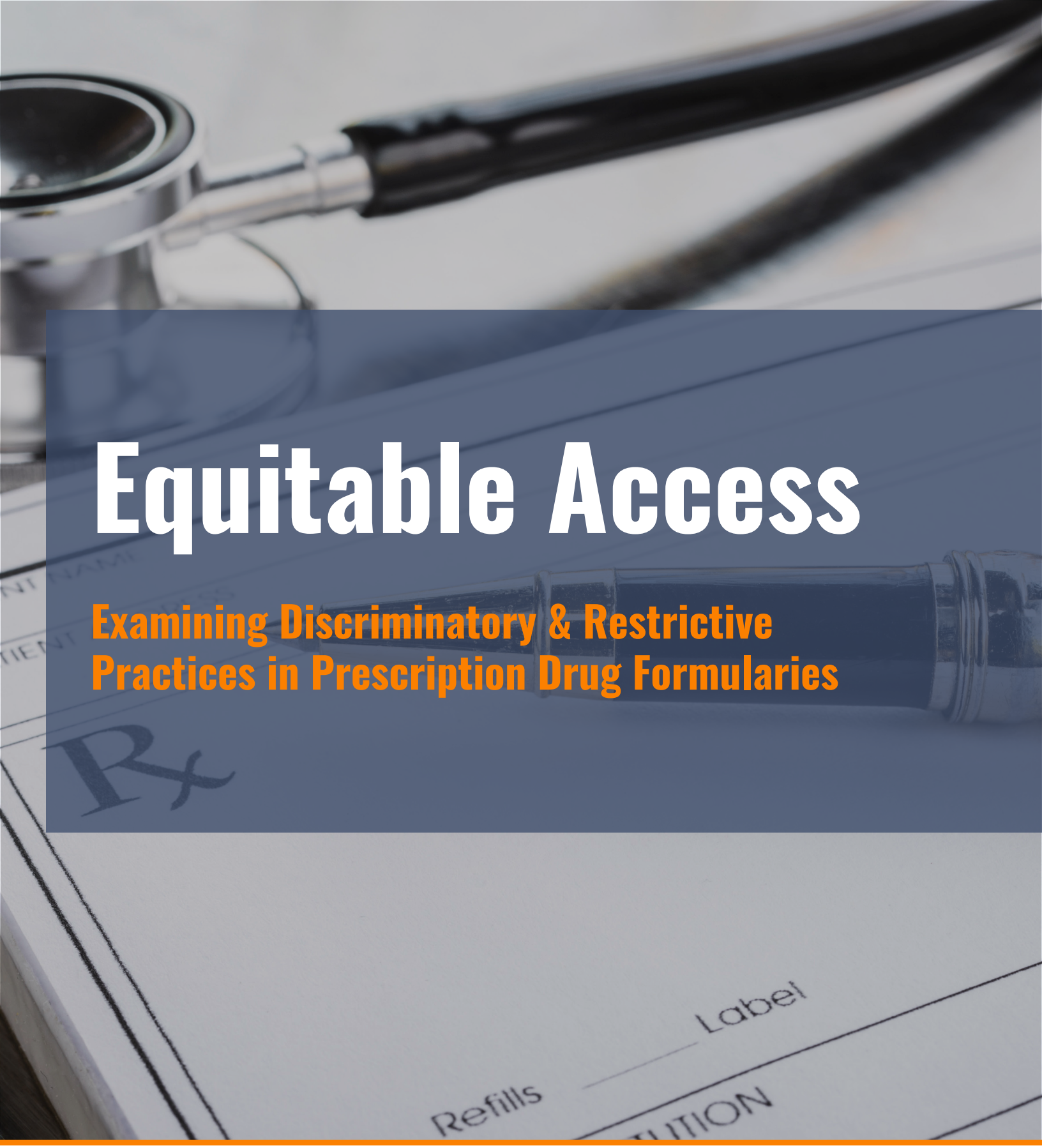

Equitable Access

Examining Discriminatory & Restrictive Practices in Prescription Drug Formularies

PATIENTS RISING

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Executive Summary

Modern formularies initially emerged in the 1980s and 1990s as tools for managing prescription drug costs within healthcare institutions. However, significant changes occurred after the passage of the Affordable Care Act (ACA) in 2010, which imposed new standards on prescription drug coverage. Despite these reforms, prescription drug spending continued to rise after the ACA took effect. This led to wider adoption of tiered formularies and complex cost-sharing structures. This period also witnessed the expanded influence of PBMs playing a central role in negotiating drug prices and benefits management.

Today, nearly all major U.S. health plans contract with PBMs that influence formulary decisions, often hinging on price negotiations, and wielding substantial bargaining power within the healthcare system. The lack of enforceable rules and transparency in formulary placement decisions, coupled with PBMs' financial incentives tied to rebates, have made them influential but controversial players in the prescription drug market.

Formulary practices driven by Pharmacy Benefit Manager (PBM) negotiations and health plans' cost-cutting motives often create unfair situations for patients. Many of these harms stem from the fact that PBMs negotiate rebates based on contract terms and volume, with little transparency on how much is passed to patients. This complex incentive structure can prioritize rebate volume over drug value, leading to formulary practices that limit patient access, increase costs, and hinder competition.

The suppression of competition is particularly acute for generic drugs and biosimilars, which are designed to make prescription drugs more affordable. Health plans may place generics on non-generic tiers, preferring higher-cost drugs over affordable alternatives. Despite cost-saving potential, generics face hurdles in obtaining coverage, delaying patient access. PBMs' incentives also lead to biased formulary placements, resulting in patients overpaying for generics and biosimilars. Beyond cost implications, these practices can lead to drug shortages as manufacturers lose incentives to produce new products, increasing the market’s vulnerability to supply chain issues and demand spikes.

Discriminatory tiering tactics like "adverse tiering" disproportionately impact patients with chronic or severe conditions. The practice of "lasering" high-cost patients out of a health plan’s coverage further exacerbates the issue, creating hurdles for patients relying on specialty drugs. Access and utilization restrictions, such as prior authorization and step therapy, often burden patients, particularly those with chronic illnesses, even when they may not be medically necessary.

Congress has shown increased interest in addressing the role of PBMs in rising prescription drug prices, including their influence on drug formularies. Several bipartisan PBM reform bills have recently been reported by Senate committees, all of which contain provisions related to formulary practices. Meanwhile, the FTC has launched an inquiry into PBMs' influence on prescription drug access and affordability, specifically examining the impact of rebates and fees from drug manufacturers on formulary design and drug costs for payers and patients.

Addressing these harms requires raising awareness among patients and advocates about formulary complexities and their rights, along with implementing specific policy reforms. In addition, policymakers should prioritize reforms that increase transparency, prohibit unethical practices, incentivize more open formularies, and require more generics and biosimilars to be placed on the lowest cost tiers. These changes can transform formularies into patient-focused tools, aligning with broader goals of a more equitable healthcare system.

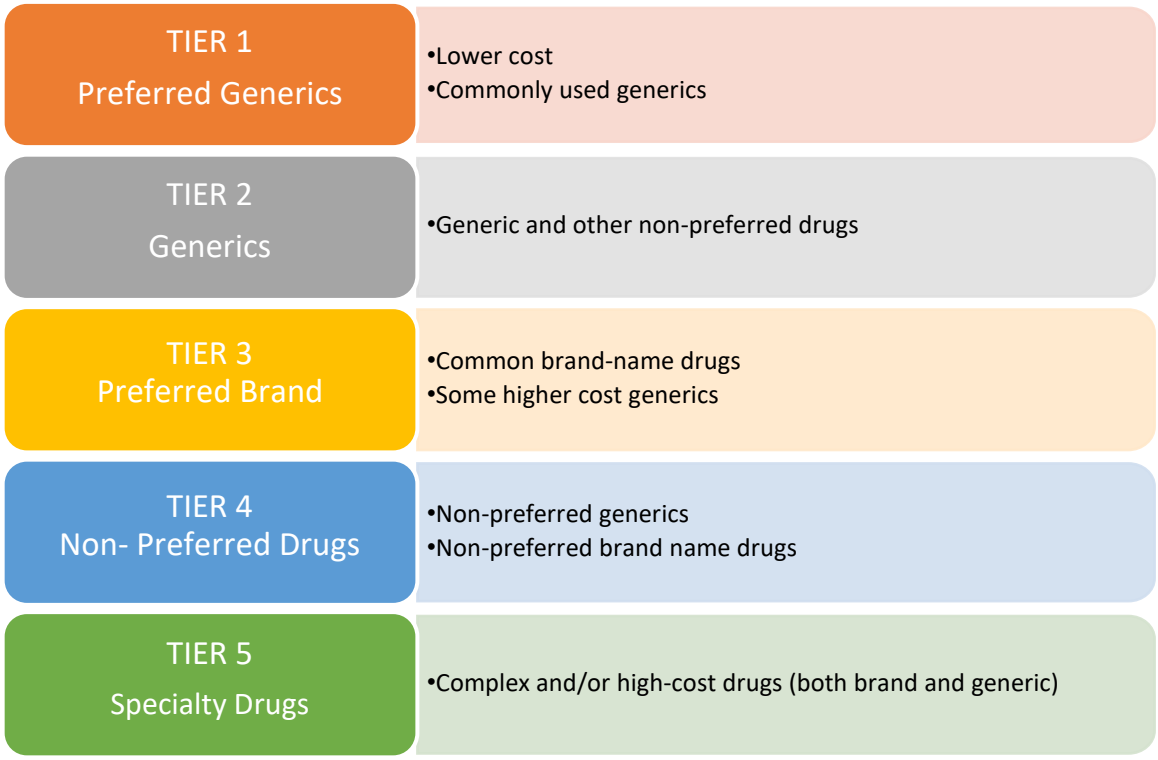
Formularies – An Overview

A prescription drug formulary is a list of medications, both generic and brand name, covered by a health plan. Ostensibly, formularies are designed by experts using clinical evidence to ensure patients have access to safe, effective treatments. Generally speaking, a formulary is usually considered a tool for insurers to promote the use specific treatments while managing costs.

Drug formularies typically follow either an open or closed model. In an open formulary, a plan will offer coverage for medications not listed in the formulary with a higher co-payment. Under a closed model, treatments not listed in the formulary are not covered, unless the insurer offers an exception due to extraordinary circumstances.

Most insurance plans use a tiered structure to categorize medications based on several factors, including cost, clinical evidence, and availability. In most cases, each tier comes with its own copayment or coinsurance requirements. Lower tiers typically contain generic or low-cost drugs and have lower patient cost-sharing requirements. Brand-name and specialty treatments are usually placed in higher tiers and cost patients more out-of-pocket (See Figure 1).

Figure 1: Typical Five-Tier Formulary Design



History of Formularies & The Rise of PBMs

Modern formularies became prominent in the 1980s and 1990s as a way for hospitals, managed care organizations, and other institutions to manage prescription drug costs. However, like many elements of the U.S. health care system, the role of formularies evolved dramatically after the passage of the Affordable Care Act (ACA) in 2010. The ACA imposed new standards for formularies, requiring health plans to cover at least one drug in every category and class of treatment to ensure patients had access to a broad range of options. It also required health plans offered in the individual and small group markets to cover "Essential Health Benefits," (EHB), a core set of ten items and services, including prescription drugs. These new rules were designed to ensure patients had access to necessary medications and prevent health plans from designing formularies in a discriminatory matter.

But, after the enactment of the ACA, prescription drug spending continued to go up. This led to wider adoption of tiered formularies and complex cost-sharing arrangements as health plans sought to reduce their overheads. It also led to an expanded role for pharmacy benefit managers (PBMs). Before the ACA, PBMs played a significant role in the U.S. health care system, though they were primarily focused on processing claims and contracting with pharmacies. Since 2010, health plans have relied on PBMs more and more to negotiate prices and rebates with drug manufacturers and manage prescription drug benefits. As a result, the PBM market has expanded dramatically as these entities have played a larger role in shaping the drug pricing landscape.

Today, virtually all major health plans in the U.S. contract with PBMs to negotiate with manufacturers, set prices, and oversee programs and benefits. In most cases, a PBM selects the medications that are included in a formulary, leaving the final tiering decisions to the insurance companies or plan sponsors. However, the input and advice offered by the PBM are usually essential factors in determining the final structure of the formulary. Indeed, the difference between a drug's placement on a preferred or non-preferred tier is often the price negotiated by PBM on a plan's behalf.

In theory, PBMs simply serve as intermediaries that help insurers manage their benefit programs. However, their influence extends far beyond this role. For better or worse, they are crucial pillars of the health care system, wielding immense bargaining power. The largest PBMs are part of vertically integrated corporate structures and are key drivers of revenue.

For example, while CVS is known primarily for its 10,000 drugstores in the U.S., it is also a major healthcare provider and insurer. Over the past two years, the company has spent nearly $20 billion to acquire multiple nationwide clinician networks.[1] However, even with all these overlapping lines of business, CVS's PBM – CVS Caremark – is by far its largest source of revenue, earning nearly $170 billion in 2022.[2] Two other major PBMs – Express Scripts and

[1] https://www.fiercehealthcare.com/providers/oak-street-health-deal-cvs-doubled-down-healthcare-strategy-investment-value-based-care

[2] https://www.cvshealth.com/news/company-news/cvs-health-reports-results-2022-q4.html

OptimumRx – both generate over $100 billion in revenue every year. These three companies control nearly 80% of the PBM market.[3]

Not surprisingly, this kind of market power has had a major impact on almost every element of the prescription drug market, including the formularies of leading health plans. There are no enforceable rules for determining where any particular drug should be listed on a formulary, and the processes PBMs and their client health plans use to make these decisions are rarely transparent. In addition, a PBM's fees are typically proportional to the savings they produce for an insurer in negotiations with manufacturers, which usually come in the form of rebates off the drugs' list prices.[4] In other words, the PBM business model creates built-in incentives, not to lower costs for patients or insurers, but to increase rebates and revenue while maintaining an illusion of larger savings for insurance plans.

The Formulary Status Quo – Patient Harms

The incentives arising from PBM negotiations, combined with health plans' continual need to reduce costs and offer competitive premiums, lead to formulary practices that unfairly limit patient access to treatments, increase their out-of-pocket costs, and, in many cases, produce discriminatory results. Decision-makers also use formularies to stifle competition, preventing patients from accessing lower cost alternatives to brand-name medications. In addition, formulary practices such as "adverse tiering" and "lasering" were designed specifically to either disincentivize certain classes of patients from obtaining coverage or move patients with complex illnesses off a health plan's books entirely. Other formulary practices take the form of literal access and utilization restrictions presented as cost-saving measures.

Negotiations and Rebates

Negotiations between PBMs and manufacturers primarily revolve around contract terms and volume. PBMs negotiate rebates from pharmaceutical manufacturers for preferential tiering, where the PBM collects a percentage of the rebate on the manufacturer list price. Unlike the medical loss ratio, which limits administrative and overhead costs for insurers and requires most of their revenue to be spent on healthcare cost and quality, PBMs are not subject to such limitations. Therefore, there is little transparency regarding how much of the collected rebate is passed back to the patient through lower premiums or reduced out-of-pocket costs.

Unfortunately, negotiation practices do not only prioritize a drug's medical value, but also the volume of the rebate offered to the PBM. A higher rebate or a greater product volume can be a significant driver for placing products in a preferred tier, potentially displacing crucial medications into less accessible tiers.

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[3] https://www.drugchannels.net/2023/05/the-top-pharmacy-benefit-managers-of.html

[4] https://www.commonwealthfund.org/publications/explainer/2019/apr/pharmacy-benefit-managers-and-their-role-drug-spending

Anti-Competitive Treatment of Generics and Biosimilars

The modern regulatory frameworks for generic drugs and biosimilars were designed to make effective prescription drugs more affordable by fostering increased competition. And, by most objective measures it works. Generics and biosimilars save the U.S. healthcare system hundreds of billions of dollars a year.[5] Ideally, when a high-cost medication or biologic treatment's exclusivity period ends, more affordable alternatives should emerge, giving patients more options and lower costs. Yet, many health plans employ formulary practices that hinder this vital competition.

A prototypical formulary places generic drugs in the lowest – and cheapest – coverage tier. However, in practice, that is not always the case. In many instances, health plans place generic drugs on non-generic tiers, effectively setting a preference for high-cost drugs over these lower priced alternatives.[6] This practice is all too common in Medicare Part D where, as of 2022, more than half of generic drugs on the market were not listed on generic tiers and were instead placed on higher cost-sharing tiers typically reserved for brand-name drugs.[7] These kinds of placements unnecessarily increase costs for Medicare beneficiaries by restricting access to FDA-approved, lower-cost generic medications, or charging beneficiaries brand prices for generic drugs. The situation is marginally better in the ACA exchanges where roughly one-third of generics and biosimilars currently sit on non-generic tiers.[8]

Even when generics and biosimilars are placed in the correct tiers, formulary practices tend to limit their availability to patients. According to a study released in 2020 by the Association of Accessible Medicines (AAM), generic drugs face significant headwinds in obtaining coverage, both under Medicare Part D and in the commercial insurance market. On average, it takes three years before the first generic offered for a brand name drug is covered on more than half of Part D formularies. By the end of that same three-year period, new lower-priced generics are typically covered by only 75% of commercial health plans.[9] These practices are at least partially motivated by the adverse incentives among PBMs and health plans. As stated previously, manufacturers of branded medications tend to offer more substantial rebates in exchange for favorable formulary placement, and PBMs receive larger fees from health plans when they can demonstrate significant savings off the manufacturer's list price. As a result, PBMs have a built-in incentive to favor branded drugs with higher list prices accompanied by larger rebates over low-cost generics or biosimilars.

This complex incentive structure prevents patients from reaping the full benefits of lower-priced generics and biosimilars. According to another AAM study from 2022, while the price of generic drugs has decreased significantly over the last decade, out-of-pocket spending among

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[5] https://accessiblemeds.org/sites/default/files/2021-10/AAM-2021-US-Generic-Biosimilar-Medicines-Savings-Report-web.pdf
[6] https://accessiblemeds.org/sites/default/files/2022-05/FTC-PBM-Business-Practices-05-20-2022_0_0.pdf
[7] https://avalere.com/insights/57-of-generic-drugs-are-not-on-2022-part-d-generic-tiers
[8] https://oversight.house.gov/wp-content/uploads/2023/09/AAM-PBM-Hearing-testimony-Burton.pdf
[9] https://accessiblemeds.org/sites/default/files/2020-02/AAM-White-Paper-Medicare-Part-D-New-Generics-to-Seniors-web.pdf

Medicare patients has more than doubled as Part D plans have steadily moved more generics into higher formulary tiers and delayed coverage for many others.[10] Patients with commercial insurance aren't reaping the full benefits of generic competition either. During roughly the same period outlined above, direct out-of-pocket payments by insured consumers for generic drugs declined by 50%. Yet, at the same time, the total price – patients 'payments + the price paid by insurer to the pharmacy – declined by over 80%, meaning a significant portion of the savings produced by generic and biosimilar competition has not reached patients.[11] Moreover, a recent analysis of Medicare drug claims found that, as a result of strategies utilized by PBMs, including biased formulary placements, patients are overpaying for generic drug prescriptions by as much as 20 percent.[12]

Beyond the cost implications, formulary restrictions on generics and biosimilars can also result in drug shortages. When a PBM delays the adoption of new generics or biosimilars, places them in higher-cost formulary tiers, or prioritizes branded medications, it diminishes the manufacturers 'financial incentives to maintain production. If drug companies cannot recover their investments in new products, fewer products will be launched, reducing options for patients, regardless of any coverage or formulary placement decisions. Fewer available products can lead to an increased reliance on single-source generics, making the market susceptible to supply chain disruptions or unforeseen spikes in demand.[13]

Discriminatory Tiering Practices

One of cornerstones of the ACA was its prohibition against insurers denying coverage or charging higher premiums for patients with pre-existing conditions. However, some major health plans attempt to sidestep those restrictions, resorting to other discriminatory tactics to avoid covering certain classes of patients and illnesses. One such practice is "adverse tiering," or placing certain drugs – particularly those for chronic or severe conditions – in a higher cost-sharing tier, even if there are no lower-cost alternatives available. This tactic garnered significant attention when several health plans took this approach with HIV treatments shortly after the ACA went into effect.[14] It also became a common practice for covering treatments for hepatitis B and C and multiple sclerosis. These strategies effectively allowed insurers to dissuade patients with these conditions from enrolling, skirting the ACA's nondiscrimination requirements.[15] Beyond the obvious discrimination against patients with severe illness, adverse tiering disproportionately impacts people of color and individuals with disabilities, who are often more susceptible to these conditions and face higher uninsured rates.[16]

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[10] https://accessiblemeds.org/resources/blog/patients-pay-more-when-generic-drugs-are-placed-non-generic-tiers-even-though-0
[11] https://healthpolicy.usc.edu/research/u-s-consumers-overpay-for-generic-drugs/
[12] https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2781810
[13] https://accessiblemeds.org/sites/default/files/2023-06/AAM_White_Paper_on_Drug_Shortages-06-22-2023.pdf
[14] https://ldi.upenn.edu/our-work/research-updates/chart-of-the-day-adverse-tiering-for-hiv-aids-patients/
[15] https://www.nejm.org/doi/full/10.1056/NEJMp1411376
[16] https://nashp.org/states-curb-racial-inequities-in-rx-drug-affordability-with-targeted-legislation/

Legal challenges[17] and state-level regulations[18] have led many major health plans to reconsider adverse tiering. Despite this progress, the problem persists in many parts of the country.[19]

A benefit carve-out, often referred to as "lasering," is another strategy health plans use to avoid covering certain classes of treatments, by intentionally attempting to take higher-cost patients off their books entirely. Under this approach, insurers "laser" certain specialty drugs out of their formularies, anticipating that the costs will be covered by nonprofit charitable assistance programs funded by drug manufacturers. When employing this tactic, health plans place specialty drugs in their highest tier, deny related claims, enroll patients into assistance programs, and then require the claims to be resubmitted with the new assistance information.[20] Patients whose claims are denied become "functionally uninsured" for the specialty drug, making them eligible for assistance from a nonprofit.[21]

In addition, these arrangements allow commercial insurers to essentially access need-based funds from charitable foundations established to help the uninsured to avoid payment, ultimately requiring truly needy patients to compete with large insurance companies for often limited charitable support. Similar to adverse tiering, practices like lasering and the indirect consequences imposes disproportionate burdens on patients relying on specialty drugs, typically those battling severe or chronic illness.

Access & Utilization Restrictions

In addition to setting tiers for coverage and cost-sharing, health plan formularies often establish policies for patient utilization and access to covered treatments. These protocols are typically cost-saving measures designed to prevent the over-utilization of covered therapies. Common examples include:

- **Prior Authorization**: Requires the prescribing provider to get pre-approval from the insurer before specified medications can be dispensed.
- **Step Therapy:** Requiring patients to try a lower-tier – and typically less expensive – alternative before "stepping up" to a more costly treatment if the first option is ineffective.
- **Quantity Limits:** Insurers set maximum limit on the amount or dosage of a particular drug they will cover within a specific time period.
- **Duration Limits:** Approval for short-term use only, with a required review or new authorization before an extension is granted.

In some cases, these types of limitations are medically appropriate, as when the CDC has recommended limiting quantities of opioids that can be prescribed for non-cancer pain.[22]

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[17] https://www.fiercehealthcare.com/payers/blue-cross-blue-shield-nc-removes-hiv-drugs-costly-price-tiers
[18] https://nashp.org/states-curb-racial-inequities-in-rx-drug-affordability-with-targeted-legislation/
[19] https://chlpi.org/wp-content/uploads/2022/06/CHLPI-FTC-Final92.pdf
[20] https://www.globallegalinsights.com/practice-areas/pricing-and-reimbursement-laws-and-regulations/usa
[21] https://www.drugchannels.net/2022/08/the-shady-business-of-specialty-carve.html
[22] https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm

However, in many instances, utilization restrictions impose significant and unnecessary burdens on patients, particular those with chronic or long-term illnesses.[23]

For example, in a recent physician survey conducted by the American Medical Association (AMA), 89% of doctors reported that prior authorization requirements led to negative clinical outcomes; 94% reported that such requirements delayed access to necessary care; and 80% said some patients had abandoned treatment due to difficulties in obtaining insurer authorization.[24] Many experts have also criticized step therapy – also referred to as "fail first" – restrictions for forcing patients to try lower cost treatments before moving on to more expensive ones, even when their doctor is confident the cheaper alternatives will not work[25] or the patient has previously tried lower cost options under their prior insurance plan.[26]

Federal Reform Efforts

Recently, Congress has taken a more active interest in PBMs and role they have played – including their influence on drug formularies – in rising prescription drug prices. In 2023, three Senate committees have reported several major bipartisan PBM reform bills, all of which have provisions that would impact formulary practices.

The Senate bills include:

- **PBM Reform Act** (Reported by the Senate Help Committee): Would increase oversight of PBMs, including a requirement that each PBM submit an annual report to plan sponsors and insurers that includes information on copayment costs and formularies.[27]
- **Modernizing and Ensuring PBM Accountability Act (**Reported by the Senate Finance Committee): Would set out new reporting requirements for PBMs participating in Medicare Part D, including submitting information about drug pricing, and generic and biosimilar formulary placement to plan sponsors and the Department of Health and Human Services. Would also prohibit PBMs in Part D to derive income based on a manufacturer's list price.[28]
- **PBM Transparency Act (**Reported by the Senate Commerce Committee): Would require PBMs to report to the FTC and provide an explanation if they switched a prescription drug to a higher formulary tier.[29]

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[23] https://ascopubs.org/doi/full/10.1200/OP.21.00500

[24] https://www.ama-assn.org/press-center/press-releases/toll-prior-authorization-exceeds-alleged-benefits-say-physicians#:~:text=Bad%20Outcomes%20%2D%20Nearly%20nine%20in,delayed%20access%20to%20necessary%20care.

[25] https://www.statnews.com/2016/08/22/step-therapy-patients-insurance-treatments/

[26] https://www.arthritis.org/advocate/federal/reform-step-therapy-practices

[27] https://www.congress.gov/bill/118th-congress/senate-bill/1339?q=%7B%22search%22%3A%5B%22s1339%22%5D%7D&s=9&r=1

[28] https://www.finance.senate.gov/imo/media/doc/Section-By-Section%20MEPA_Final.pdf

[29] https://www.congress.gov/bill/118th-congress/senate-bill/127?s=1&r=1&q=%7B%22search%22%3A%5B%22s127%22%5D%7D

Notably, the Senate Finance Committee's report on its legislation mentioned but did not include bipartisan legislation that would address formularies directly to dramatically expand beneficiary access to generic and affordable medicines. The Ensuring Access to Lower-Cost Medicines for Seniors Act would require Part D plans to place generics and biosimilars in a lower cost-sharing tier from brand-name drugs.[30] Senator Lankford, one of the authors of the bill, is currently working with Finance Committee leaders on the proposal and conversations about its inclusion in the final Senate PBM legislation are ongoing.

Coinciding with congressional efforts, the Federal Trade Commission launched a formal inquiry in June 2022 into PBMs 'influence on prescription drug access and affordability. Among several issues included in the inquiry, the FTC is looking to determine "the impact of rebates and fees from drug manufacturers on formulary design and the costs of prescription drugs to payers and patients."[31] While the inquiry is ongoing, the Commission voted in July 2023 to withdraw its prior statements related to PBMs – which had been issued between 2004-2014 – acknowledging that they "no longer reflect current market realities."[32] Industry advocates had been citing the FTCs previous statements to challenge the current investigation.

Reform at the State Level

As the political dynamics in Washington are often unpredictable, many advocates have shifted their focus to individual states. There is a broad and sometimes inconsistent range of state-level policies meant to address discriminatory formulary management practices. Approximately 19 states have passed copay accumulator legislation, with almost every state considering the measure at various levels of interest and viability.[33] When it comes legislation to address prior authorization and step therapy (fail first) practices, there is a much broader, less consistent range of proposed policies – more than 26 states considered some form of prior authorization measure in the 2023 legislative season.[34] Texas has taken a unique approach with prior authorization, passing a piece of "gold card" legislation which would allow doctors with a 90% approval rate to circumvent the prior authorization process.[35] The "gold card" concept has now also been introduced at the federal level.[36]

Other approaches have had varying measures of success at the state level. For example, Texas law has prohibited negative formulary changes in the middle of a plan year since 2012, and five other states with have varying levels of protection in place for patients along these same

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[30] https://www.menendez.senate.gov/newsroom/press/sens-menendez-lankford-introduce-legislation-to-tackle-pbms-reduce-the-cost-of-prescription-drugs
[31] https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry
[32] https://www.ftc.gov/news-events/news/press-releases/2023/07/ftc-votes-issue-statement-withdrawing-prior-pharmacy-benefit-manager-advocacy
[33] https://avalere.com/insights/state-copay-accumulator-bans-impact-11-of-us-commercial-lives
[34] https://axios.com/2023/01/27/states-target-doctor-authorization
[35] https://www.texmed.org/Template.aspx?id=59701
[36] https://www.ama-assn.org/practice-management/prior-authorization/gold-card-approach-prior-authorization-introduced-congress

lines.[37] Meanwhile, states like Florida, where the health plans and PBMs have a stronger footprint, similar legislation is seemingly introduced every year, but the state has not been able to implement any significant protections for mid-year formulary changes.

One issue recently gaining traction is the establishment of "Prescription Drug Affordability Boards" (PDAB), panels of (typically) healthcare professionals that set upper payment limits for certain types of prescription drugs. PDAB-related laws have been enacted in eight states: Maine, New Hampshire, Oregon, Ohio, Colorado, Washington, and Minnesota. Five of those states (Washington, Oregon, Colorado, Maryland, and Minnesota) have provisions setting a maximum price for prescription drugs. At the time of writing, Michigan was close to joining these states as the ninth state with a PDAB.[38] Some states have sought to pass sweeping reforms to the way PBMs do business. In fact, in the 2023 legislative season, estimates say that more than a quarter of all legislation introduced at the state level dealt with regulating PBMs.[39] Predictably, the provisions in the bills varied significantly across the board[40], with states like Florida, the latest state to enact PBM-targeted legislation, focusing heavily on protecting independent pharmacists by prohibiting gag clauses, spread pricing, and clawbacks, as well as implementing transparency and reporting requirements.[41]

Across all 50 states, patient advocates have made progress in implementing patient protections against discriminatory formulary management practices with varying levels of success. As novel issues, solutions, and proposals continue to matriculate across all 50 states, state legislatures will clearly continue to be a key battleground for regulating formulary management practices.

Conclusion

In an ideal world, health insurers and pharmacy benefit managers (PBMs) would prioritize equitable access to affordable care and treatments for all patients, regardless of the costs associated with their individual cases. Prescription drug benefits would be designed to promote competition ultimately benefiting patients through sustainable markets and lower prices. Unfortunately, the current reality falls short of this ideal for many patients. All too often, patients are subjected to unfair and abusive formulary practices that either restrict their access to optimal treatments or unfairly raise their out-of-pocket costs. In addition, many insurers and PBMs design their formularies to limit competition, favoring manufacturers that offer the highest rebates, leaving patients with fewer treatment options and higher co-pays and premiums.

Ultimately, solving these problems demands decisive action on the part of policymakers. While Congress and relevant agencies are rightfully focusing on broader reforms to combat PBM abuses, those efforts should include specific measures to address harmful and discriminatory formulary practices.

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[37] https://www.cga.ct.gov/2017/rpt/2017-R-0203.htm
[38] https://news.bloomberglaw.com/health-law-and-business/state-drug-pricing-boards-tee-up-new-front-in-pharma-legal-fight
[39] https://www.ncsl.org/state-legislatures-news/details/prescription-drug-bills-in-2023-5-emerging-policy-trends
[40] https://nashp.org/state-pharmacy-benefit-manager-legislation/
[41] https://www.groom.com/resources/states-continue-expansion-of-pbm-regulation/

In particular, reform efforts should aim to achieve the following policy goals:

- Increasing transparency for formulary placement decisions made by insurers and PBMs.
- Prohibiting lasering and similarly unethical formulary practices.
- Requiring more open formularies to prevent plans from blocking access to certain FDA-approved generics and biosimilars.
- Ensuring all generics and biosimilars are placed on the lowest possible cost-sharing tiers.

Preventing unfair and discriminatory formulary practices is essential to the ongoing effort to establish a healthcare system that is equitable, accessible, and patient-focused. Reforms that prioritize these principles will help ensure formularies are structured to help patients access the treatments they need without excessive financial burden. Ultimately, implementing these types of reforms will make change formularies from instruments that benefit insurers and PBMs through higher rebates and increased fees into tools that genuinely serve the interests of patients.