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# 'Reform School' for Pharmacy Benefit Managers: How Might Legislation Help Patients?

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The term “reform school” is a bit outdated. It used to refer to institutions where young offenders were sent instead of prison. Some argue that pharmacy benefit managers (PBMs) should bypass reform school and go straight to prison. “PBM reform” has become a ubiquitous term, encompassing any legislative or regulatory efforts aimed at curbing PBMs’ bad behavior. When discussing PBM reform, it’s crucial to understand the various segments of the healthcare system affected by PBMs. This complexity often makes it challenging to determine what these reform packages would actually achieve and who they would benefit.

Pharmacists have long been vocal critics of PBMs, and while their issues are extremely important, it is essential to remember that the ultimate victims of PBM misconduct, in terms of access to care, are patients. At some point, we will all be patients, making this issue universally relevant. It has been quite challenging to follow federal legislation on this topic as these packages attempt to address a number of bad behaviors by PBMs affecting a variety of victims. This discussion will examine those reforms that would directly improve patient’s access to available and affordable medications.

## Policy Categories of PBM Reform

There are five policy categories of PBM reform legislation overall, including three that have the greatest potential to directly address patient needs. The first is patient access to

medications (utilization management, copay assistance, prior authorization, etc.), followed by delinking drug list prices from PBM income and pass-through of price concessions from the manufacturer. The remaining two categories involve transparency and pharmacy-facing reform, both of which are very important. However, this discussion will revolve around the first three categories. It should be noted that many of the legislation packages addressing the categories of patient access, delinking, and pass-through also include transparency issues, particularly as they relate to pharmacy-facing issues.

## **Patient Access to Medications — Step Therapy Legislation**

One of the major obstacles to patient access to medications is the use of PBM utilization management tools such as step therapy (“fail first”), prior authorizations, nonmedical switching, and formulary exclusions. These tools dictate when patients can obtain necessary medications and for how long patients who are stable on their current treatments can remain on them.

While many states have enacted step therapy reforms to prevent stable patients from being whip-sawed between medications that maximize PBM profits (often labeled as “savings”), these state protections apply only to state-regulated health plans. These include fully insured health plans and those offered through the Affordable Care Act’s Health Insurance Marketplace. It also includes state employees, state corrections, and, in some cases, state labor unions. State legislation does not extend to patients covered by employer self-insured health plans, called ERISA plans for the federal law that governs employee benefit plans, the Employee Retirement Income Security Act. These ERISA plans include nearly 35 million people nationwide.

This is where the [Safe Step Act \(S.652/H.R.2630\)](#) becomes crucial, as it allows employees to request exceptions to harmful fail-first protocols. The bill has gained significant momentum, having been reported out of the Senate HELP Committee and discussed in House markups. The Safe Step Act would mandate that an exception to a step therapy protocol must be granted if:

- The required treatment has been ineffective
- The treatment is expected to be ineffective, and delaying effective treatment would lead to irreversible consequences
- The treatment will cause or is likely to cause an adverse reaction
- The treatment is expected to prevent the individual from performing daily activities or occupational responsibilities
- The individual is stable on their current prescription drugs

- There are other circumstances as determined by the Employee Benefits Security Administration

This legislation is vital for ensuring that patients have timely access to the medications they need without unnecessary delays or disruptions.

## **Patient Access to Medications — Prior Authorizations**

Another significant issue affecting patient access to medications is prior authorizations (PAs). According to an American Medical Association survey, nearly one in four physicians (24%) report that a PA has led to a serious adverse event for a patient in their care. In rheumatology, PAs often result in delays in care (even for those initially approved) and a significant increase in steroid usage. In particular, PAs in Medicare Advantage (MA) plans are harmful to Medicare beneficiaries.

The [Improving Seniors' Timely Access to Care Act \(H.R.8702 / S.4532\)](#) aims to reform PAs used in MA plans, making the process more efficient and transparent to improve access to care for seniors. Unfortunately, it does not cover Part D drugs and may only cover Part B drugs depending on the MA plan's benefit package. Here are the key provisions of the act:

- **Electronic PA:** Implementing real-time decisions for routinely approved items and services.
- **Transparency:** Requiring annual publication of PA information, such as the percentage of requests approved and the average response time.
- **Quality and Timeliness Standards:** The Centers for Medicare & Medicaid Services (CMS) will set standards for the quality and timeliness of PA determinations.
- **Streamlining Approvals:** Simplifying the approval process and reducing the time allowed for health plans to consider PA requests.

This bill passed the House in September 2022 but stalled in the Senate because of an unfavorable Congressional Budget Office score. CMS has since finalized portions of this bill via regulation, zeroing out the CBO score and increasing the chances of its passage.

## **Delinking Drug Prices from PBM Income and Pass-Through of Price Concessions**

Affordability is a crucial aspect of accessibility, especially when it comes to medications. Over the years, we've learned that PBMs often favor placing the highest list price drugs on formularies because the rebates and various fees they receive from manufacturers are

based on a percentage of the list price. In other words, the higher the medication’s price, the more money the PBM makes.

This practice is evident in both commercial and government formularies, where brand-name drugs are often preferred, while lower-priced generics are either excluded or placed on higher tiers. As a result, while major PBMs benefit from these rebates and fees, patients continue to pay their cost share based on the list price of the medication.

To improve the affordability of medications, a key aspect of PBM reform should be to disincentivize PBMs from selecting higher-priced medications and/or require the pass-through of manufacturer price concessions to patients.

Several major PBM reform bills are currently being considered that address either the delinking of price concessions from the list price of the drug or some form of pass-through of these concessions. These reforms are essential to ensure that patients can access affordable medications without being burdened by inflated costs.

The legislation includes the [Pharmacy Benefit Manager Reform Act \(S.1339\)](#); the [Modernizing & Ensuring PBM Accountability Act \(S.2973\)](#); the [Better Mental Health Care, Lower Cost Drugs, and Extenders Act \(S.3430\)](#); the [Protecting Patients Against PBM Abuses Act \(H.R. 2880\)](#); the [DRUG Act \(S.2474 / H.R.6283\)](#); and the [Share the Savings with Seniors Act \(S.2474 / H.R.5376\)](#).

## Federal PBM Reform Policies

Federal PBM Reform Policy	Delinking	Pass-Through
Pharmacy Benefit Manager Reform Act (S.1339)	<b>NO</b>	<b>YES</b> <i>But to the payers</i>
Modernizing and Ensuring PBM Accountability Act (S.2973)	<b>YES</b> <i>But limited</i>	<b>YES</b> <i>But limited</i>
Better Mental Health Care, Lower-Cost Drugs, and Extenders Act (S.3430)	<b>YES</b> <i>But limited</i>	<b>YES</b> <i>But limited</i>
Protecting Patients Against PBM Abuses Act (H.R.2880)	<b>YES</b>	<b>NO</b>
DRUG Act (S.1542/H.R.6283)	<b>YES</b>	<b>NO</b>
Share the Savings with Seniors Act (S.2474/H.R.5376)	<b>NO</b>	<b>YES</b> <i>But limited</i>

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As with all legislation, there are limitations and compromises in each of these. However, these bills are a good first step in addressing PBM remuneration (rebates and fees) based

on the list price of the drug and/or passing through to the patient the benefit of manufacturer price concessions. By focusing on key areas like utilization management, delinking drug prices from PBM income, and allowing patients to directly benefit from manufacturer price concessions, we can work toward a more equitable and efficient healthcare system. Reigning in PBM bad behavior is a challenge, but the potential benefits for patient care and access make it a crucial fight worth pursuing.

Please help in efforts to improve patients' access to available and affordable medications by contacting your representatives in Congress to impart to them the importance of passing legislation. The CSRO's [legislative map tool](#) can help to inform you of the latest information on these and other bills and assist you in engaging with your representatives on them.

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