might potentially benefit employers/employees if such reporting would address an observed malfunction in the market for PBM services. However, the precise problems and how reporting might improve performance are unclear. The evidence from PBMI (2013) does suggest that large employers manage their pharmacy benefit more actively than do small employers, and large employers get somewhat better contract terms for retail pharmacy drugs but with no significant differences for mail order and specialty drugs. However, multiple factors may contribute to this outcome. For 79% of small employers, the person managing their pharmacy benefit spends <25% of time on this function, compared to 58% for larger employers (PBMI 2013). If limited time spent implies limited expertise, providing better data might be helpful.

However, PBMI (2013) also reports that 66% of small employers contract for their PBM services through their health plan administrators. These administrators should be sophisticated, well-informed purchasers of PBM services, since some operate their own PBMs and/or contract with independent PBMs themselves. Given this reliance by small employers on health plan administrators, the apparently inferior PBM contracting performance of small employers seems unlikely simply to reflect their own limited information. Other possible explanations include imperfect agency by health plan administrators, diseconomies of small scale of their PBMs and/or the small employer business, or simply differences in contract design and cost allocation that are not captured by the PBMI (2013) analysis. FTC (2005) emphasizes that PBM contracts differ in how they structure fees and charges. For example, contracts where PBMs retain a larger share of rebate dollars may charge lower fees for other services. The available evidence is thus inconclusive on what information gaps, if any, exist in employer contracting with PBMs; the causes of any perceived problems; and how/whether additional PBM reporting requirements might improve market functioning.

5.2. Potential Costs of Reporting Requirements for Employer-Sponsored Plans

Requiring additional reporting would entail administrative costs for PBMs that would inevitably be passed on to employers. Perhaps less obvious but more significant, such reporting could have unintended consequences and competitive harms:

5.2.1. Competitive Harms. There are significant grounds for concern that reporting requirements could enable some PBMs to know the terms that their competitors are offering, which could facilitate tacit collusion and reduce rather than increase price competition in the highly concentrated PBM industry. Such anticompetitive effects could apply not only to the PBM's pricing of its own services but also to its contracting with individual pharmacy

chains or drug manufacturers. The latter risks may be mitigated if reporting of retail spreads and rebate dollars is for total amounts, aggregated over retail and mail-order business, rather than for retail versus mail business separately or for specific drug or pharmacy contracts. However, aggregate reporting requirements could lead to audit demands to verify compliance, which could reveal sensitive data about pharmacy and manufacturer contracts. Of particular concern is the risk of divulging competitively sensitive data about the PBM's costs and contract terms related to its mail business.

The standard concern – that information about a competitor's prices can promote tacit collusion in concentrated industries (Stigler 1964) – is exacerbated in the case of PBMs' contracts with health plans and employers because of overlapping business models resulting from vertical integration. Specifically, health insurers that offer health plans on exchanges or Medicare MA-PD plans may operate their own in-house PBMs and hence be both customers of independent PBMs and competitors with these same PBMs. As health plans or health plan administrators for employer sponsors, they could be recipients of the mandated reported information from independent PBMs with whom they compete on other PBM contracts.

To illustrate, consider the case where independent PBM X is required to report its retail and mail spreads to an employer that is also considering contracting for PBM services with its health plan. The employer may naturally pass on the cost data reported by PBM X to its health plan, which operates its own in-house PBM that competes with PBM X on this and/or other contracts. This would give the health plan unfair insights into its competitors' costs and contracting terms.

Further, PBMs contract with retail pharmacies but PBMs also operate mailorder pharmacies that are an important competitive check on the increasingly concentrated retail pharmacy sector. If PBMs are required to reveal cost and spread information on their mail business, separate from their retail pharmacy purchases, this information could potentially become visible to retail pharmacy chains that compete with PBMs' mail pharmacies.

5.2.2. Accounting vs. Commercial "Data.". Because some vertically integrated PBMs own retail pharmacies and most PBMs own a mail-order pharmacy, their reporting of "acquisition costs" and "spreads" for services from these owned pharmacies would inevitably reflect internal transfer prices that are created for corporate accounting (and reporting?) purposes, rather than "arms' length," commercial prices. It would be competitively inappropriate to compare these transfer prices with true commercial prices of less vertically integrated PBMs. Moreover, such transfer "costs" are more likely to lead to challenges and demands for audit, which increases the risk of disclosure of competitively sensitive cost information.

5.2.3. Undermining Generic Competition and Saving. The interests of plan sponsors and PBMs are currently strongly aligned to drive generic substitution and price competition, which has provided large savings for employers/consumers. There is a risk that transparency reporting might reduce PBMs' margins on generics, which could undermine their incentives to

encourage generic utilization and demand deep discounts from generic suppliers. This risk is greatest for generics that PBMs buy and dispense through their mail-order pharmacies, which currently provide a powerful competitive counterweight to retail pharmacies. More generally, protecting the confidentiality of generic acquisition prices and the incentives of PBMs to demand generic discounts is essential to preserving competitive discounting by generic companies and the pass-through to payers of generic discounts by both retail and mail-order pharmacies. Generic conversion has already yielded dramatic savings to payers and consumers, and preserving competition in generic markets is essential to preserving and expanding these savings in the future, as more brand patents expire.

5.2.4. Preserving Appropriate Agency Incentives. If the PBM business were so transparent that any savings they made on brand rebates or generic discounting would be fully passed through to plan sponsors, their incentives to seek such savings aggressively would be undermined. Further, since rebates are usually related to the restrictiveness of formulary choice, the contractual promise of a specified level of rebates by a PBM cannot be meaningfully evaluated without information on restrictions on drug choice for plan beneficiaries. There is a risk that simple rebate and spread reporting could lead employers to focus on maximizing their rebate dollars, ignoring the effects of such demands on PBM incentives and the effects of restrictive formularies that generate rebate dollars on employees' drug choice, other medical costs and health outcomes.

Can 5.2.5. Attempts Base Reimbursement Costs Be to onCounterproductive. Transparency requirements that attempt to set actual reimbursement for drugs at the pharmacy's or PBM's actual cost or acquisition price may have unintended consequences, leading to higher real costs and/or manipulated prices. For example, AWP was originally a measure of actual average wholesale price, but it became distorted once it was widely adopted as a basis for reimbursement of pharmacies and dispensing physicians. In 2005, Medicare replaced AWP reimbursement for physician-dispensed drugs with reimbursement at average sales price (ASP) plus 6%. This now creates incentives for manufacturers to set high list prices for these specialty drugs and discourages competitive discounting, because ASP is measured net of volume-weighted discounts. More generally, any widespread attempt to tie reimbursement to a measure of the provider's "cost" will likely lead to distortions in the reported "cost." To the extent that demand for transparency reporting by PBMs is motivated by a desire for cost-based reimbursement, it will likely have perverse consequences for costs, similar to prior attempts at cost-based reimbursement.

5.3. Concluding Comments

The nature of competition for PBM services is complicated by the vertical integration of some health plans into the PBM business and some PBMs into the supply of retail pharmacy services, in addition to their traditional mail-

dispensing pharmacies. The demand for more regulation of PBMs has sometimes come from these competing suppliers, rather than from the ultimate customers of PBMs (employers and consumers), whose interests the regulations are allegedly intended to serve. There is no compelling evidence of contracting problems, if any, faced by health plans and employers in contracting with PBMs, or how proposed transparency reporting would address these problems.

The risks of requiring PBM transparency reporting to qualified health plans and to self-insured employers are considerable. Although Medicare PDPs are subject to similar reporting requirements to CMS, in this context the risks of competitive harms and disclosure of competitively sensitive information are much less. In contrast to CMS, private health plans and self-insured employers are much more numerous and are in situations that could lead to inappropriate disclosure of confidential PBM information to potential competitors at various levels of the value chain, which could reduce competition in these already concentrated sectors.

Employers do need better information to evaluate PBMs' performance. However, meaningful information requires metrics that enable employers to evaluate their current PBM's performance in controlling total drug expenditures and, ideally, the effects of drug spending on total healthcare quality and costs, of which the PBM's spreads and compensation are a tiny fraction. Moreover, evidence on the cost and effects of one PBM competitor should ideally be compared to the counterfactual of what a competitor PBM might have achieved. For example, if PBM A charges 10% more for administering the drug benefit than PBM B, but PBM A also reduces wasteful drug spending by 10%, it would be worth paying for the extra administrative cost. To evaluate overall PBM performance thus requires measures of drug spending growth, risk adjusted, normalized for national trends, patient choice and cost-sharing, and trends in other health costs and outcomes. Designing and validating appropriate metrics of PBM performance would be a useful and pro-competitive step toward monitoring PBMs and promoting competition in this industry. By contrast, requirements to report competitively sensitive information to customers offer little benefit but could entail significant cost and anticompetitive risk.

Notes

- 1. See Shepherd (2013) and references therein. The argument goes back to Stigler (1964).
- 2. "Payers" and "sponsors" refer to health plans and/or employers that contract with PBMs.
- 3. Pharmacies may do generic substitution (between generically equivalent versions for the same molecule) without the physician's permission, but therapeutic substitution (between different molecules) requires permission from the prescribing physician.
- 4. AWP laws require managed care organizations to grant network participation to any provider willing to meet network requirements. See NCSL (2014).
- 5. Drug manufacturers usually provide a WAC, but sometimes a Direct Price (DP) and/or a SWP. See Medi-Span (2010a) and Medi-Span (2010b).
- 6. Some pharmacy chains compete for this generic business by offering patients very low copayment on generics; e.g., Walmart's \$4/30-day prescription program for many generics.
- 7. Express Scripts FY2013 10-K filing accessed through SEC EDGAR Database.
- 8. Medco Health Solutions FY2004 & FY2011 10-K filings accessed through SEC EDGAR Database.
- 9. Social Security Act SEC. 1150A. [42 USC 1320b-23].

- 10. In 2003, lawsuits filed by the Justice Department and state attorneys general of 20 states, Medco was accused of switching patients to higher cost drugs in order to gain higher rebate revenue. The 2004 settlement deemed it illegal for a PBM to incentivize a patient to switch to a drug that is more expensive for the plan sponsor. "State and federal officials said it would be a precedent for other large PBMSs" (Freudenheim 2004).
- 11. DST Systems FY2013 10-K filing accessed through SEC EDGAR Database.
- 12. See Kaiser Family Foundation (2014) (based on Georgetown/NORC analysis of CMS Enrollment files, 2006–2014. Includes PDP and MA-PD plans).
- 13. Catamaran FY2013 10-K filing accessed through SEC EDGAR database.
- 14. MedImpact website, https://www.medimpact.com/manufacturer-contract-management.
- 15. HR Policy Association website, http://www.hrpolicy.org/initiatives/pharma-direct
- 16. Express Scripts FY2013 10-K filing accessed through SEC EDGAR Database.
- By contrast, Medicare Part D PDPs are at risk for 15% of drug spending beyond the per patient catastrophic threshold.
- 18. Social Security Act SEC. 1150A. [42 USC 1320b–23]. Medicare Part D reporting has been required since the start of the program.
- 19. See Shepherd (2013) for details.

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