March 13, 2025

Via Electronic Correspondence

Abigail Spanberger
Commonwealth of Virginia
Constituent Services
P.O Box 1475
Richmond, VA 23218

RE: House Bill 483 – Establishing Price Caps for Referenced Drugs at the Maximum Fair Price

Dear Governor Spanberger:

Aimed Alliance is a not-for-profit health policy organization that seeks to protect and enhance the rights of healthcare consumers and providers. We are writing to provide comments on House Bill 483, which would establish caps on certain prescription drug prices using the Medicare "maximum fair price" standard. While we share the bill's goal of improving patient access to affordable medications, we urge the Governor to consider the potential unintended consequences of the legislation as drafted and to amend the bill to require a study of price-cap mechanisms and how they incorporate and prioritize patient feedback.

I. Consider the Unintended Consequences of Setting a UPL

House Bill 483 attempts to address rising prescription drug costs by setting reimbursement caps based on Medicare's "maximum fair price" (MFP) for drugs subject to the Centers for Medicare & Medicaid Services' (CMS) Inflation Reduction Act (IRA) negotiations. However, these caps apply only to the amount payors reimburse pharmacy benefit managers (PBMs), not the prices patients pay at the pharmacy counter. These caps only affect one point in the supply chain, so changes in price do not necessarily translate into lower copayments or premiums for consumers.

Moreover, existing research suggests that upper payment limits (UPLs), which function similarly to MFP-based caps, may produce adverse effects on access and affordability. A recent *Avalere* study found that health plans anticipate increasing the use of utilization management tools, such as step therapy and prior authorization, when UPLs are imposed on certain drugs.[1] Plans also expect to modify formularies by shifting drugs and their therapeutic alternatives into different tiers.[2] These changes risk raising costs for patients and restricting access to necessary medications, underscoring the need for caution when implementing price cap policies.

Price caps may also undermine patient access in other ways. Providers may stop dispensing medications if reimbursement rates fall below acquisition costs. Payers may also prioritize drugs that are not subject to price caps or may steer patients toward alternative therapies, as many rebates are tied to the drug's price, reducing PBMs' incentives from offering these options. Conversely,

[1] Avalere Health, *Update: Health Plans' Perceptions of PDABs and UPLs* (Mar. 28, 2025), https://advisory.avalerehealth.com/insights/update-health-plans-perceptions-of-pdabs-and-upls.
[2] *Id*.

even if price caps operate as intended, patients who are clinically stable on therapeutic alternatives may be subject to non-medical switching to drugs targeted by these price caps. In each of these scenarios, continuity of care may be disrupted, health outcomes compromised, and safety-net providers strained, ultimately increasing overall healthcare costs.

II. Price Capping Methods Universally Fail to Account for Critical Patient Engagement

Unlike many similarly situated countries, the United States has not historically used price caps, in large part due to its uniquely structured health insurance system, which relies substantially on private insurance. As such, the United States broadly, and Virginia specifically, is engaging in an experimental endeavor to address prescription drug affordability.

Therefore, Aimed Alliance urges Virginia to consider the lessons learned from international stakeholders who have been implementing price caps for much longer. Aimed Alliance's recent review of 23 international drug pricing systems found that regulators across countries consistently struggle to meaningfully engage patients and caregivers, understand how treatments provide value to them, and incorporate this feedback into pricing decisions. As a result, price caps may not reflect the *true patient value* of a treatment, as patients can value treatments in a variety of ways, including improved independence, quality of life, and symptom relief, all of which may be difficult to quantify using traditional value-assessment frameworks.

Importantly, across global health technology assessment (HTA) systems, best practices consistently emphasize integrating patient perspectives into affordability and reimbursement decisions. Meaningful stakeholder engagement also enhances HTA processes by identifying evidence gaps, validating claims, and facilitating evidence interpretation.[3] Without such engagement, price-cap systems often fail to reflect real-world patient needs.

Critically, countries like Australia, which have been establishing price caps for over a decade, are still struggling to value patient feedback in pricing decisions. Recognizing these challenges, in 2024 Australia produced a report highlighting over 40 recommendations to improve the price-cap setting process. Importantly, one of these recommendations includes "ensur[ing] consideration of the value elements is explicit before, during and after consideration of a technology, and transparently communicate these considerations in public summary documents." This report highlights how simply hearing from patients is insufficient in price-cap frameworks and that there must be transparent reconciliation between patient feedback and regulatory decisions.

Importantly, CMS's negotiations under the IRA to establish MFPs have faced similar criticisms. Under the 2027 IPAY Negotiated Price fact sheet, CMS only acknowledges that an opportunity was provided to hear from patients, patient advocacy organizations, and providers on the selected drugs.[4] The resource does not explain how the information received was reconciled

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[3] Commonwealth of Australia, *Health Technology Assessment Policy and Methods Review* (2024), https://www.health.gov.au/sites/default/files/2024-09/health-technology-assessment-policy-and-methods-review-final-report_0.pdf.

[4] CMS, Fact Sheet: Medicare Drug Price Negotiation Program, Negotiated Prices for Initial Price Applicability Year 2027, https://www.cms.gov/files/document/fact-sheet-negotiated-prices-ipay-2027.pdf.

with the decision and established price. The lack of reconciliation of patient, provider, and caregiver feedback remains a serious concern as CMS negotiations expand, and we risk creating a price-cap framework that grows without patients, the very people this program is intended to help.

This is particularly relevant to HB 483, which currently proposes establishing reimbursement caps equivalent to MFPs. As a result, Virginia would accept and adopt the underlying analysis completed by CMS when establishing the MFP. Aimed Alliance is concerned that this would perpetuate a value assessment framework that is not required to assess and reconcile patient, provider, and caregiver perspectives and feedback. Thus, Aimed Alliance urges Virginia not to adopt a price cap model that adopts MFP pricing.

III. The Need for a Comprehensive Study Before Implementing Price-Cap Policies

Given the significant challenges facing regulators in valuing and reconciling patient, provider, and caregiver feedback, as well as the uncertainty surrounding the real-world impact and savings of price-cap mechanisms for consumers, Aimed Alliance respectfully urges the Governor to amend House Bill 483 to require a comprehensive study before any price-cap policy is adopted in Virginia. As currently drafted, these price caps may not function as intended and could worsen affordability and access challenges for patients.

Importantly, a study on affordability and prescription drug costs may also identify additional forms that are needed to better address consumer affordability and determine whether price caps could directly benefit consumers. For instance, the study could examine whether a price cap would impact consumers without passing additional PBM reforms, such as delinking rebates from prescription drug prices, banning spread pricing, and ensuring rebate pass-through requirements.

In addition to evaluating effects on patient access and affordability, the study should assess how to ensure meaningful and effective patient engagement in any future affordability framework. This could include a review of how U.S.-based affordability boards have reversed and reformed policies to better include patients, as well as an examination of international efforts aimed at improving patient participation, feedback, and reconciliation. Virginia has an opportunity to learn from these examples by proactively determining how to integrate patient perspectives into the design, implementation, and oversight of any affordability policies.

IV. Conclusion

Aimed Alliance urges the Governor to amend the bill to require a study of price-cap benefits, challenges, and alternatives and how these mechanisms can best incorporate, prioritize, and reconcile patient feedback. Such a study would allow the Commonwealth to assess the effectiveness of price caps, anticipate unintended consequences, and consider alternative approaches that may better reduce prescription drug costs. This evidence-driven process will help ensure that any policy adopted is practical, effective, and aligned with the needs of Virginia's healthcare consumers.

Please contact us at policy@aimedalliance.org if you have any questions or would like to further discuss our concerns.

Sincerely,

Olivia Backhaus
Staff Attorney