

State Prescription Drug Affordability Boards (PDAB) and Analysis of Patient Impact: A US Physician Survey Study

Specialist Physicians Are Concerned PDABs Will Limit Patient Access and Burden Providers and the Healthcare System

Executive Summary

- Endocrinologists, rheumatologists, and human immunodeficiency virus (HIV) specialists/infectious disease specialists from Colorado, Maryland, Oregon, and Washington participated in an online survey to capture insights on Prescription Drug Affordability Boards' (PDABs) impact on patient accessibility and affordability of treatments
- Almost universally, physicians (93%) report a lack of sufficient knowledge-sharing between PDABs and clinicians
- Physicians (93%) are also concerned PDABs unaffiliated with a state medical board will make decisions that may affect medication access
- Clinicians surveyed (96%) were somewhat or very concerned that UPLs may lead to non-medical switching
- All specialists surveyed (100%) are concerned that additional administrative burdens related to PDABs will cut into office staff time and patient care
- "There are no benefits to PDABs. Decisions will be based on money, not on patient safety."
 Maryland Endocrinologist

Background

Lawmakers in several states have enacted Prescription Drug Affordability Boards (PDABs) with the overarching goal of lowering the price of prescription drugs. Under state law, PDABs' mandate is to identify high-cost drugs, determine if such drugs present affordability challenges to patients or payers, like the state, and to establish and apply an Upper Payment Limit (UPL), a maximum amount a payer will reimburse for a drug that is determined to be unaffordable.¹ Depending on the state, UPLs may apply broadly across public and state-regulated commercial plans, while others focus on specific state-funded programs, such as state employees. Some state laws recognize that self-insured plans with enrollees in the state can choose to utilize the UPLs established.

¹ https://nashp.org/qa-on-nashps-model-act-to-reduce-the-cost-of-prescription-drugs-by-establishing-a-prescription-drug-affordability-board/



Eleven states have established PDABs, and PDAB legislation is pending in additional states.²⁻¹⁵There is significant variability by state with respect to the authority granted to PDABs, including seeking supplemental Medicaid rebates, making policy recommendations, carrying out affordability reviews, and price setting.

Legislation permits a variety of factors to be considered during an affordability review, including price and utilization of the drug under review and its therapeutic alternatives in the state, patient cost and access factors, and evaluation of the drug's value based on comparative effectiveness to the therapeutic alternatives. States may gather input from various sources, including payers, manufacturers, patients/caregivers, healthcare providers, and other stakeholders, to help inform PDABs of a treatment's affordability. However, the methods of soliciting stakeholder input and how information is used are unclear and vary widely.

Once a drug is selected for affordability review, the PDAB or a delegate (e.g., supportive staff, contractors) will determine therapeutic alternatives, requiring agreement or final vote by the PDAB. The approach for selecting therapeutic alternatives for a drug determined to be unaffordable can vary: all treatment options for a specific condition may be included; therapeutic alternatives may be limited to products within the same pharmacologic class; or multiple drugs that are considered therapeutic alternatives to each other may be reviewed.

Study Methodology

Considering the significant impact PDABs may have on patients and providers, Magnolia Market Access conducted a survey of US specialty physicians to capture the physician perspective related to PDABs' impact on:

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<sup>2</sup> SB21-175, Colorado 2021 Regular Session. (2021)
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³ HB23-1225, Colorado 2023 Regular Session. (2023)

⁴ HB0768, Maryland 2019 Regular Session. (2019)

⁵ HB0279, Maryland 2023 Regular Session. (2023)

⁶ SB5532, Washington 2022 Regular Session. (2022)

⁷ <u>SF2744</u>, Minnesota 2023-2024 Regular Session. (2023)

⁸ <u>S2007B</u>, New York 2017-2018 Legislative Session. (2017)

⁹ <u>H.4000</u>, Massachusetts 2019-2020 Legislative Session. (2019)

¹⁰ LD1499, Maine 2019 Regular Session. (2019)

¹¹ HB1280, New Hampshire 2020 Regular Session. (2020)

¹² SB844, Oregon 2021 Regular Session. (2021)

¹³ SB192, Oregon 2023 Regular Session. (2023)

¹⁴ HB166, Ohio 2019-2020 Regular Session. (2019)

¹⁵ <u>S1615</u>, New Jersey 2022-2023 Session. (2023)



- Critical patient accessibility and affordability of treatments, including therapeutic areas most impacted by PDABs
- Provider administrative burden
- Health system burden

Physicians from Colorado, Maryland, Oregon, and Washington were selected to participate in this research. The four states of interest identified for this study were the most established in their respective PDAB initiatives at the time of survey fielding and have authority (or may in the near future) to set UPLs on prescription drugs determined to be unaffordable after PDAB review.^{16.17}

Selected Therapeutic Areas of Focus for PDAB Affordability Reviews

Endocrinology

GLP-1 receptor agonists SGLT-2 inhibitors

Rheumatology

Self-administered TNF-a inhibitors Interleukin inhibitors

HIV

Single-tablet regimen of ART for the treatment of HIV Injectable ART for HIV PrEP

For this survey, specialist types were chosen based on specific drugs or classes of drugs that have been selected for review by PDABs. A trusted third-party vendor recruited study participants; qualified physicians were required to have >3 and <30 years of clinical experience post-residency/fellowship and spend at least 50% of their professional time practicing direct patient care. Additionally, physicians selected for study participation were required to have a high degree of familiarity with types or classes of drugs within their specialty selected for review by Colorado, Maryland, Oregon, and Washington's PDABs. Physicians were not required to have prior knowledge of PDABs to participate in this research; 57% of all physicians surveyed were not at all familiar with PDABs prior to this study. The final study sample (N = 27) included 9 physicians from each specialty of interest across the four selected states and had an average of 16 years of clinical experience post-residency/fellowship.

The 30-minute survey instrument was designed by researchers experienced in survey methodology. The survey was programmed and hosted in Qualtrics, and online data collection occurred between November 21, 2024, and January 8, 2025. Survey questions were both open- and close-ended in nature, and participant responses were coded during data analysis to identify meaningful themes and trends. To level set participant knowledge, physicians were oriented to PDABs throughout the survey. The survey consisted of questions pertaining to general feedback on PDABs, patient access and affordability, therapeutic alternatives and affordability reviews, UPL/price setting, and case studies/scenarios based on specialty specific drug classes.

Treatments/drug classes and conditions of interest by specialty that were evaluated by participating physicians included:

- Endocrinology: Glucagon-like-peptide-1 (GLP-1) receptor agonists and sodium-glucose cotransporter 2 (SGLT-2) inhibitors (type 2 diabetes)
- Rheumatology: Self-administered tumor necrosis factor-α (TNF-α) inhibitors and interleukin inhibitors (rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, and psoriasis)

¹⁶ https://www.multistate.us/insider/2024/12/18/states-take-action-on-upper-payment-limits-to-address-prescription-drug-affordability

¹⁷ https://dfr.oregon.gov/pdab/Pages/upper-payment-limit-plan.aspx



 HIV: Single-tablet regimen (STR) of antiretroviral therapy (ART) and an injectable ART for pre-exposure prophylaxis (PrEP)

Detailed Findings

Many Physicians Are Unfamiliar with PDABs and Are Concerned About Their Impact on Patient Treatment Options and Access

Despite years of operation in three of the states surveyed, 93% of specialists surveyed in states with active PDABs did not feel like they have received sufficient information about PDABs and their impacts on both patients and provider prescribing autonomy. Similarly, 93% of those surveyed did not believe there was sufficient knowledge-sharing between PDABs and clinicians. This critical disconnect may result in suboptimal patient care.

Physician insights on possible future approaches to purchasing medicine in classes impacted by UPLs

"I would avoid prescribing drugs that take up more of my time trying to get approved." –Rheumatologist, Maryland

"I would avoid these medications if possible." –Endocrinologist, Maryland

"If affected patients' medical plans have essentially created a PDAB formulary, this will limit prescribing freedom and particularly be problematic in patients with limited options (patients that MUST have a certain antiretroviral drug due to resistances). Further nuances in prescribing based on risk factors is less possible as all patients could be funneled to PDAB-selected drugs." –HIV Specialist, Oregon

Patient affordability and accessibility to clinically appropriate treatment options are at the forefront of many physicians' minds when making prescribing decisions, as affordability and accessibility are important factors in adherence, persistence, and better patient-centered outcomes. To this end, 96% of all providers surveyed in this study reported considering affordability when weighing patient treatment options. But while physicians report considering affordability, they also reported concern about the impact of upper payment limits on accessibility to the treatments they prescribe.

Endocrinological Treatments

Since their inception, many PDABs have focused on affordability reviews specifically on diabetes treatments (i.e., insulin, GLP-1 receptor agonists, SGLT2 inhibitors), which may be impacted by UPLs. Of endocrinologists surveyed, two-thirds (67%) noted concern that PDABs/UPLs will impact available treatment options, and two-thirds (67%) reported they anticipate UPLs will impact their prescribing patterns and clinical choice. This is likely to drive physicians to avoid prescribing drugs; 33% of endocrinologists confirmed this assumption and reported they would avoid prescribing all drugs/biologics with UPLs or if/when UPLs lead to access restrictions.

Rheumatological Treatments

PDABs have similarly focused on affordability efforts on TNF-a inhibitors and interleukin inhibitors, and it is anticipated that these drug classes may also be impacted by UPLs. Most (89%) rheumatologists surveyed noted concern that PDABs/UPLs will impact available treatment options for their patients and

¹⁸ Fusco N, Sils B, Graff JS, Kistler K, Ruiz K. Cost-sharing and adherence, clinical outcomes, health care utilization, and costs: A systematic literature review. J Manag Care Spec Pharm. 2023 Jan;29(1):4-16. doi: 10.18553/jmcp.2022.21270. Epub 2022 Apr 7. PMID: 35389285; PMCID: PMC10394195.



limit provider prescribing autonomy. More than half of rheumatologists (56%) reported they would either likely avoid prescribing drugs/biologics with UPLs all together or if/when UPLs lead to access restrictions.

HIV Treatments

Both injectable ART for HIV PrEP and initial single-tablet regimen of ART for the treatment of HIV have appeared on initial eligible drug lists or been selected for affordability review by various PDABs, concerning HIV specialists/infectious disease specialists about patient access to clinically appropriate treatment and prevention approaches. 78% of participating HIV specialists/infectious disease specialists expressed concern that PDABs/UPLs will impact available treatment options for their HIV+ patients, negatively impacting key clinical outcomes (i.e., virologic success (undetectable viral load) and immunologic success (increased CD4 cell count)). This is particularly concerning for patients who have developed HIV drug resistance; an HIV specialist who contributed to this research noted that "if patients have HIV resistance, choices for therapy become limited." Additionally, 67% of HIV specialists/infectious disease specialists reported they would avoid prescribing all drugs with UPLs or if/when UPLs lead to access restrictions.

Many Physicians Are Reticent to Switch Patients to Therapeutic Alternatives

Participating physicians expressed concern about UPLs resulting in non-medical switching, forced change in a patient's treatment regimen for reasons unrelated to their health. **Nearly all (96%) of the clinicians surveyed were somewhat or very concerned that UPLs may lead to non-medical switching.** Specialists (HIV specialists/infectious disease specialists in particular) cited concerns related to adherence and ease of use, switching when disease is stable, and if a patient has a history of multiple trialed and failed treatments.

Physicians surveyed reported that, on average, 41% of their patients fail first-line therapy and require another clinically appropriate treatment option. Perhaps because of this, the majority (56% of endocrinologists, 78% of rheumatologists, and 56% of HIV specialists/infectious disease specialists) would not be willing to switch their patients to a therapeutic alternative in the same class. When presented hypothetical scenarios, providers across specialties offered variable responses (by treatment type) regarding their willingness to switch to a therapeutic alternative if the patient was clinically stable even if the therapeutic alternative met the patient's needs:

Endocrinologists

- GLP-1 receptor agonist to another GLP-1 receptor agonist: 56% not willing to switch
- SGLT2 inhibitor to numerous other alternatives (including GLP-1 receptor agonist, DPP-4 inhibitors, metformin, insulin) = 33% **not** willing to switch

Rheumatologists

- TNF-α inhibitors to TNFi = 33% **not** willing to switch
- Interleukin inhibitor to numerous other classes: 78% not willing to switch



HIV specialists/infectious disease specialists

- STR to other STR or multi-tablet regimen (MTR) = 56% **not** willing to switch
- Injectable PrEP to oral PrEP = 56% **not** willing to switch

Less than one third of clinicians surveyed indicated that all therapeutic options indicated for the same condition should be considered as therapeutic alternatives to drugs targeted by PDABs, while the plurality of respondents believe the appropriateness of therapeutic alternatives depends on the individual patient's clinical needs and preferences.

Specialists Want Input in PDAB Decision Making and Selection of Therapeutic Alternatives

Surprisingly, many PDABs are not comprised of practicing healthcare providers or specialists with the required clinical experience and nuance to understand drugs being evaluated for affordability review. As such, providers were concerned that non-medical or non-specialist members serving on PDABs evaluate complex clinical information and make decisions that will likely have clinical impacts at the patient-level.

The Colorado, Maryland, Oregon, and Washington PDABs are comprised of between 4-8 members, some of whom have an advanced degree and experience or expertise in healthcare economics or clinical medicine. PDAB members are not required to have the clinical expertise to select therapeutic alternatives. 93% of physicians surveyed are concerned PDABs unaffiliated with a state medical board will make decisions that may hinder patient access to needed medications. Physicians who participated in this study offered that specialist oversight on key PDAB decisions in each therapeutic area would be more meaningful than that of generalists or advisors without clinical experience.

Physicians reported they desire a moderate-to-high degree of involvement in the selection of therapeutic alternatives and setting of UPLs, as they are uniquely positioned given their clinical expertise to ensure clinically appropriate treatment alternatives are identified and their familiarity with patient affordability struggles. When surveyed, an overwhelming majority of providers (89% of endocrinologists, 100% of rheumatologists, 100% of HIV specialists/infectious disease specialists) believed that healthcare providers (i.e., DO, MD, NP, PA, specialists, and pharmacists) should have a moderate-to-high degree of involvement when selecting therapeutic alternatives for drugs undergoing affordability review. Specifically, 48% of all providers surveyed, including 78% of HIV specialists, believed that pharmacists should be involved in the selection of therapeutic alternatives given their close collaboration with prescribing providers and their vital role in patient adherence and treatment follow-up. However, most physicians in this study (89% of endocrinologists, 89% of rheumatologists, 100% of HIV specialists/infectious disease specialists) believed that therapeutic alternative recommendations by specialists carry more weight than alternatives offered by other provider types.

Summarizing survey respondents' concerns succinctly, one rheumatologist from Washington stated: "Non-medical people should not be making medical decisions."



PDABs May Be Burdensome to the US Healthcare System

There is concern among physicians that PDABs may place undue burden on both providers and the healthcare system by diverting resources away from patient care toward navigating complexities imposed by PDABs. All (100%) of the endocrinologists, rheumatologists, and HIV specialists/infectious disease specialists surveyed are concerned that additional administrative burdens related to PDABs will cut into office staff time and patient care. The potential administrative burden PDABs present is a factor that may contribute to negative impact on quality of patient care and outcomes.

The possible impacts of UPLs on the healthcare system are of similar concern to physicians. Most physicians who participated in this study (78% of endocrinologists, 89% of rheumatologists, 68% of HIV specialists/infectious disease specialists), envision UPLs posing a significant impact on healthcare services by increasing the overall financial burden on the healthcare system, causing delays in care, increasing the use of additional healthcare services, and creating a significant administrative burden on providers and practices due to forced non-medical switching (e.g., completion of new prior authorization requests, appeals processes, increased non-billable interactions with payers).

Conclusion

Where given the authority, PDABs attempt to address affordability challenges by creating and imposing a UPL for drugs deemed "unaffordable". However, physicians surveyed believe UPLs will limit access to drugs patients rely on and for whom therapeutic alternatives are clinically inappropriate. Physicians who participated in this study communicated their concern with respect to the impact UPLs will have on providers' prescribing habits, including the avoidance of prescribing products impacted by UPLs and an increase in non-medical switching.

Physicians voiced concern that PDABs may be grouping therapeutic alternatives too broadly; some physicians noted the therapeutic alternatives of interest evaluated in this survey were "suboptimal" and would negatively impact patients' overall health. Specialists feel uninformed about PDAB operations and that current knowledge-sharing between PDABs and clinicians is inadequate. Specialist insights and opinions should be sought out and incorporated into decision making given specialists' clinical expertise and familiarity with patient affordability challenges.

Overwhelmingly, physicians surveyed are concerned that PDABs will negatively impact clinical choice, treatment choice, and patient outcomes. While it is important to prioritize patient affordability, prescribing autonomy must be maintained, and therapeutic alternatives must be appropriate. An endocrinologist from Maryland who participated in this research reflected that, "There are no benefits to PDABs. Decisions will be based on money, not on patient safety."