

August 27, 2026

Mr. Joe Touschner
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Submitted via electronic mail: jtouschner@naic.org

RE: NAIC Health Care Affordability and Mitigation (B) Working Group – Draft Issue Briefs on “Standardizing or Limiting Utilization Review to Reduce Administrative Costs” and “Direct-to-Consumer Drug Platforms”

Dear Mr. Touschner,

On behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA), thank you for the opportunity to comment on two draft issue briefs recently released by the National Association of Insurance Commissioners’ (NAIC) Health Care Affordability and Mitigation (HCAM) Working Group: “Standardizing or Limiting Utilization Review to Reduce Administrative Costs” (Utilization Review Brief) and “Direct-to-Consumer Drug Platforms” (DTC Brief). PhRMA represents the country’s leading innovative biopharmaceutical research companies, which are focused on developing innovative medicines that transform lives and create a healthier world. Together, we are fighting for solutions to ensure patients can access and afford medicines that prevent, treat and cure disease. PhRMA member companies have invested more than \$850 billion in the search for new treatments and cures over the last decade, supporting nearly five million jobs in the United States.

We appreciate the Working Group’s continued effort to help state insurance regulators and their staff evaluate the tools that affect patients’ ability to access and afford their medicines. Both briefs are useful starting points, and we support NAIC’s broader goal of examining these issues objectively. We offer the following observations and recommendations in the same constructive spirit that has guided our prior engagement with the NAIC on utilization management and related topics, and we have organized our comments to address each brief in turn.

Part I. Draft Issue Brief on Standardizing or Limiting Utilization Review to Reduce Administrative Costs

The Utilization Review Brief identifies three approaches states have adopted to reduce the administrative burden of utilization review: (1) prohibiting or limiting prior authorization for certain services, medications, and supplies; (2) standardizing prior authorization forms and required information; and (3) implementing electronic prior authorization (ePA) and interoperability requirements. PhRMA supports each of these approaches and commends the Working Group for cataloging the growing body of state

activity in this area. We offer two recommendations to help the Brief present a more complete picture of how utilization management affects patients' access to prescription medicines.

1. The Brief Should Recognize the Growth of Utilization Management on Prescription Medicines and Its Impact on Patients

Recommendation: PhRMA recommends the Working Group supplement the Brief's administrative-cost framing with the patient-access dimension of utilization management. Specifically, the documented growth of prior authorization and step therapy applied to prescription medicines and the delays and abandonment that result, so that regulators can weigh the full cost of these practices, not administrative expense alone.

Rationale: The number of medicines subject to utilization management tools such as prior authorization and step therapy has grown substantially over time. Avalere Health found that prior authorization and step therapy for single-source brand medicines increased for all therapeutic areas studied, including conditions such as cancer, depression, rheumatoid arthritis, and diabetes, between 2014 and 2020.¹ This growth has real consequences for patients at the pharmacy counter. A 2025 study performed by IQVIA for patients in the commercial market found that more than 75% of patients were initially denied coverage when trying to fill a new prescription across five therapeutic areas. Initially denied patients who successfully overturned the payer rejection experienced average coverage delays of three to five weeks and had to overcome an average of two to four rejections before obtaining the medicine their provider prescribed.² Because the Brief is framed around affordability, we encourage the Working Group to consider potential downstream costs (delayed care, additional provider and patient administrative effort, and prescription abandonment) alongside the administrative savings it describes.

2. The Brief Should Address “Embedded Step Therapy” and Step Therapy Beyond FDA-Approved Labeling

Recommendation: PhRMA recommends the Working Group add a discussion of two utilization management practices that are largely invisible to patients and providers: (1) “embedded step therapy” and step therapy beyond FDA-approved labeling, and (2) transparency measures, such as requiring insurers to disclose these practices in consumer-facing materials.

Rationale: Although prior authorization and step therapy are sometimes treated as distinct tools, they may be indistinguishable to the provider or patient in practice. In the case of “embedded step therapy,” a drug is listed as having prior authorization rather than step therapy, but the prior authorization criteria require a patient to step through at least one drug before authorization can be granted.³ A recent analysis of the

¹Avalere Health. Utilization Management Trends in the Commercial Market, 2014–2020. November 24, 2021. <https://avalere.com/insights/utilization-management-trends-in-the-commercial-market-2014-2020>.

²IQVIA. The Impact of Formulary Controls on Commercially Insured Patients in Five Chronic Therapeutic Areas. July 2025. <https://www.iqvia.com/locations/united-states/library/white-papers/the-impact-of-formulary-controls-on-commercially-insured-patients-in-five-chronic-therapeutic-areas>.

³Avalere. Part D Prior Authorization Policies May Include Step Therapy. March 2025. <https://advisory.avalerehealth.com/insights/part-d-prior-authorization-policies-may-include-step-therapy>.

commercial market quantified how common these hidden practices are: step therapy was embedded in prior authorization requirements 59% of the time for psoriatic arthritis drugs, 51% for chronic myelogenous leukemia drugs, and 32% for multiple sclerosis drugs; and determined plans applied step therapy beyond FDA-approved labeling 63% of the time for psoriatic arthritis drugs, 39% for chronic myelogenous leukemia drugs, and 37% for multiple sclerosis drugs.⁴ Because these practices are not transparent, the standardization and electronic prior authorization reforms the Brief catalogs are not likely, by themselves, to bring these practices to light. We therefore encourage the Working Group to identify transparency into embedded step therapy and step therapy beyond FDA labeling as a complementary reform. For example, insurers could be required to disclose the use of these practices in consumer-facing materials so that the Brief's goal of a more efficient and transparent utilization review process fully extends to prescription medicines.

Part II. Draft Issue Brief on Direct-to-Consumer Drug Platforms

We appreciate the Working Group's effort to help regulators understand the range of drug purchasing options now available to consumers. We write to raise concerns with two aspects of the DTC Brief as drafted: (1) the inclusion of manufacturer cost-sharing assistance programs within a paper otherwise devoted to true direct-to-consumer platforms; and (2) the inclusion of unsupported assertions that this assistance drives brand-name reliance and/or shifts costs to consumers. We address each below.

3. Manufacturer Cost-Sharing Assistance Does Not Necessarily Belong in a Direct-to-Consumer Platform Framework

Recommendation: PhRMA recommends that the Working Group either (a) remove manufacturer cost-sharing (copay) assistance programs from this Brief and address them in a separate, dedicated brief that accounts for the growing body of state law governing their use, or (b) at minimum, add a clear disclaimer distinguishing manufacturer assistance from direct-to-consumer and discount card models, including acknowledgment of state Accumulator Adjustment Program (AAP) bans.

Rationale: The Brief asks regulators to understand three categories of prescription drug distribution: discount cards, manufacturer assistance programs, and direct-to-consumer platforms. We do not believe manufacturer cost-sharing assistance clearly belongs in this framework alongside discount cards and direct-to-consumer platforms. Discount cards and direct-to-consumer platforms share a defining and correctly described characteristic: the transaction is typically adjudicated outside the health plan's benefit structure, and payments "generally are not applied toward plan deductibles, out-of-pocket maximums, or other cost-sharing accumulators."

Manufacturer cost-sharing assistance operates fundamentally differently: it is applied within the insurance claims-adjudication process, at the point of sale, to reduce a patient's cost-sharing obligation for a covered benefit. It is not a mechanism for consumers to bypass insurance, and it should not be evaluated using the

⁴Avalere. Commercial Step Therapy May Include Steps Beyond FDA Label. May 2025.
<https://advisory.avalerehealth.com/insights/commercial-step-therapy-may-include-steps-beyond-fda-label>.

same lens as products that are generally purchased outside of insurance. The Brief’s own text – stating that this assistance “generally is not applied toward the consumer’s deductible or out-of-pocket maximum” – is also not accurate. Twenty-six states, the District of Columbia, and Puerto Rico have enacted laws prohibiting accumulator adjustment programs, instead requiring insurers to credit manufacturer and other cost-sharing assistance toward patients’ deductibles and out-of-pocket maximums. The Brief should reflect this growing body of state law to more accurately describe how this assistance interacts with patient cost-sharing and patient out-of-pocket costs.

4. The Brief’s Statement That Manufacturer Coupons Drive “Brand Reliance” Is Not Supported by the Evidence

Recommendation: PhRMA recommends the Working Group remove the statement that manufacturer coupons “encourage” consumers to use brand medicines over available generics, rather than presenting it as settled fact, and incorporate the data below.

Rationale: The Brief states that “[m]anufacturer coupons are issued for brand name drugs to keep them competitive with generics... [c]onsumers pay less out of pocket, which encourages them to use the brand-name version of a drug, even when a cheaper, generic version might be available through their plan,” concluding that “[s]ome insurers say this encourages the unnecessary use of more expensive drugs.” This characterization is not supported by the available data.

Recent data analysis found that in 2021–2022, less than 1% of commercial pharmacy claims filled using cost-sharing assistance were for a brand medicine with an available generic equivalent.⁵ Cost-sharing assistance is overwhelmingly used to help patients afford brand medicines for which no generic alternative exists, particularly in therapeutic areas such as multiple sclerosis, HIV, and oncology, where formularies and utilization management already tightly control access.⁶ An analysis of California’s cost-sharing assistance ban found no impact on the rate of generic substitution during the first year of the law’s implementation⁷, suggesting that cost-sharing assistance was not a significant factor in influencing substitution decisions.

Cost-sharing assistance also is not intended to bypass a health plan’s formulary or utilization management determinations. A patient may use assistance for a medicine that has already been prescribed by a treating physician and approved for coverage by the patient’s health insurer, meaning the insurer retains full control over which medicines are covered in the first instance. To the contrary, a substantial body of peer-reviewed research shows that cost-sharing assistance improves medication adherence. For example, one found that assistance was associated with up to a 47% increase in the share of patients staying on treatment

⁵IQVIA analysis for PhRMA, 2023.

⁶IQVIA. Faced with High Cost Sharing for Brand Medicines, Commercially Insured Patients with Chronic Conditions Increasingly Use Manufacturer Cost-Sharing Assistance. July 2020.

⁷ Rome BN, Gagne JJ, Kesselheim AS. Association of California’s Prescription Drug Coupon Ban With Generic Drug Use. JAMA. 2021;325(23):2399–2402.

for one year⁸ – and, in another analysis, reduced the likelihood that patients would abandon a newly prescribed brand medicine at the pharmacy counter by an estimated 82%.⁹ These outcomes directly advance, rather than undermine, the affordability goals this Brief and Working Group are trying to promote.

Conclusion

PhRMA appreciates the NAIC HCAM Working Group's efforts to give state insurance regulators and their staff a clear, high-level understanding of both utilization review and the tools available to help patients access and afford their medicines. We believe these briefs can better serve those goals by accounting for the growth and patient impact of utilization management on prescription medicines, addressing hidden practices such as embedded step therapy, separating manufacturer cost-sharing assistance from true direct-to-consumer models, and grounding any discussion of brand utilization in the available evidence. We stand ready to serve as a resource to the Working Group as it finalizes these briefs and look forward to continued engagement.

Sincerely,

Charise Richard
Sr. Director, State Policy
PhRMA

⁸Hung A, Blalock DV, Miller J, et al. Impact of Financial Medication Assistance on Medication Adherence: A Systematic Review. *Journal of Managed Care & Specialty Pharmacy*. 2021;27(7):924–935.

⁹IQVIA analysis of the Longitudinal Access and Adjudication Data (LAAD) dataset for PhRMA. February 2021. Only 5% of patients abandoned newly prescribed brand medicines when using cost-sharing assistance; analysis suggests abandonment would have been 28% absent this assistance.