August 17, 2026

Senator Ron Wyden
Ranking Member
Senate Finance Committee
drugs@finance.senate.gov

VIA ELECTRONIC CORRESPONDENCE

Re: Request for Information: Commonsense Policy Options to Lower Drug Prices for Patients

Dear Senators Wyden, Cortez-Masto, Welch, and Gallego:

Aimed Alliance is a non-profit health policy organization that seeks to protect and enhance the rights of health care consumers and providers. We are writing to provide feedback to the Senate Finance Committee's ("Committee") Request for Information on Commonsense Policy Options to Lower Drug Prices for Patients. Aimed Alliance appreciates the opportunity to comment and the Committee's commitment to centering consumer affordability.

I. Address Affordability for Health Care Consumers

Aimed Alliance appreciates the Committee's commitment to addressing prescription drug affordability and ensuring reforms impact consumers' health care costs. Aimed Alliance supports policies that address affordability while also protecting innovation and access. As such, Aimed Alliance urges the Committee to consider the global implications of MFN pricing; adopt cost-sharing caps on Part B drugs; protect rare disease innovation; and expand reporting requirements for claims, denials, and appeals.

A. Adopting International Reference Pricing Can Harm Patients Globally, Violate Federal Law, and Rely on Flawed Pricing Assessments

In February 2026, Aimed Alliance published a paper reviewing international pricing mechanisms to better understand how these pricing systems engage patients and value patient feedback in decision-making. As part of the initiative, Aimed Alliance met with international patient advocacy organizations to discuss their first-hand experience with international drug pricing boards. These discussions revealed three key challenges to adopting an international reference pricing model in the U.S.

First, Aimed Alliance's Report recognizes that the United States drug pricing system operates substantially differently from those of OECD countries. Unlike OECD countries, the United States has pharmacy benefit managers (PBMs) that play an important role in establishing formularies and prescription drug costs. In this role, PBMs determine which drugs are included on formularies, utilization management policies, and cost-sharing requirements. PBMs often receive rebates based on a drug's list price, which creates a perverse incentive to prioritize high-

price drugs with higher rebates over lower-cost alternatives. While Congress has prohibited tying rebates to list prices in Part D, these prohibitions do not extend to Part B drugs.[1] As such, using a reference price may not improve affordability for consumers, even where international reference pricing is adopted, because it does not address the underlying PBM incentives.

Second, the Report recognizes that importing international reference pricing inherently entails adopting Quality-Adjusted Life Years (QALY) assessments, as 18 OECD countries use QALYs in drug pricing.[2] Importantly, federal law prohibits using QALYs. Specifically, 42 U.S.C. 1320(e)-1 prohibits the Secretary of Health and Human Services (HHS) from using "evidence or findings from comparative clinical effectiveness research [. . .] in determining coverage, reimbursement, or incentive[s] [. . .] in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill." This prohibition applies to the direct and indirect use of these metrics. Thus, adopting a foreign price that relies on QALYs indirectly adopts QALY findings in violation of federal law.

Lastly, the Report noted that a U.S. adoption of international reference pricing would likely negatively affect patients' access to care internationally. As the Committee's Request for Information recognizes, the United States accounts for a substantial share of pharmaceutical profits. As such, international participants expressed concern that if the U.S. were subject to international reference pricing, there could be global repercussions that are not equally reflected when smaller countries adopt similar policies. For example, contributors to the Report expressed concerns that pharmaceutical companies would remove products from existing markets and delay or forgo new product launches in certain countries to avoid U.S. reference pricing. For patients, this would mean that lifesaving treatments once available are no longer accessible, or that new products are unavailable. This not only could harm patients globally but also increase medical tourism for those who can afford it, creating an unfair and inequitable global access challenge based on individuals' economic status.

For these reasons, Aimed Alliance urges the Committee to consider alternatives to drug pricing reform that do not rely on international reference pricing.

B. Protect Investment and Innovation in Rare Disease Drugs

The Committee has requested feedback on removing the "orphan" drug exemption from the Medicare negotiation program. An "orphan drug" is defined as a drug intended to treat a rare

---

[1] Aimed Alliance, *Delinking PBMs: The Federal Breakthrough and the State Call to Action,* https://aimedalliance.org/wp-content/uploads/2026/06/AimedAlliance_Delinking-OnePager-May2026.pdf.

[2] Aimed Alliance, *International Reference Pricing: Lessons Learned from Abroad,* https://aimedalliance.org/wp-content/uploads/2026/02/Aimed-Alliance-MFN-WhitePaper-Feb2026.pdf (Aimed Alliance's Report also provides key recommendations for the Committee if they continue to move forward with international reference pricing despite patient, provider, and caregiver concerns. Aimed Alliance welcomes the opportunity to discuss this Report in greater detail with Committee staff).

disorder.[3] A rare disorder is defined as a disease or condition that affects fewer than 200,000 people in the United States. Currently, an estimated 95 percent of rare disorders lack treatments.[4] Developing treatments for rare disorders is challenging, as these conditions involve small populations and complex treatment mechanisms, which can complicate clinical trials, drug development, and interest in developing these treatments.[5] The orphan drug exclusion is an important protection that helps overcome some of the aforementioned barriers and ensures investment in rare disease treatments continues.

Aimed Alliance urges the Committee to continue clarifying portions of the Medicare negotiation program that can impair rare disease drug development. Specifically, Aimed Alliance urges the Committee to support clarifying that genetically targeted therapies (GTTs) are large molecule drugs under the Inflation Reduction Act (IRA). GTTs are particularly promising for rare disorders because this technology allows the body to correct an abnormal output caused by a genetic mutation, essentially addressing these mutations at their source. Without disorder-specific treatments, individuals living with rare disorders are required to manage the symptoms of their disorder, which can include multiple prescription drugs, therapies, and other clinical and non-clinical interventions. GTTs allow health care providers to treat the root causes of these conditions rather than their symptoms. GTTs are also being used in research for new cardiovascular disease treatments, pediatric conditions, and neurological conditions like Parkinson's, multiple sclerosis, and Alzheimer's disease. The IRA does not address GTTs; therefore, by default, these therapies are considered "small molecule" treatments.

To ensure these treatments are negotiated within the appropriate timeline, Aimed Alliance urges Congress to support the Maintaining Investment in New Innovation Act (MINI Act), as it recognizes the complexity of GTTs and clarifies that these treatments are "large molecule" drugs under the IRA.

C. Expand Out-Of-Pocket Caps

Aimed Alliance applauds the Committee's commitment to expanding opportunities to address affordability for consumers. The Medicare Part D prescription drug cap and smoothing program provide consumers with opportunities to manage their health care costs throughout the year, rather than paying a large lump sum at the beginning of the year. However, these protections apply only to Part D drugs. Therefore, consumers requiring access to covered drugs in Part B still face high out-of-pocket costs to access their medications. Moreover, Part B drugs can be more

[3] FDA, *Rare Diseases at FDA,* https://www.fda.gov/patients/rare-diseases-fda.
[4] The Landscape for Rare Diseases in 2024, 12 Lancet Glob. Health e341 (2024), https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(24)00056-1/.
[5] *Id.*

expensive for consumers, as consumer cost-sharing is typically a 20 percent coinsurance for the prescription drug's cost.[6]

Importantly, research has found that over 40 percent of Medicare beneficiaries pay more than $2,000 in cost sharing for Part B drugs.[7] Therefore, Aimed Alliance encourages the Committee to pass protections similar to those in Part D, including a comparable annual cap and smoothing program. Although an annual cap alone could help consumers, imposing one without a smoothing program could leave consumers facing unaffordable upfront costs at the beginning of the plan year. Thus, Aimed Alliance encourages the Committee to pass both cost-sharing and smoothing protections for Part B.

D. Holding Plans Accountable for Inappropriate Pharmacy Rejections

As the Committee recognized, in 2019 the Office of the Inspector General (OIG) found that Medicare Advantage plans denied 84 million claims due to limited formularies, prior authorization, step therapy, and quantity limit restrictions.[8] However, in 2019, CMS also changed its reporting requirements and stopped requesting data on how consumers access their medications after a claim denial, such as filing an appeal, paying out of pocket, or switching medications.[9] Fortunately, CMS previously conducted a similar report reviewing claims data from 2014-2016 and found that of the millions of claim denials, only one percent of all claims were appealed. However, of the denied claims that were appealed, 75 percent were overturned.[10] The detailed data from the 2014-2016 report is essential, and HHS should collect it, as it provides a better understanding of how often claims are denied, the reasons for denial, and whether and how consumers navigate the appeals process. This data is critical to understanding whether plans are providing the benefits consumers are entitled to.

Importantly, the OIG report is not unique to Medicare; Aimed Alliance's research has also identified similar challenges across state-regulated health plans. In 2025, Aimed Alliance conducted a comprehensive fifty-state analysis to assess how state insurance departments monitor health plan compliance with consumer protection laws.[11] The research focused on reporting requirements related to utilization management, step therapy, and internal and external appeals.

---

[6] Juliette Cubanski, et al., *Medicare Part B Drugs: Cost Implications for Beneficiaries in Traditional Medicare and Medicare Advantage*, KFF (Mar. 15, 2022), https://www.kff.org/medicare/medicare-part-b-drugs-cost-implications-for-beneficiaries-in-traditional-medicare-and-medicare-advantage/.
[7] *Id.*
[8] HHS OIG, *Some Medicare Part D Beneficiaries Face Avoidable Extra Steps That Can Delay or Prevent Access to Prescribed Drugs* (Sept. 2019), https://oig.hhs.gov/documents/evaluation/3141/OEI-09-16-00411-Complete%20Report.pdf.
[9] *Id.*
[10] *Id.*
[11] Aimed Alliance, *2025 State Report: Step Therapy, Oversight, & Artificial Intelligence Trends and Best Practices* (Jun. 2025), https://aimedalliance.org/wp-content/uploads/2025/06/AA-2025StateReport_June_2025.pdf.

The findings reveal significant gaps in data collection, transparency, and proactive oversight. Specifically:

- Four states require health plans to report specific data on the use of step therapy and prior authorization.[12]
- Twenty-four states require reporting related to internal appeals, external appeals, or both.[13]
- Seventeen states make this data publicly available, either through annual reports or upon request.
    - Nine states publish annual reports with this data.[14]
    - Eight states provided the data to Aimed Alliance upon request.[15]
- Three states maintain consumer-facing reports or databases related to grievances or complaints filed with insurance departments.[16]
    - More than twenty states do not provide publicly available information regarding oversight activities or compliance monitoring.[17]

When appeals data was publicly available, Aimed Alliance attempted to evaluate how often denials were overturned. However, inconsistent reporting standards, timeframes, and data elements across states made meaningful comparisons difficult. Despite these limitations, the available data consistently showed that when utilized, external appeals are approved at least one-third of the time. Data from Indiana and Pennsylvania further revealed that over 40 percent of internal appeals are reversed in favor of the consumer, suggesting that many claims denied in the first instance should never have been denied. While this data is slightly lower than Medicare reversal data, it indicates a consistent pattern of using denials to mitigate costs rather than determining whether certain claims are genuinely entitled to coverage.

Despite the high reversal rate of first-level appeals, these protections are underutilized by consumers. Notably, Pennsylvania's 2023 data showed that out of 2,135,041 denied claims, only 3,156 internal appeals were filed, which is less than one percent of all denials. This disparity demonstrates the fundamental inadequacy of relying on appeals and consumer complaints as the primary mechanism for regulatory oversight.

Due to the burdensome nature of the appeals and complaint processes across state-regulated plans and Medicare, it is critical that HHS impose reporting requirements on health plans regarding the number of claim denials, the reasons for denials, appeals, and appeal outcomes.

---

[12] Kentucky, Maine, Massachusetts, and Maryland.
[13] Arkansas, California, Connecticut, Delaware, Hawaii, Indiana, Iowa, Kansas, Kentucky, Maine, Maryland, Michigan, Minnesota, Missouri, Montana, Nebraska, New York, Oklahoma, Pennsylvania, Rhode Island, Tennessee, Utah, Washington, and Wisconsin.
[14] California, Connecticut, Hawaii, Indiana, New York, Pennsylvania, Utah, Washington, and Wisconsin.
[15] Delaware, Iowa, Kentucky, Minnesota, Missouri, Nebraska, Oklahoma, and Rhode Island.
[16] Colorado, Michigan, and Wisconsin.
[17] Alabama, Alaska, Colorado, Florida, Idaho, Illinois, Louisiana, Mississippi, Nevada, New Hampshire, New Jersey, New Mexico, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, South Carolina, South Dakota, Texas, Vermont, Virginia, West Virginia, Wyoming.

Importantly, this would not be a new initiative for Medicare. Before 2019, CMS operated a "formulary administration analysis" monitoring program that reviewed pharmacy rejections to determine whether the plan was acting consistently with its requirements. Under the program, if a health plan had a pharmacy claim failure rate of 20 percent or higher, the plan would receive a letter notifying it of non-compliance.[18] If a plan was found to be non-compliant, CMS could also send warning letters, impose civil monetary penalties, and impose sanctions on health plans.[19] These active reporting requirements, with monetary penalties, and public disclosure requirements are critical to ensuring consumers receive the benefits they are entitled to under their health plan.

Therefore, Aimed Alliance encourages the Committee to reinstate the formulary administration analysis program and require plans to disclose, annually, the number of claim denials, reasons for denials, appeals, and appeal outcomes. Moreover, Aimed Alliance urges the Committee to require plans to disclose the cost savings resulting from utilization management policies such as step therapy and prior authorization, as this ensures that these policies are intended to manage plan costs rather than to steer patients toward higher-rebate drugs or arbitrarily deny claims.

E. Conclusion

Aimed Alliance urges the Committee to act swiftly to protect consumers from high health care costs and address prescription drug affordability. Moreover, we support initiatives that address affordability, support innovation, and ensure accountability for benefit denials. Please contact us at avantrees@aimedalliance.org with any questions or comments regarding this submission.

Sincerely,

Ashira Vantrees

Ashira Vantrees
Director of Legal Strategy & Advocacy

[18] U.S. Dep't of Health & Hum. Servs., Off. of Inspector Gen., *Some Medicare Part D Beneficiaries Face Avoidable Extra Steps That Can Delay or Prevent Access to Prescribed Drugs*, OEI-09-16-00411 (Sept. 2019), https://oig.hhs.gov/documents/evaluation/3141/OEI-09-16-00411-Complete%20Report.pdf.
[19] *Id.*