



August 27, 2024

*VIA ELECTRONIC CORRESPONDENCE*

Office of Governor Ned Lamont  
State Capitol  
210 Capitol Avenue  
Hartford, CT 06106

Re: Call for Consideration of Alternative Legislative Reforms Beyond PDABs

Dear Governor Lamont:

Aimed Alliance is a not-for-profit health policy organization that seeks to protect and enhance the rights of health care consumers and providers. During the 2024 legislative session, the Connecticut legislature considered a bill that would have created a Prescription Drug Affordability Board, also known as a PDAB.

While Aimed Alliance supports measures that lower prescription drug costs for health care consumers, we urge you to consider PDAB alternatives that can directly impact consumer access to care and affordability. Additionally, if a PDAB is pursued in the future, we urge you to ensure that its Board membership is required to include a consumer representative; provide a means of genuinely valuing consumer, caregiver, and provider perspectives; and ensure cost savings from any price-setting mechanisms are directly passed down to consumers.

### **I. PDABs are Experimental and Lack Guaranteed Consumer Savings**

Legislation to establish PDABs aims to control the rising costs of prescription drugs by setting caps, known as upper payment limits (UPL) for select prescription drugs. UPLs restrict the amount that *payors* reimburse pharmacy benefit managers for a prescription drugs. As such, without specific requirements to pass cost saving to consumers, any savings will not impact what consumers pay at the pharmacy counter.

New research has also revealed that UPLs may increase patient access and affordability challenges. For example, a recent study published by Avalere found that health plan representatives anticipate greater implementation of utilization management tactics, such as step therapy and prior authorization, in response to UPLs being set on certain prescription drugs.<sup>1</sup> Plan representatives also anticipated adjustments to formularies, such as reassigning selected drugs and therapeutic alternatives to different tiers.<sup>2</sup> These anticipated changes have the potential to increase costs and hinder patients' access to essential medications, underscoring the need to use caution and explore alternative approaches to enhance prescription drug affordability.

### **II. PDAB Alternatives Can Have a Direct Impact on Consumer Affordability**

Currently, no state PDAB has completed the drug selection and UPL-setting process. As such, PDABs are experimental initiatives with significant upfront costs that provide no guarantee



that any cost savings generated from these programs will lower costs for health care consumers. As stated above, the way many PDABs are structured, any savings accrued would likely only benefit payors, as UPLs restrict what *payors* reimburse PBMs, without any requirement these savings be passed down to the consumers through prescription drug costs or premiums.

Given the uncertainty regarding whether PDABs will effectively lower costs for consumers, Aimed Alliance urges members to consider alternatives for reducing consumers' out-of-pocket expenses, including step therapy guardrails and copay accumulator bans.

### A. Step Therapy

Step therapy, also known as “fail-first,” requires consumers to try and fail on alternative treatments before covering the originally prescribed treatment. Step-therapy policies can be unethical and inconsistent with standards of care, resulting in interference with the practitioner-patient relationship, impose significant delays in access to prescribed treatments, and in some cases, increase challenges with treatment compliance.<sup>1</sup> In addition, several studies have found that step-therapy protocols can increase, rather than decrease, health care spending. For example, one study found that while step-therapy protocols decreased prescription drug costs by approximately \$20 per month, they increased outpatient service costs by nearly \$32 per month.<sup>2</sup> Additionally, another study found that implementing step-therapy protocols could increase total costs paid by the insurer by 37 percent for individuals who failed the first-step alternative to current best-practice care.<sup>3</sup> As such, these practices can not only inflict harm on patients, but also may contribute to increased long-term healthcare costs.<sup>4</sup>

Aimed Alliance commends Connecticut for taking steps to regulate step-therapy practices, including establishing exceptions where a step-therapy override is warranted and implementing clinical review criteria for establishing step-therapy protocols.<sup>5</sup> While these protections are important for ensuring consumers are entitled to an exemption when appropriate, these protections do not place guardrails on the *types* of step-therapy policies that can be used. Therefore, we urge you to consider proposing additional step-therapy protections, such as prohibiting step-therapy policies for certain progressive diseases and mandating additional safeguards, such as banning stepping through an off-label medication or trying and failing on more than one drug before covering the originally prescribed medication. These measures would strengthen patient protections and improve access to essential medications while minimizing unnecessary obstacles or delays for consumers and health care providers.<sup>6</sup>

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<sup>1</sup> Louis Tharp and Zoe Rothblatt, *Do patients benefit from legislation regulating step therapy?*, 1 HEALTH ECONOMICS, POLICY AND LAW 282-97 (Jul. 2022).

<sup>2</sup> Joel Farley, et al., *Retrospective assessment of Medicaid step-therapy prior authorization policy for atypical antipsychotic medications*, 30 CLINICAL THERAPEUTICS 1524–1539 (2008).

<sup>3</sup> Louis Tharp and Zoe Rothblatt, *Do patients benefit from legislation regulating step therapy?*, 1 HEALTH ECONOMICS, POLICY AND LAW 282-97 (Jul. 2022).

<sup>4</sup> *Id.*

<sup>5</sup> National Psoriasis Foundation, *Connecticut*, <https://steptherapy.com/step-therapy-legislation-by-state/>.

<sup>6</sup> Rachel Sachs and Michael Kyle, *Step Therapy's Balancing Act — Protecting Patients while Addressing High Drug Prices*, 386 NEW ENGLAND JOURNAL OF MEDICINE 901-4 (Mar. 5, 2022); Louis Tharp and Zoe Rothblatt, *Do patients benefit from legislation regulating step therapy?*, 1 HEALTH ECONOMICS, POLICY AND LAW 282-97 (Jul. 2022).



By placing reasonable guardrails on step therapy, patients can access the most effective treatments without unnecessary delays. This not only improves patient outcomes but also reduces overall healthcare costs by avoiding the need for additional treatments or medical interventions resulting from ineffective medications, or delays in accessing the most appropriate treatment. We urge you to consider this type of legislation to promote patient-centered care and reduce healthcare expenditures for consumers.

## **B. Prior Authorization**

Prior authorization policies require a health care provider or an insurance plan enrollee to obtain approval from the insurer or its PBM before the plan will cover the cost of a health care product or service. This practice can delay access to life-saving treatments and can be applied in a manner that is inconsistent with medical standards of care.<sup>7</sup>

Fortunately, 37 states have recognized prior authorization policies must be subject to time-based requirements to ensure patients can receive timely access to their medications. For example, states have passed legislation that requires published utilization review procedures, mandates the use of standardized paperwork, imposes a response time for acting on prior authorization requests, and prohibits retrospective denials.<sup>8</sup> Meanwhile, other states have taken further steps to remove prior authorization requirements for health care providers who receive prior authorization approvals in 80-90 percent of requests.<sup>9</sup> Ultimately, by optimizing prior authorization procedures, patients can receive prompt and appropriate care, and providers can spend less time on administrative matters and more time treating patients, leading to improved health outcomes and reduced healthcare costs in the long run.<sup>10</sup>

Therefore, Aired Alliance urges you to consider these legislative alternatives, which hold promise in effectively lowering costs for patients, while emphasizing patient outcomes, access, and affordability.

## **III. PDABs Must Prioritize Patient Access and Affordability**

If Connecticut does reconsider PDAB legislation in 2025, Aired Alliance urges you to ensure that a PDAB is required to prioritize patient input by including a consumer or patient representative on the Board, mandating ongoing consumer engagement, and requiring that UPL-derived cost savings be passed on to patients.

### **A. Prioritize Patients' Perspectives and Lived Experiences**

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<sup>7</sup> American Medical Association, *Prior authorization practice resources* (May 18, 2023), <https://www.ama-assn.org/practice-management/sustainability/prior-authorization-practice-resources>; Tanya Henry, *9 states pass bills to fix prior authorization*, AMERICAN MEDICAL ASSOCIATION (Mar. 8, 2024), <https://www.ama-assn.org/practice-management/prior-authorization/9-states-pass-bills-fix-prior-authorization>.

<sup>8</sup> Aired Alliance, *Prior Authorization Enacted Laws*, <https://aimedalliance.org/prior-authorization-enacted-laws/>.

<sup>9</sup> *Aired Alliance releases new Gold Card tool*, <https://aimedalliance.org/aimed-alliance-releases-updated-gold-card-tool/>.

<sup>10</sup> *Id.*



Research consistently highlights the benefits of actively involving patients in healthcare decisions. For example, studies have found that patient inclusion has created positive effects on improving health outcomes, enhancing satisfaction with the care experience, and lowering health care costs.<sup>11</sup> Including patients in health policy decisions can also improve the quality of healthcare delivery and improve accessibility.<sup>12</sup>

Moreover, given that patients are the intended beneficiaries of these medications, their perspectives are essential for accurately assessing the value of these medications. Involving patients in the decision-making process can also provide insights into disease management, access challenges, treatment preferences, and other pertinent considerations associated with various medications.<sup>13</sup> Their firsthand experiences can help ensure that healthcare policies address the needs of those they aim to serve.<sup>14</sup> It also enables PDABs to access a wealth of firsthand knowledge that is essential for making well-informed and patient-centered decision about prescription drug affordability and value.<sup>15</sup>

To ensure the patient, caregiver, and provider perspectives are appropriately valued and considered, Aimed Alliance urges members to ensure that any PDAB legislation mandates that a member of the Board be a consumer/patient representative. Providing a permanent and formal position for this perspective will ensure the development of PDAB surveys, questions, and processes are consumer-friendly and inclusive. Moreover, appropriately valuing lived experiences of consumers with chronic conditions can help ensure that healthcare policies address the needs of those they aim to serve.<sup>16</sup>

Recently, the federal government has 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 government recognized that consumer representatives can provide “insights into real consumer experiences unknown to P&T committees.”<sup>17</sup> Thus, a similar permanent position could be equally as valuable and beneficial for a Connecticut PDAB.

## **B. Mandate a Continuous Consumer Engagement and Oversight Process**

The obligation to engage the patient, provider and caregiver community should not be satisfied simply by creating a Board member position for consumers. Any drug selection and UPL-setting process should have a continuing obligation to actively seek input from a broad

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<sup>11</sup> Lisa Baumann, et al., *Public and patient involvement in health policy decision-making on the health system level – A scoping review*, 126 HEALTH POL. 1023-38 (Oct. 2022), <https://www.sciencedirect.com/science/article/pii/S0168851022001919>.

<sup>12</sup> *Id.*

<sup>13</sup> Alex Krist, et al., *Engaging patients in decision-making and behavior change to promote prevention*, 240 STUDENT HEALTH TECHNOLOGY INFORMATION 284-302 (2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6996004/>.

<sup>14</sup> *Id.*

<sup>15</sup> *Id.*

<sup>16</sup> *Id.*

<sup>17</sup> 2025 NBPP; See also, Lisa Baumann, et al., *Public and patient involvement in health policy decision-making on the health system level – A scoping review*, 126 HEALTH POL. 1023-38 (Oct. 2022), <https://www.sciencedirect.com/science/article/pii/S0168851022001919>



range of stakeholders, including patients, caregivers, and community representatives. The continuous inclusion of these voices and perspectives can help ensure the development of a fair and comprehensive drug review framework.

Furthermore, it is imperative to acknowledge that the governmental entity responsible for developing the drug selection process has a shared responsibility in engaging these communities. Patients and caregivers must manage work and family commitments, and their treatment regimens, all while striving to navigate complex healthcare systems to ensure optimal care for themselves or their loved ones. Therefore, the responsibility to be aware of and engage in the drug selection and UPL-setting process cannot rest solely on consumers to advocate for their needs; the Board must have an affirmative obligation to engage these communities.

Additionally, the engagement process must also extend beyond the initial review stage. Once the Board establishes a UPL, the Board should continuously monitor its impact on access and affordability. Establishing clear channels for consumers to voice concerns and grievances regarding any access barriers stemming from pricing policies is critical to ensuring equitable access to essential medications. By fostering a culture of transparency and responsiveness, a Board can effectively address emerging challenges following the adoption of UPLs.

### **C. Require Payors and PBMs to Pass UPL-derived Cost Savings to Patients**

UPLs serve as a cap on what *payors* can reimburse for a drug. Without precise legislative language mandating that these savings be passed down to consumers, payors are likely to retain the benefits of these savings without alleviating the financial burden on patients. Therefore, PDAB legislation should incorporate statutory language requiring any cost savings resulting from UPLs to be passed on to consumers through reduced prescription drug costs, lowered cost-sharing requirements, or decreased premiums.

### **D. Prohibit the Use of QALYs in PDAB Assessments**

Determining the value of a medication is a challenging endeavor that can lead to the creation of formulaic, mathematical “value assessment frameworks” that can inhibit patient access to care by applying a singular value to a product or service regardless of individual consumers’ needs or circumstances.

Quality-adjusted life years (QALY) are a measure used to quantify the health benefits of medical interventions or healthcare programs that are often used in decision-making to ration healthcare resources.<sup>18</sup> Aimed Alliance reiterates its longstanding recommendation against relying on QALY measures to evaluate any treatment. The use of QALY measures to evaluate the value of a treatment raises significant ethical concerns, as these measures place a price tag on the value of human life that merely reflects the individual’s diagnosis and deems those with chronic, debilitating, and rare conditions as being less valuable than those with common conditions. They treat individuals’ lives and health as a commodity and ignore patients’ and practitioners’

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<sup>18</sup> Gabriel Andrade, *Ethical Shortcomings of QALY: Discrimination Against Minorities in Public Health*, CAMBRIDGE QUARTERLY OF HEALTHCARE ETHICS 1-8 (Jan. 15, 2024).



individualized concept of the value of treatments.<sup>19</sup> Therefore, Aimed Alliance urges you to prohibit the use of QALYs throughout the PDAB processes.

#### **IV. Conclusion**

In conclusion, Aimed Alliance urges you to consider alternatives to PDABs that can directly impact consumer access and affordability. Moreover, we urge members to ensure that any PDAB legislation provides a permanent, consistent, and genuine process for valuing patient and provider perspectives and lived experiences through the above recommendations. Lastly, we urge you to ensure any PDAB legislation prohibits the use of QALYs in any value assessments.

Please contact us at [policy@aimedalliance.org](mailto:policy@aimedalliance.org) if you have any questions or would like to further discuss this letter.

Sincerely,

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Aimed Alliance

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<sup>19</sup> *Id.*