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Pharmacy Benefits Managers (PBMs):

Everything you wanted to know about what they are and how they're regulated

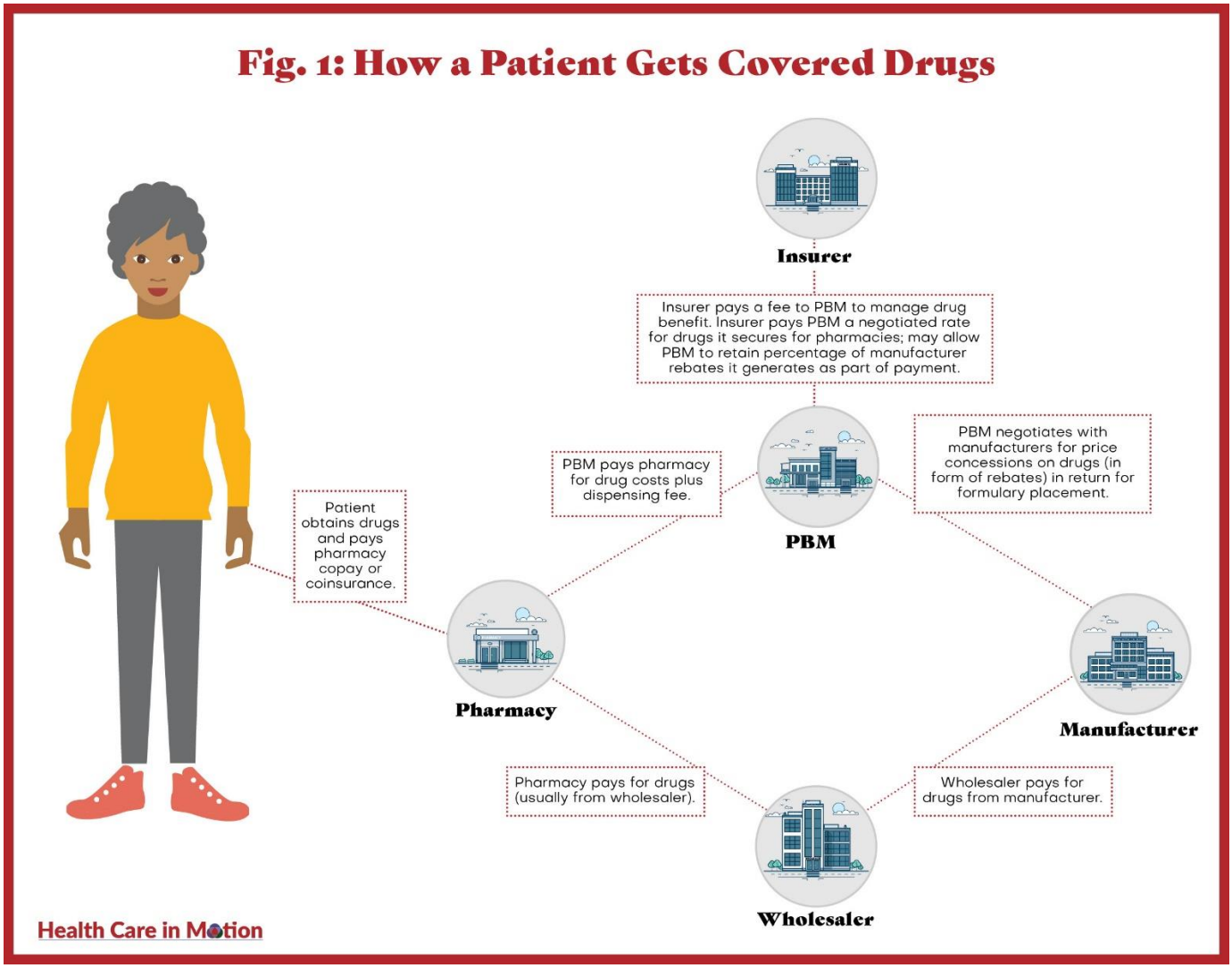
Pharmacy Benefits Managers (PBMs) are getting a lot of attention from state and federal regulators, not to mention patient groups representing individuals who depend on consistent, affordable prescription drug access. Read on for a rundown of how these complex entities work, why we should care about them, and what some of the state and federal policy options are to more closely regulate them.

PBMs: What Are They and Why Should I Care?

PBMs are the middlemen between pharmaceutical manufacturers and payers, including private health insurance plans, large employers, Medicaid managed care organizations, and Medicare Part D plans. They are the entity that payers hire to do the complex work of managing a plan's prescription drug benefit. This includes working with manufacturers to negotiate pricing, an endeavor that includes persuading manufacturers to provide rebates for their drugs in return for favorable placement of their drugs on a formulary that the PBM develops. PBMs also manage the particulars of formulary design, including making decisions about what drugs are covered, cost-sharing tiers, and utilization management. And, PBMs work directly with pharmacies to negotiate and effectuate reimbursement for drugs pharmacies have purchased from wholesalers and dispensed to patients. Patients pay a cost-sharing amount determined by the PBM when they receive their prescriptions from the pharmacy. Figure 1 below depicts the role of PBMs in the complex system that ultimately enables patients to obtain covered medications from pharmacies.

CHLPI Advocates for Federal Trade Commission (FTC) Action on PBMs

In May 2022, CHLPI sent a letter to the FTC urging it to review and regulate PBM business practices, including discriminatory formulary designs, that impact access to prescription drugs for people living with chronic and complex conditions.



Landscape of State and Federal Policy Action Regulating PBMs

The PBM regulatory landscape has drastically changed over the past several years, particularly as PBMs have gained market share and power. Currently, three PBMs (CVS Caremark, Express Scripts, and OptumRx) control 80% of the PBM market. Vertical integration – where PBMs merge with insurance companies and/or retail pharmacy chains – is also contributing to an increasingly powerful role for PBMs in determining patient access to medications. At the same time, PBMs have historically existed in a regulatory no man's land at the state and federal level, although that is beginning to change as state and federal regulators consider direct regulation of PBM activities.

State PBM regulation

Resource Highlight
The National Council of State Legislators has been tracking state PBM legislation in a database that categorizes laws by topic and state.

Advocates at the state level have pushed for more direct regulation of PBMs in recent years, and the different directions PBM laws have taken reflect the different interests at stake. For instance, community pharmacists have been a powerful lobby in state legislatures, arguing that PBMs are undercutting the community pharmacist role in health care delivery by manipulating pricing policies and pharmacy network designs in ways that favor retail pharmacies directly affiliated with PBMs. Community pharmacists have taken aim at PBMs for designing benefits in ways that push consumers toward retail pharmacy networks affiliated with PBMs over non-affiliated independent pharmacies and for employing practices that reimburse pharmacies at less than the acquisition cost of drugs. Many state laws regulating PBMs outlaw these specific practices. Patient advocacy groups have also increasingly promoted PBM regulation, focusing on the impact PBMs have on patient access and affordability through their control over formulary design and tiering decisions. These groups have been successful in integrating formulary access protections into state laws by, for example, outlawing the use of copay accumulator or maximizer programs.

Drug pricing advocates have also been in the mix, pushing for transparency provisions that shine light onto the opaque system of rebate negotiations and perverse incentives PBMs may have to preference high-cost drugs. For instance, this perverse incentive may appear when PBM formulary decisions are driven by the size of the rebate, pushing list prices higher and higher so that the manufacturer is absorbing less and less of the rebate negotiated by the PBM. Requiring PBMs to disclose granular rebate information may help regulators to better understand how these incentives play out and how they ultimately impact formulary access for patients. Drug pricing advocates have also urged lawmakers to require that a minimum percentage of rebates PBMs negotiate be passed on to the payer and/or consumers.

More recently, 340B covered entities (which include Ryan White HIV/AIDS Program recipients, STD clinics, and family planning clinics, among others) in many states have lobbied for protections that preserve 340B spread-generation opportunities (i.e., laws requiring 340B entities to be reimbursed at a private insurer's usual and customary price, not acquisition cost). 340B advocates have also argued for network protections that prohibit PBMs from excluding 340B pharmacies from pharmacy networks on the basis of their 340B status.

The U.S. Supreme Court's decision in *Rutledge v. Pharmaceutical Care Management Association* has put wind in the sails of these state-level PBM regulation activities. In *Rutledge*, the Court held that the Employee Retirement Income Security Act (ERISA) did not preempt Arkansas's law regulating PBMs. The Arkansas law required PBMs to pay pharmacies no less than their acquisition costs for prescription drugs. While the Supreme Court did not give a blanket blessing to all PBM regulations, it was a highly anticipated ruling that opens the door for a more active state role in PBM regulation. Since *Rutledge*, there has been more activity at the state level to pass legislation regulating PBMs.

Federal PBM regulation

At the federal level, both Congress and the Administration have been increasingly concerned about PBM activities and have moved to push forward policy responses.

In Congress, the Pharmacy Benefit Manager Transparency Act was reintroduced by Senator Maria Cantwell (D-WA) and Senator Chuck Grassley (R-IA) in January 2023. Among other things, the bill would eliminate spread pricing (where a PBM charges an insurance company more for a drug than it pays a pharmacy for the same drug). The bill would also prohibit the PBM practice of charging pharmacies fees after claims are processed, a practice decried by pharmacies as unfair and economically damaging because pharmacies are not able to rely on upfront cost estimates. The bill does not directly mandate that rebates generated by PBMs be spent in a certain way, but incentivizes PBMs to pass on to consumers a bigger proportion of rebates generated. The bill would empower the Federal Trade Commission (FTC) and state attorneys general to enforce the provisions. Senators Cantwell and Grassley have also introduced a companion bill, the Prescription Pricing for the People Act. This bill would require the FTC to examine PBM behavior and its effects on access and pricing, including the increasing consolidation in the PBM industry.

Within the Administration, HHS added several new provisions regarding PBM data reporting and transparency in its 2022 Notice of Benefit and Payment Parameters. This rule requires PBMs to report a considerable amount of data about services provided to Qualified Health Plans (QHPs), including:

- The percentage of all prescriptions that were provided under a QHP through retail pharmacies compared to mail order pharmacies, and the percentage of prescriptions for which a generic drug was available and dispensed compared to all drugs dispensed;
- Aggregate data on rebates and other price concessions that a PBM negotiates in exchange for favorable formulary placement (e.g., tiering placement and utilization management), including the amount of rebates passed through by the PBM to the QHP; and
- Aggregate data to capture PBM "spread," including the difference between what the QHP paid the PBM for medications and what the PBM paid retail pharmacies for medications.

The Administration has also taken steps to expand these types of disclosure requirements to the group and employer plan markets as well as the Federal Employee Benefits Plan. However, these broader prescription drug reporting provisions have been delayed and not yet gone into effect.

Meanwhile, in June of 2022, the FTC announced an investigation into PBM practices. The investigation includes data requests sent to CVS Caremark, Express Scripts, OptumRx, and other PBMs. The FTC followed up its announcement of its investigation with new guidance indicating that it will take a closer look at agreements between manufacturers and PBMs that involve rebates paid in "exchange for excluding lower cost drug products" as potentially violating federal law.

The FTC has said it will investigate the following:

- fees and clawbacks charged to unaffiliated pharmacies;
- methods to steer patients towards pharmacy benefit manager-owned pharmacies;
- potentially unfair audits of independent pharmacies;
- complicated and opaque methods to determine pharmacy reimbursement;
- the prevalence of prior authorizations and other administrative restrictions;
- the use of specialty drug lists and surrounding specialty drug policies;
- the impact of rebates and fees from drug manufacturers on formulary design and the costs of prescription drugs to payers and patients.

PBMs: What's Next?

It is likely that PBMs will continue to generate heated debate in health policy circles as state and federal lawmakers consider how to address the rising prices of drugs and consumer access and affordability challenges. With a divided Congress, legislative action is more likely to continue at the state level, but federal administrative action could get a boost once the FTC releases the results of its investigation. Watch this space for updates over the coming months.

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