



PHARMACY BENEFIT MANAGERS

LPRO: LEGISLATIVE POLICY AND RESEARCH OFFICE BACKGROUND BRIEF

INTRODUCTION

Self-insured employers and private and publicly funded health plans contract with pharmacy benefit managers (PBMs) to design, administer, and manage prescription drug benefits, process prescription claims, and negotiate rebates, discounts, and pricing for brand-name and generic drugs with drug manufacturers. These entities also work to establish plan networks with national and local retail pharmacies by specifying when and how patients fill their prescriptions while working to control costs for their clients.

Recent trends in prescription drug spending have led states to examine the distribution of and supply chain for prescription drugs, which involves manufacturers, wholesaler distributors, clinics and hospitals, retail pharmacies, insurers, and pharmacy benefit managers (PBMs). Underlying much of the nation's drug distribution system are complex pricing methodologies used to calculate drug pricing, reimbursement approaches, and rebates that often involve PBMs. This brief provides an overview of PBMs, tools used by PBMs, a description of the drug distribution chain and pricing mechanisms, and a history of the legislative and regulatory environment of PBMs in Oregon.

PRESCRIPTION DRUGS AND SPENDING

Increases in prescription drug spending and prices, coupled with rising out-of-pocket drug costs, contribute to rising health care costs in the United States. Research indicates a number of factors impact pharmaceutical costs: drug innovation through research and development, brand-name and generic drug competition, new specialty drugs including rising use of new biologics and biosimilars, patent-protections (which provide market exclusivity), complex distribution systems, negotiating power, and federal and state regulations (Kesselheim, Avorn, & Sarpatwari, 2016).

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From 2013 to 2015, national spending on prescription drugs increased by approximately 20 percent and accounted for an estimated 17 percent of health care spending (Kesselheim et al., 2016). In general, brand-name drugs make up the largest percentage of drug costs, but account for only about 10-15 percent of filled prescriptions, while generic medications make up approximately 85 percent of dispensed medications (Grabowski, Long, and Mortimer, 2013). Specialty medications account for approximately 30 percent of total prescription drug costs in the U.S. In Oregon, from 1991 to 2014, the annual growth of prescription drug spending increased on average 7.2 percent (Center for Medicare and Medicaid Services (CMS), 2017). In 2014, \$3.5 billion was spent in Oregon on total sales for prescription drugs filled by retail pharmacies (Kaiser Family Foundation).¹ Nationally, CMS projects prescription drug expenditures will increase, annually, by 6 percent from 2018-2025.²

OVERVIEW OF PHARMACY BENEFIT MANAGERS (PBMs)

In the 1980s and 1990s, the health care industry saw the creation of PBMs. Initially, these new intermediaries worked with employers and insurers to ease the administrative claims process with prescription drugs, payment, and reimbursement among insurers, drug manufacturers, and pharmacies. The role of PBMs has changed over the years. Currently, self-insured employers and health plans contract with PBMs to design, administer, and manage prescription drug benefits (i.e., plans) including electronic claims processing. PBMs develop and manage networks with national and local pharmacies, specifying when and how patients fill their prescriptions while working to control costs for their clients through contracted reimbursement rates and dispensing fees with pharmacies.

Recently, mergers and acquisitions have resulted in the consolidation of the PBM industry. Several PBMs have also been purchased by pharmaceutical companies in the last decade (Werble, C., Dusetzina, S., Robinson, J., & Tollen, L., 2017). As of 2014, reports indicate that the top three PBMs account for 80 percent of the total PBM market. It is estimated that the majority of all prescriptions filled for approximately 180-260 million insured individuals pass through PBMs (Werble, C., et al., 2017). The Pharmaceutical Care Management Association (PCMA), a trade group representing the largest PBMs, reports that PBMs have saved employers 25 percent in prescription drug costs in past years. A report prepared for the PCMA (2016) estimates that the use of PBMs in the next decade (2016-2025) will save insurers and consumers approximately \$654 billion with the majority of savings incurred by commercial and Medicare plans (Visante, 2016).

In general, PBMs generate revenue by charging administrative fees and using different pricing indices, negotiating manufacturer rebates, and formulary designs. Currently, three predominate types of PBM business models exist (CVS Caremark 2013 [testimony](#) to House Health Care Committee; Werble, C., et al., 2017):

¹ Kaiser Family Foundation (2017). Accessible at: <https://www.kff.org/health-costs/state-indicator/total-sales-for-retail-rx-drugs/?currentTimeframe=0&sortModel=%7B%22collId%22:%22Location%22,%22sort%22:%22asc%22%7D>

² Centers for Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group. National Health Expenditure Data: Health Expenditures by State of Provider (includes employer sponsored and other private insurance, Medicare, Medicaid and other insurance programs). Accessible at <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet.html>.

1. a traditional or stand-alone PBM model with a mail-order and specialty pharmacy capability in which the PBM does not own a health insurance company (e.g., Express Scripts);
2. a health plan carve-in model that is owned or integrated with a health insurer (e.g., OptumRx associated with UnitedHealth Group); and
3. an integrated model, which has traditional PBM components, but expanded services as well (e.g., clinical support and access to retail health clinics, such as CVS Health).

The three approaches offer alternative models to coordinate the distribution, sale, and reimbursement of prescription drugs among health insurance plans, drug manufacturers, and retail pharmacies, including securing rebates and discounts from drug manufacturers and pharmacies. Pharmacy services administrative organizations (PSAOs) are yet another set of entities used by independent pharmacies to increase their group purchasing power and reimbursement leverage with PBMs. The complexity of the distribution system, multiple PBM business models, and flow of payments all affect the pricing of pharmaceuticals.

TOOLS USED BY PBMS

PBMs provide a range of services that include clinical services, prescription drug processing, drug formulary development and maintenance, utilization and cost management tools, and pharmacy network management. For example, a PBM will develop guidelines around the efficacy and safety of new medications (e.g., conduct therapeutic reviews), as well as develop a drug formulary and tiering (plan benefit design) that includes deductibles and co-payment amounts—often to encourage the use of clinically appropriate but lower cost alternatives. The most common formulary tiers (lowest to highest) are generics, preferred brands, nonpreferred brands and specials. The use of formulary tiers and cost sharing helps control overall costs. Another set of tools are utilization management that include prior authorization, quantity limits, and step therapy, which requires the use of a cheaper medication before trying a more expensive alternative. PBMs can also monitor and evaluate medication use intended to improve the quality of medications and reduce prescription costs (e.g., overutilization, incorrect dosage, preventable drug interactions, or nonadherence). Figure 1 describes some of the tools used by PBMs (see next page).

Figure 1: PBM Tools

Formulary

- PBMs provide a list of covered and preferred (i.e., approved) drugs under a health plan, and member co-pays, which are often offered as a three-tier plan.
- Tier one involves generic drugs with the lowest member co-pay, with the second and third tiers reserved for preferred and nonpreferred brand-name drugs. The third tier often having the highest member co-pays.

Manufacturer rebates and discounts

- PBMs can require manufacturers to provide rebates for preferred placement of drugs on a PBM's formulary (CBO, 2007). This results in manufacturers paying rebates directly to PBMs in exchange for the PBM placing their drugs on an insurance plan's formulary.
- PBMs negotiate pricing discounts with drug manufacturers, which offer larger discounts (i.e., rebates) to a PBM (or insurers) by purchasing a large volume of drugs (CBO, 2007). Rebate levels and structure vary for brand-name drugs and are used to incentivize formulary placement, including specialty drugs (CBO, 2007).

Specialty and Mail-order pharmacies

- PBMs may also offer their clients the benefit of contracting with a limited number of pharmacies that can fill specialty medications (specialty networks).
- PBMs own or contract with mail-order pharmacies, offering individuals convenience and cost savings such as providing a larger supply of medication and lower out-of-pocket costs for individuals (e.g., 90-day supply vs. 30-day supply provided by retail pharmacy).

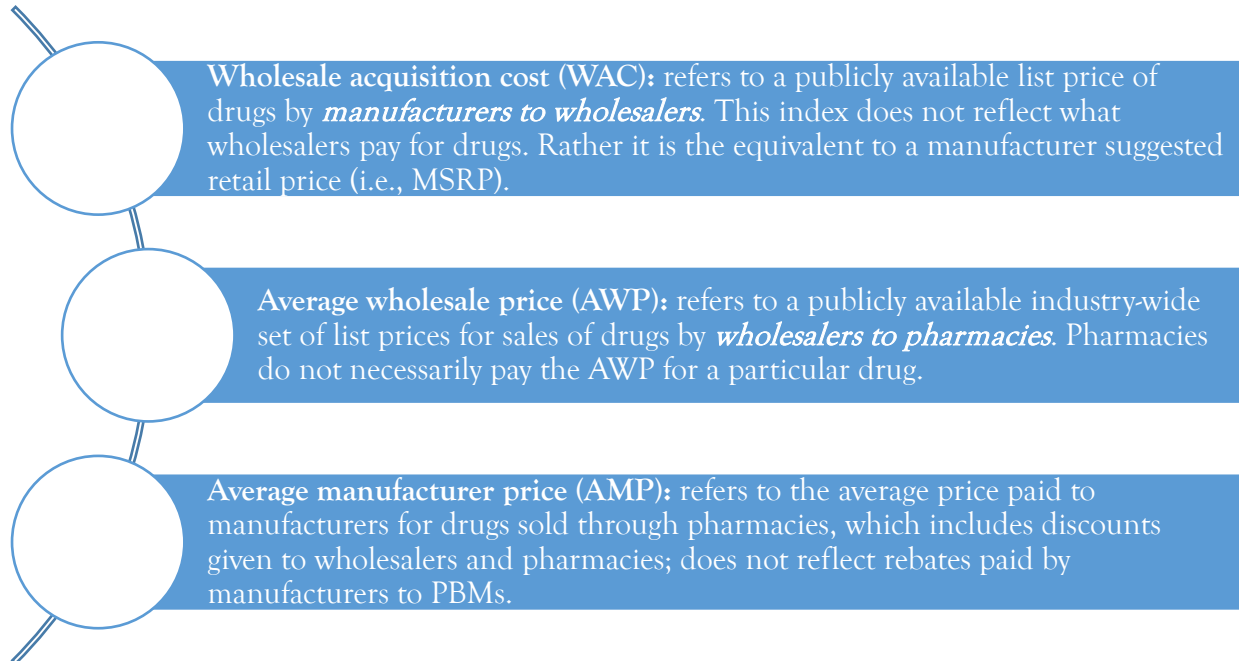
Pricing spreads

- PBMs may use multiple pricing indices for generic drugs, including different maximum allowable cost (MAC) price lists.
- For example, a PBM may negotiate with manufacturers using a lower-priced cost for a drug and then use a different MAC list to set its reimbursement rates with health plans. The difference between the two list prices is referred to as "spread."

PRESCRIPTION DRUGS AND PRICING MECHANISMS

PBMs negotiate rebates, discounts, and pricing indices for brand-name and generic drugs with drug manufacturers and retail pharmacies for their clients (i.e., health insurers and self-insured employers). This results in complex pricing mechanisms). According to Mark Meador (2011), the drug pricing methodology entails three main pricing measures for brand-name drugs: (1) wholesale acquisition cost (WAC), (2) average wholesale price (AWP), and (3) average manufacturer price (AMP). Figure 2 describes these three measures.

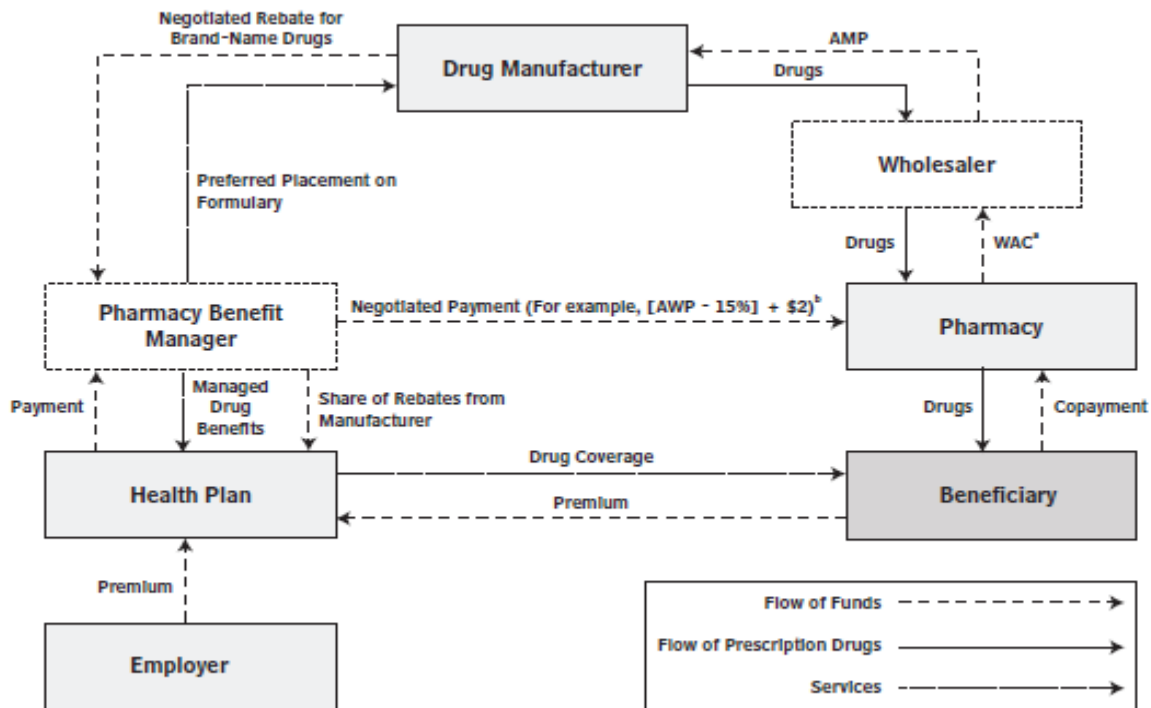
Figure 2: Brief Descriptions of Key Pricing Mechanisms



For generic drugs, a different price index is used: maximum allowable cost (MAC). The MAC is the upper limit or maximum amount a plan will pay for generic drugs. The MAC differs from pricing indices used for brand-name drugs such as the AWP because multiple MACs can have a range of prices compared to a single list of prices occurring in AWP (Meador, 2011). According to CVS Caremark ([testimony](#) March 15, 2013), the range of factors used in establishing MAC lists includes: “*First Databank/Medispan data, the federal upper limits of CMS, wholesaler information, pharmacy incentive to dispense the generic over the brand, pharmacy feedback, non-MAC discounts and client performance guarantees,*” among others (pg. 7). Lists establishing generic pricing are often considered proprietary business information or trade secrets, and confidential property protected by law. The multiple price indices used in the supply chain are depicted in Figure 3 (see next page).

Figure 3: Flow of Funds for Brand-Name Drugs

Flow of Funds for Single-Source Brand-Name Drugs Purchased at a Retail Pharmacy and Managed by a Pharmacy Benefit Manager for an Employer's Health Plan



Source: Congressional Budget Office.

Note: AMP = average manufacturer price; WAC = wholesale acquisition cost; AWP = average wholesale price.

Source: Congressional Budget Office (2007, January). Prescription Drug Pricing in the Private Sector.

ROLE OF PBMs IN OREGON

According to the Oregon Board of Pharmacy, PBMs provide the following services and products in Oregon (2013):

- Design and manage drug formularies;
- Perform drug utilization review and drug regimen review for individual patients;
- Maintain patient dispensing records;
- Employ pharmacists to make therapeutic decisions about individual patients;
- Purchase and dispense drugs via contract pharmacies;
- Operate as a mail-service pharmacy; and
- Negotiate rebates and discounts from drug manufacturers to lower prescription drug costs for “sponsors and beneficiaries.”

HISTORY OF PBM LEGISLATION AND REGULATION IN OREGON

Oregon was one of the first states to pass legislation that required PBMs to register with the state. In 2012, the Oregon Legislative Assembly convened a PBM work group directed by the House Committee on Health Care. The objectives of the work group were to:

- (1) define the problem,
- (2) understand how PBMs interface with Oregon's prescription delivery system,
- (3) review what other states were doing around PBMs, and
- (4) develop a legislative concept for the 2013 session.

The product of the 2012 work group was [House Bill 2123](#) (2013), which required PBMs to annually register with the Department of Consumer and Business Services (DCBS). The bill also provided DCBS with regulatory oversight of PBMs conducting business in Oregon, and imposed an appeal process for PBMs and pharmacies in which certain pharmacies could appeal a reimbursement received for generic drugs.

In 2016, the Oregon Legislative Assembly introduced [Senate Bill 1505](#), which was intended to "strengthen and clarify" aspects of [House Bill 2123](#) (2013) (DCBS 2016, pg. 1). In lieu of passing SB 1505, the legislature included a budget note to [Senate Bill 5701](#). The note directed DCBS to convene a work group to develop recommendations for rulemaking on PBM compliance. The work group recommended two key changes: (1) increase registration and renewal fee(s) to cover program expenses incurred by the department, and (2) grant the department the authority to suspend or revoke a PBM's registration, if warranted. The 2016 work group did not explore the role of PBMs in terms of overall prescription drug costs in Oregon (DCBS 2016, pg. 2).

In the past five years (2012-2017), key issues to PBM regulation in Oregon have centered on:

- registration of PBMs and compliance and enforcement tools, including fines;
- fair and uniform auditing standards between PBMs and pharmacies, including the appeals process and enforcement activities; and
- transparency with pricing of generic drugs, specifically maximum allowable costs reimbursement methodology and rates.

In 2017, based on the recommendations developed by the 2016 PBM work group, the legislature passed [House Bill 2388](#), granting the department additional oversight and enforcement authority over PBMs. As of the fall of 2017, DCBS was engaged in a rulemaking process. Table 1 describes legislative activity in Oregon on PBMs (see next page).

Table 1: Oregon PBM Legislation

| Year | Bill # | Summary | ORS |
|------|---------------------------------------|--|---------------------------------|
| 2012 | HB 4122 | Would have required PBMs to be licensed by the State Board of Pharmacy, annually. Established transparency and disclosure requirements for PBMs. | Not enacted |
| 2013 | HB 2123 | Requires PBMs to register with DCBS, establishes regulations for audits of pharmacies, and creates regulations around maximum allowable cost (MAC) pricing lists used by PBMs. | ORS 735 (2015) |
| 2015 | HB 2875 | Would have directed DCBS to conduct a study on the effectiveness of laws establishing processes and procedures for PBMs. | Not enacted |
| 2016 | HB-1505-A | Would have authorized DCBS to adopt fees to pay costs associated with regulating PBMs. | Not enacted |
| 2016 | SB 5701 (budget note) | Directed DCBS to convene a work group to develop recommendations for rulemaking regarding PBM compliance. | Report submitted to legislature |
| 2017 | HB 2388 | Allows DCBS to deny, revoke, or suspend registration of PBM if manager engages in specified conduct. | Enacted |

Source: Legislative Policy and Research Office

As of 2016, Oregon had 165 manufacturers licensed as wholesalers (Oregon Board of Pharmacy, July 7, 2017) and 40 entities registered as a PBM (DCBS, 2016). In 2016, DCBS received 68,000 complaints of alleged violations by 25 PBMs. The majority of the complaints represent independent pharmacies (DCBS, 2016, pg. 4) and focus on the appeal process for pharmacy claims paid by a PBM using the MAC methodology. The common areas of complaints were (pg. 4):

- PBM failed to respond to an appeal within seven days;
- PBM provided no information after denial of a MAC appeal, specifically an alternative national drug code (NDC), which identifies the manufacturer of the drug but not the wholesalers;
- PBM increased the MAC, but did not reprocess claims back to the date of initial complaint; and
- PBM told the pharmacy to appeal through their pharmacy services administrative organization (PSAO).

According to DCBS, PBMs responded that Oregon law did not apply, the alleged violation(s) did not occur, or that the PBM never received the complaint. Moreover, the department identified the following issues: (1) different interpretations of Oregon statute, (2) lack of documentation, and (3) complexity and limited transparency in the MAC reimbursement process used by PBMs to reimburse pharmacy claims. The work group, led by DCBS in 2016, concluded by offering a set of additional considerations that were beyond the scope of the budget note and are highlighted on next page (DCBS, 2016, pg. 15).

- Independent pharmacies were concerned with underpayment due to MAC reimbursement, creating a financial strain, especially in rural areas.
- Pharmacies expressed an interest that PBMs, when a MAC appeal is upheld, reimburse all similarly situated pharmacies.
- Oregon law should be broadened to include pharmacy claims reimbursement in Medicaid and Medicare Part B.
- DCBS should be granted authority to levy fines against an organization that files frivolous appeals.

OTHER STATES' REGULATION OF PBMS

States have developed and implemented a range of regulatory approaches. The common features across the regulatory models include: oversight and monitoring of PBMs by the state pharmacy board or insurance commissioner, mandated disclosures and transparency requirements among PBMs and drug manufacturers, and prohibiting drug substitutions and mandates (i.e., drug-switching).

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