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PRESCRIPTION DRUG AFFORDABILITY BOARDS: Challenges & Alternatives

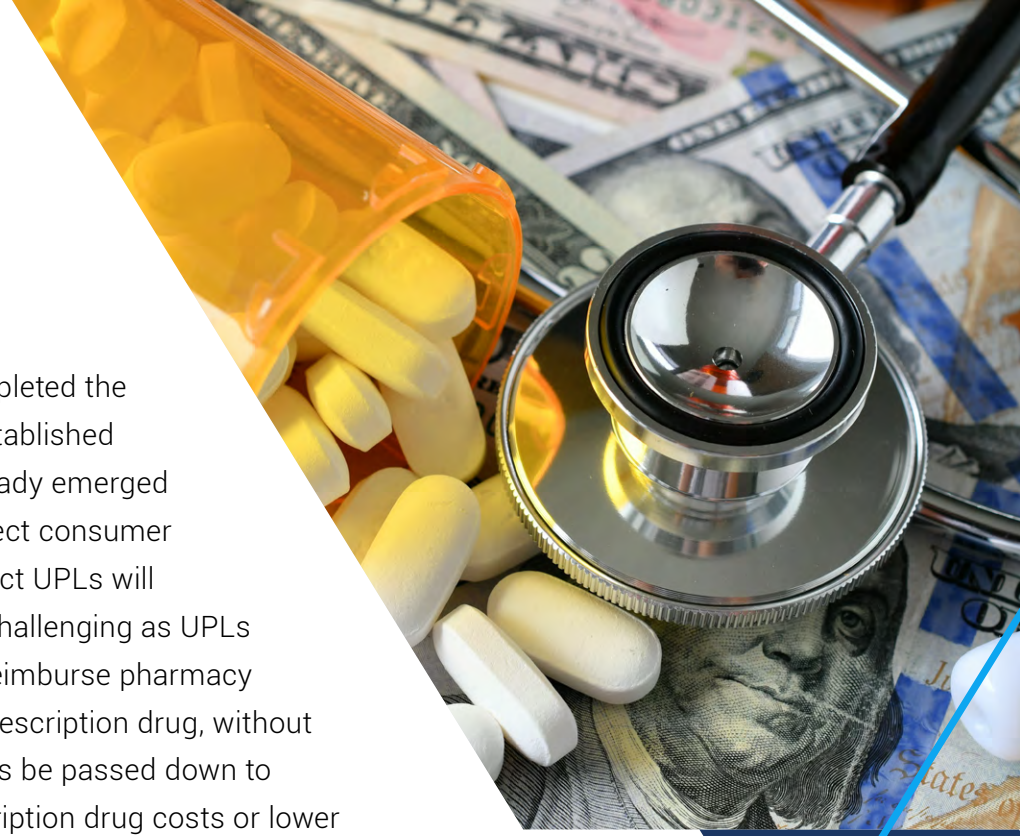
Prescription drug affordability boards, also known as PDABs, are state-level regulatory bodies focused on addressing the rising costs of prescription drugs through a range of strategies, including monitoring drug prices, conducting data analysis, reporting on pricing trends and drug markets, formulating policy, and implementing price controls.

Currently, nine states have implemented PDABs; four of them (CO, MD, MN, WA) have the authority to establish upper payment limits (UPLs), while the remaining five (ME, NH, NJ[1], OH[2], and OR) do not. However, as of April 2024, no PDAB has completed both the drug selection and UPL processes.

QUANTITATIVE & QUALITATIVE CONSIDERATIONS

PDABs are often tasked with determining the "affordability" of prescription drugs for either consumers, the state, or both. This analysis presents considerable challenges, given that affordability considerations for consumers and public payors can significantly vary. Determining affordability requires PDABs to consider numerous quantitative factors, including wholesale acquisition costs; availability of therapeutic alternatives; the impact of price on consumers' access to prescription drugs; orphan drug status; consumer copays and cost-sharing requirements; and any impact on 340B programs.[3] PDABs must also review several qualitative factors, such as input from patients and caregivers; individuals with scientific or medical training relating to a particular condition that is treated by the prescription drug under review; and any other factors deemed relevant by the board. Balancing both quantitative metrics and qualitative insights poses considerable challenges for PDABs, particularly when these boards are attempting to assign a monetary value to an individual's lived experience and perspective on treatment benefits. This complexity was most recently demonstrated by the Colorado PDAB's need to re-open its patient and caregiver survey after the board found it needed additional input from patients, caregivers, and individuals with scientific and medical training.[4]

IMPACT ON CONSUMER AFFORDABILITY



As of April 2024, no PDAB has completed the affordability review process and established UPLs. However, concerns have already emerged about how UPLs will potentially affect consumer affordability.[5] Determining the impact UPLs will have on consumer affordability is challenging as UPLs only limit the amount that *payors* reimburse pharmacy benefit managers (PBMs) for the prescription drug, without any requirements that these savings be passed down to the consumer through either prescription drug costs or lower premiums. Therefore, while the implementation of UPLs could lead to savings, there are no statutory guarantees that these savings will reduce the consumer's cost-sharing requirements.

UNINTENDED CONSEQUENCES

While PDABs are intended to lower prescription drug costs and improve access and affordability for consumers, this novel method may have unintended consequences that negatively impact consumer access to certain prescription drugs. Notably, a recent survey of health plans reported that the establishment of UPLs could potentially result in increased utilization of selected drugs and their therapeutic alternatives, leading to the implementation of measures like step therapy or prior authorization requirements, as well as adjustments to formularies, such as reclassification of selected drugs and therapeutic alternatives to different tiers.[6] These changes could impede patient access to essential medications, delay access to new or novel treatments, and increase administrative burdens on health care providers who are already treating stable patients. Given the array of uncertainties, lawmakers and regulators should explore alternative strategies aimed at enhancing prescription drug affordability while simultaneously safeguarding patient access and outcomes. Moreover, should they choose to move forward with the UPL process, they must diligently address how to alleviate these concerns.

ALTERNATIVES

With considerable concerns regarding the effectiveness of PDABs, Aimed Alliance encourages state legislators to pursue alternative legislation that can ensure a timely and direct impact on consumer cost-sharing and affordability. Examples of alternatives to PDABs include:

Prioritizing utilization management reform

Without appropriate guardrails, utilization management policies can result in increased administrative burdens on providers, delays in access to treatments, and increased costs for health care consumers.

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Prior Authorization & Gold Card Reform

Prior Authorization:

Prior authorization is a benefit utilization policy that requires health care providers or insurance plan enrollees to obtain approval from insurers or PBMs before the health plan will cover the cost of the originally prescribed health care product or service. Without proper guardrails, this practice can delay access to life-saving treatments and increase administrative burdens for physicians. State legislatures have recognized the need for prior authorization reforms and have passed laws creating guardrails on prior authorizations, such as imposing time requirements on insurers for prior authorization reviews, prohibiting retrospective denials, and requiring the use of standardized paperwork. Despite these efforts, prior authorization polices continue to delay access to necessary treatments for patients and impose unnecessary administrative burdens on providers. As a result, states are starting to introduce "gold card" laws to help alleviate the prior authorization burdens on providers. Typically, under a gold card law, providers are exempt from completing the prior authorization process for a treatment or service if they have successfully received prior authorization approvals for 80, 90, or 100 percent of their previous prior authorization requests within the preceding six-month period. Championing prior authorization reform and gold card legislation would have a direct impact on health care consumers and providers by helping alleviate the administrative burden on provider offices and ensuring patients have timely access to care.[7]

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Step Therapy Reform

Step Therapy:

Step therapy, also known as "fail first," are benefit utilization policies that require consumers to try and fail on alternative treatments, before the insurer or PBM will cover the originally prescribed treatment. As a result, consumers may find that the most effective treatments for their conditions may be inaccessible until alternative options have been exhausted and proven ineffective. Without proper guardrails, step therapy policies may also require patients to try and fail on off-label treatments; multiple different treatments; and treatments consumers have previously failed on under a different health plan. In addition, policies can

require consumers to try and fail a treatment for more than thirty days, forcing consumers to continue to experience symptoms without relief. While several states have enacted legislation that provides circumstances under which an individual is entitled to an exemption from a step therapy policy,[8] states can and should do more. For example, states can prohibit plans from requiring consumers from trying and failing on off-label medications; limit failures to one or two medications; and prohibit requiring consumers from trying and failing for more than 30 days. Ensuring the use of *reasonable* step therapy protocols can ensure patients have prompt and stable access to their treatments.[9]

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Copay Accumulators

Copay Accumulator:

When patients cannot afford their medications, they may rely on financial assistance from pharmaceutical manufacturers and other third parties to meet their health plan's cost-sharing responsibilities and obtain their prescriptions. The value of this financial assistance typically counts toward the health plan's deductible or maximum out-of-pocket limit, unless the health plan has implemented a copay accumulator program. Copay accumulator programs exclude the value of financial assistance distributed by third parties from counting toward the health plan's deductible or maximum out-of-pocket limit. These programs may force patients to switch or stop taking their treatment because they cannot afford their out-of-pocket costs once their financial assistance has been exhausted. Copay accumulator programs may disproportionately affect patients whose conditions are managed or treated by drugs in specialty formulary tiers that require greater cost-sharing from the patient. Twenty states, the District of Columbia, and Puerto Rico have already recognized that banning the use of copay accumulators in state-regulated plans can have a direct impact on consumer affordability and health care costs.

Supporting PBM reform:

PBMs are middlemen who negotiate with pharmaceutical manufacturers to determine which medicines will be included in health insurance companies' formularies and how much insurers' plans will pay the manufacturers for those prescription drugs. They also determine consumers' cost-sharing requirements for medications. PBMs have historically been loosely regulated, but attention to the prices consumers pay for their medications has led to scrutiny and calls for stricter regulation of the industry.

- PBM reform can encompass various measures, such as enhancing transparency surrounding prescription drug prices; prohibiting the use of mandated mail-order pharmacies; preventing higher reimbursements for PBM-owned pharmacies compared to non-affiliated pharmacies; and requiring protections to maintain access to local pharmacies. These measures collectively help ensure stable access to treatments for consumers.[10] PBM reform that can directly impact consumer affordability may also include rebate pass-through legislation that requires the PBM-negotiated rebates to be shared with consumers through either lower prescription drug costs or reduced premiums.[11]

MOVING FORWARD WITH PDABS

Despite concerns regarding the effectiveness of PDABs as a cost-saving measure, some state legislature will continue to pursue and implement PDABs. For those advancing in this direction, Aimed Alliance has developed several key considerations that should be included in PDAB legislation:

Require a consumer/patient representative to be included in the board membership.

- Currently, no state PDAB requires board membership to include health care consumers or patients. Consequently, boards may overlook the needs of patients, caregivers, and providers, and may experience challenges in engaging these communities. In some cases, engagement of these diverse communities may be an unintentional afterthought, resulting in boards modifying existing procedures to engage communities rather than ensuring the initial procedures are consumer-friendly. Ensuring the processes engage impacted communities ensures that the board will prioritize the affordability and needs of the communities they are attempting to serve.
- Recently, the federal government has also recognized the value of ensuring a permanent position for the patient perspective by requiring all Pharmacy & Therapeutics (P&T) committees to include at least one patient representative as a member of the committee. In making this decision, the federal government recognized that consumer representatives can provide "insights into real consumer experiences unknown to P&T committees."[12] Thus, a similar permanent position could be equally valuable and beneficial for the PDABs.
- The inclusion of a consumer or patient representative and selection of an individual to fulfill this role should also consider the value of this individual having lived experiences in chronic, complex, or rare disorders; as well as professional or lived experience in health equity, disability rights, and/or disability and racial justice.

Require a mandated process for continued consumer engagement.

- Currently, no PDAB requires a specific process for engaging health care consumers and the public. While some boards are required to establish "advisory councils" that include relevant stakeholders such as patients, patient advocates, and members of the prescription drug industry, there are no requirements as to how these councils are to be engaged, how their feedback is valued, or the frequency of their engagement with the board. As such, PDAB legislation should include clearer requirements as to how boards should engage advisory councils. This should include a consistent obligation to engage these councils on a quarterly, bi-annually, or annually basis to ensure that as UPLs are established and implemented, the board is continuing to assess how UPLs impact affordability and access for consumers.

Prioritize the role of the patient's voice and lived experience throughout the drug review process.

- As the ultimate recipients of these medications, patients play a crucial role in evaluating the value of these treatments. Engaging patients throughout the drug selection and affordability review processes will provide PDABs with valuable insights into disease management, access barriers, treatment preferences, and other relevant factors related to the selected medications.
- The responsibility to engage patients, caregivers, and providers must rest with the PDAB. Besides managing their health conditions, these individuals have personal lives, careers, and families they are responsible for. Therefore, it is unreasonable to expect them to be fully aware of regulatory processes like PDABs that may impact access to their treatments. Thus, the board should proactively identify trusted stakeholders within the relevant disease communities who can be engaged to facilitate sharing experiences about specific drugs and effectively reach the desired communities. The board must also recognize that engagement across racial and ethnic communities requires a nuanced approach that considers cultural stigmas and diverse perspectives on disease management and treatment.

Require payors and PBMs to pass UPL-derived cost savings to patients.

- As previously mentioned, UPLs serve as a limit to what payors can reimburse for a drug. Consequently, without precise legislative language mandating that these cost savings be passed down to consumers, payors are likely to retain the benefits of these savings without alleviating the financial burden on patients. Thus, legislators should incorporate statutory language that requires any cost savings resulting from UPLs to be passed on to consumers through either reduced prescription drug costs, lowered cost-sharing requirements, or decreased premiums.

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