



February 23, 2026

Dr. Mehmet Oz  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, Maryland 21244

**Re: CMS-5546-P: Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model**

Dear Administrator Oz:

The **HIV+Hepatitis Policy Institute** is a national organization promoting quality and affordable healthcare for people living with or at risk of HIV, hepatitis, and other serious and chronic health conditions.

We believe that CMS has not met the statutory burden necessary to justify the Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model, particularly in light of its projected beneficiary cost increases, unresolved design flaws, and significant downstream uncertainties. **For these reasons, the HIV+Hepatitis Policy Institute opposes the GUARD Model.** We urge CMS to withdraw the proposal and pursue alternative approaches that directly improve patient affordability without threatening access to care or destabilizing essential safety nets.

### **Summary of Comments**

While Section 1115A(b)(3) of the Social Security Act authorizes CMS to test payment models intended to reduce Medicare spending, that authority reflects Congress's expectation that such models preserve or enhance quality and avoid harm to beneficiaries. As proposed, the GUARD Model, which would mandate that drug manufacturers increase their rebates to match list drug prices of a set of foreign countries for 25 percent of Medicare beneficiaries, fails to meet that standard. CMS projects the model will shift billions in costs onto beneficiaries through increased premiums and cost-sharing, potentially triggering spillover effects across other payers. Higher premiums and increased cost-sharing are well-established barriers to medication access, particularly for patients managing serious and chronic conditions who rely on consistent and uninterrupted treatment.

As detailed in this comment, the GUARD Model relies on foreign list prices that cannot be directly compared to how prescription drugs are priced, paid for, or accessed in the United States. U.S. list prices incorporate substantial downstream obligations that materially reduce net

**HIV+HEPATITIS POLICY INSTITUTE**

1602B Belmont Street NW | Washington DC 20009 | 202-462-3042 | 202-365-7725 (cell) HIVHep.org | Twitter: @HIVHep | Facebook: HIVHep

prices and support patient access, including hundreds of billions in annual domestic statutory and market-based obligations, such as Medicaid and commercial rebates, 340B discounts, and patient assistance programs. By failing to account for these dynamics, the model risks undermining existing affordability mechanisms and destabilizing patient assistance and safety net programs that many patients depend on. At the same time, the proposal acknowledges potential effects on research and development and treatment advancement, yet does not require CMS to evaluate those impacts, even as patients continue to depend on advances toward better therapies and potential cures. Lastly, its monitoring framework is retrospective by design, offering no meaningful protection for patients who cannot afford even a temporary disruption in care.

### **Impact on Medicare Beneficiaries Living with HIV**

Medicare plays an increasingly central role in HIV care as people living with HIV age into the program or qualify through disability. Advances in antiretroviral therapy have dramatically improved outcomes. When the first highly effective therapies became available in 1996, a 20-year-old newly diagnosed with HIV had a life expectancy of just 10 years. Today, individuals with HIV can expect lifespans comparable to the general population and rely on newer regimens with far better tolerability and fewer side effects. As a result, more than 111,000 Medicare beneficiaries are currently living with HIV, and that number is expected to roughly double over the next decade as people live longer, healthier lives.<sup>1</sup> Medicare becomes the primary source of coverage for most, making Medicare policy decisions directly relevant to their ability to access and afford lifesaving treatment.

HIV treatment requires continuous, lifelong access to antiretroviral therapy to maintain viral suppression and prevent disease progression or the development of drug resistance. HIV is an infectious disease, meaning treatment has both individual and public health consequences. When people living with HIV achieve and maintain viral suppression, they not only protect their own health but also prevent transmission to others. Stable, affordable access to treatment is therefore central to our national strategy to end the HIV epidemic. Medicare beneficiaries living with HIV already face roughly double the average health care spending and higher out-of-pocket costs than other enrollees, reflecting lifelong treatment needs and the management of additional health conditions over time.<sup>2</sup>

Policies that increase premiums or beneficiary cost-sharing would therefore have a disproportionate impact on this population. Models such as GUARD which allow higher cost-sharing and premium increases risk further straining the ability of people living with HIV to afford both their Medicare coverage and the medications they must take to remain healthy. Increased financial barriers or instability in access can undermine adherence, jeopardize viral suppression, and slow progress toward reducing new infections, ultimately threatening decades of progress in HIV treatment, prevention, and efforts to end the epidemic in the United States.

### **Fundamental Design Flaws: Focus on Foreign List Prices, Not Patient Reality**

At its core, the GUARD Model relies on foreign list prices that do not reflect how prescription drugs are priced, paid for, or accessed in the United States. Many of the countries used as reference points operate centralized or government-run health systems that negotiate or set

drug prices on a national basis. The United States does not operate under a single national purchasing system. Instead, U.S. drug pricing reflects a complex mix of mandatory statutory rebates, negotiated discounts, and safety net programs that substantially lower net prices and support access to care. These obligations directly shape pricing decisions and play a critical role in supporting patient affordability. List prices in the United States reflect these layered requirements, which differ fundamentally from pricing structures in other countries.

These U.S.-specific obligations include:

- **Statutory rebates:** In 2023, manufacturers provided an estimated \$42.8 billion in Medicaid rebates and facilitated more than \$81 billion in prescription drug purchases through the 340B Drug Pricing Program, supporting safety net providers and the services they deliver to patients.<sup>3</sup>
- **Commercial rebates:** Total manufacturer rebates paid to Pharmacy Benefit Managers (PBMs) and insurance companies reached \$334 billion for all brand-name drugs in 2023.<sup>4</sup>
- **Additional HIV drug rebates:** HIV drug manufacturers provide over \$1.4 billion in annual rebates to states' AIDS Drug Assistance Programs (ADAPs), further offsetting the cost of HIV medications.<sup>5</sup>
- **Direct patient support:** Beyond rebates, manufacturers contributed approximately \$23 billion in copay assistance in 2024, while also maintaining patient assistance and free drug programs for people who are uninsured or underinsured.<sup>6</sup>
- **Global health commitments:** Manufacturers, particularly those that have HIV and hepatitis drugs, enter into voluntary licensing agreements that enable generic manufacturers to produce a range of medicines for low- and middle-income countries at deeply reduced prices, making therapies more affordable and accessible to patients across multiple disease areas. HIV companies also support large-scale public health initiatives, including the President's Emergency Plan for AIDS Relief (PEPFAR), which provides HIV medications at low or no cost in high-burden countries. Of the more than \$700 million in global HIV-related philanthropic contributions annually, drug manufacturers account for over \$300 million of that total.<sup>7</sup>

By failing to account for these existing responsibilities and circumstances, the GUARD Model relies on a pricing benchmark that overlooks how U.S. list prices already incorporate substantial downstream obligations that reduce net prices and help support patient access. Manufacturer revenues support not only statutory and contractual requirements, but also patient-facing and public health programs that make medications affordable in practice. At the same time, reduced manufacturer revenue may threaten the viability of copay assistance, patient assistance programs, and public health initiatives that many patients depend on to afford and access care. Policies that significantly reduce these resources risk unintended consequences for patients in the United States and globally.

In addition, the foreign prices used as benchmarks are often the product of centralized government decision-making frameworks that rely on faulty cost effectiveness assessments, including the use of the Quality Adjusted Life Year (QALY) formula which Congress banned Medicare from using in coverage and reimbursement decisions. Multiple government and private studies have concluded that the use of QALYs undervalues the lives of older adults, people with disabilities, and individuals living with chronic or life-threatening conditions.<sup>8</sup> Aligning Medicare payment policy with prices shaped by these frameworks risks importing standards that conflict with long-standing U.S. disability protections and patient access principles.

More broadly, the GUARD Model's reliance on foreign price benchmarks represents a departure from how pricing policy is approached elsewhere in the U.S. economy. The United States does not base prices for other products or services on prices set in foreign markets. For example, the average price of a loaf of bread in the United States is approximately \$3.67, compared to about \$2.00 in Germany and \$2.39 in Australia.<sup>9</sup> Yet U.S. grocery stores do not price bread based on foreign benchmarks because prices reflect domestic supply chains, labor markets, regulatory structures, and economic conditions. In health care, payment rates for physician services, hospital care, and other medical services are set through domestic systems that reflect U.S. laws and market conditions. Applying foreign list prices uniquely to prescription drugs creates an inconsistent approach that does not reflect how patients actually experience affordability in the U.S. health care system.

### **The GUARD Model Fails to Demonstrate Patient Benefit and Acknowledges Potential Harm**

While the GUARD Model is framed as an effort to address prescription drug costs, its design is focused on generating savings for Medicare rather than improving affordability for beneficiaries. CMS's own analysis acknowledges that the model is expected to increase costs for patients, estimating a combined \$3.6 billion increase in Medicare beneficiary premiums and out-of-pocket spending.<sup>10</sup> Rather than lowering what patients pay, the model anticipates higher financial burdens for enrollees as a direct result of its implementation.

Higher premiums and increased cost sharing are well-established barriers to medication access, particularly for patients managing serious and chronic conditions who rely on consistent and uninterrupted treatment. A substantial body of evidence shows that even modest increases in patient costs are associated with lower adherence, delayed care, and worse health outcomes.<sup>11</sup> A 2021 report from IQVIA found that Medicare beneficiaries who have a copay of \$75 or more abandon their medication 25% of the time.<sup>12</sup> For patients who depend on continuous therapy to maintain health and prevent disease progression, increases in premiums or out-of-pocket costs can have immediate and lasting consequences.

CMS also acknowledges that the GUARD Model may alter manufacturer pricing behavior in ways that extend beyond Medicare. CMS notes, "As a change in list prices for model drugs will shift the balance between the GUARD Model rebate amount and the inflation rebate amount, there are incentives for manufacturers to raise list prices across all payers to counteract the lost revenue from the model. This reaction could create additional effects on Medicaid or Federal Marketplace spending."<sup>13</sup> This acknowledgement highlights a fundamental concern with the

GUARD Model. Efforts to extract savings in one part of the system may shift costs elsewhere, exposing patients outside of Medicare to higher prices and increasing overall system instability.

Despite these acknowledged risks, CMS does not identify concrete, near-term patient benefits from the GUARD Model. Instead, the agency suggests that any potential improvements in affordability may occur only if manufacturers voluntarily lower launch prices or list prices and if plans subsequently choose to redesign benefits in ways that reduce patient cost-sharing. These outcomes are speculative, dependent on multiple downstream decisions, and not required by the model. As written, the GUARD Model asks patients to absorb significant projected cost increases without a clear or enforceable pathway to patient benefit.

CMS further acknowledges that the GUARD Model's impact on beneficiaries and access to care will be evaluated primarily through post-implementation monitoring conducted at least annually. The proposal relies on retrospective analytic tools, including claims-based utilization analysis, formulary and benefit design reviews, beneficiary surveys, and enrollee complaints, to identify unintended consequences associated with the model.

These monitoring mechanisms are inherently backward-looking and are designed to detect effects only after changes in pricing, benefit design, or utilization have already occurred. As such, they provide limited capacity to prevent or mitigate patient harm in real time, particularly in the early years of model implementation. This concern is compounded by the lack of clarity regarding whether beneficiaries will be informed if they are selected to be the 25 percent of enrollees who will be participating in the GUARD Model. If beneficiaries are unaware that they have been assigned to a mandatory payment model, reliance on enrollee complaints and survey instruments as early warning mechanisms is inherently unreliable. Many beneficiaries may not recognize that higher costs, formulary shifts, or access barriers are linked to the model itself, reducing the likelihood that complaints will meaningfully capture emerging harms.

For beneficiaries who depend on continuous access to medication, such as those living with HIV, any delay in identifying access disruptions or absorbing increased out-of-pocket costs presents a severe and often irreversible clinical risk. Treatment interruptions or delayed therapy initiation do not just result in temporary setbacks; they can lead directly to viral rebound, rapid disease progression, and the development of permanent drug resistance. Because these outcomes can permanently exhaust a patient's future treatment options, a monitoring and evaluation framework that identifies patient harm only after it has manifested is fundamentally insufficient. Such a retrospective approach fails to provide meaningful protection for vulnerable patients who cannot afford even a temporary lapse in care.

### **Impacts on Research, Development, and Treatment Advancements**

In other federal drug pricing efforts, including Medicare drug price negotiation, policymakers have recognized that sustained reductions in expected revenue can affect long-term investment decisions and the number of new therapies that ultimately come to market. That context matters here. The GUARD Model is projected to generate \$14.1 billion in Medicare savings by reducing manufacturer revenue, yet the proposal does not meaningfully address how additional pricing pressure could affect future drug development.

CMS acknowledges this risk, stating that it “may also consider examining any changes in drug innovation, research and development; changes in launch prices of drugs; and timing of drugs coming to market in the United States.”<sup>14</sup> But treating these impacts as something CMS *may* consider is not sufficient for a national pricing experiment of this scale. This underscores that GUARD is not a limited voluntary test, but a mandatory payment model that functions as a form of price control for affected drugs. Because reduced manufacturer revenue is a key mechanism through which the GUARD Model generates savings, understanding how that reduction affects investment and development decisions should be a required part of the evaluation, not an optional one.

This is especially important for areas like HIV and hepatitis B, where progress has depended on decades of sustained research and investment. Advances in HIV treatment have been driven by long-term commitment to developing better-tolerated regimens, long-acting therapies, and progress toward a cure. Similarly, the development of new therapies for hepatitis B remains scientifically complex and resource intensive. By not requiring CMS to evaluate how the GUARD Model may affect research and development before implementation, the proposal leaves patients with unanswered questions about what this model could mean for future treatment options.

### **Risks to the Six Protected Classes**

Existing Medicare safeguards, including the Six Protected Classes protections applicable to antiretroviral therapies, must be preserved without modification or reinterpretation under the GUARD Model. These protections, including the prohibition on utilization management for antiretrovirals, are central to ensuring uninterrupted access to treatment for people living with HIV and must remain fully intact in both policy and practice.

Although CMS states that including Six Protected Class drugs in the GUARD Model will help address so-called “deficits of care” related to cost, the proposal also acknowledges that the GUARD Model does not directly reduce patient out-of-pocket costs and is projected to increase beneficiary premiums and cost sharing overall. Notably, we are not aware of these “deficits of care” for Medicare beneficiaries living with HIV, for whom access to antiretrovirals is far better than those enrolled in commercial insurance due to Six Protected Class protections and a lower out-of-pocket maximum. This tension raises questions about how the inclusion of Six Protected Class drugs is expected to improve patient experience, particularly when the proposal does not demonstrate point-of-sale affordability benefits for beneficiaries and anticipates increases in premiums and cost sharing.

We are also concerned by the GUARD Model’s repeated use of the broad term “antivirals” without clearly distinguishing these medications from antiretroviral therapies used to treat HIV. While CMS maintains that the GUARD Model does not alter existing Six Protected Classes protections, this imprecise terminology creates unnecessary ambiguity. Antiretrovirals are a distinct clinical subset of antiviral medications, which are used primarily for the treatment of HIV, characterized by lifelong adherence requirements and protected in statute and regulation by long-standing safeguards designed to prevent access barriers for Medicare beneficiaries.

Though most antiviral drugs developed to date are for the treatment of HIV or viral hepatitis, antivirals also encompass drugs that target influenza, respiratory syncytial virus, COVID-19, and herpes.

### **Importance of Excluding 340B Drugs**

We support CMS’s proposal to exclude drugs purchased through the 340B program from the GUARD Model to avoid duplicate discounts. Without a clear exclusion, the same drug units could be subject to both 340B discounts and GUARD Model rebates, creating unnecessary complexity and conflicting pricing requirements. We would suggest that this same exclusion also apply to those drugs in the Ryan White AIDS Drug Assistance Program (ADAP) that receive similar manufacturer discounts. Consistent with CMS’s approach in other Medicare policies, maintaining clear 340B and ADAP exemptions would help prevent duplicate discounts.

### **Conclusion**

The HIV+Hepatitis Policy Institute strongly opposes the GUARD Model because it prioritizes projected federal savings over the health and financial stability of Medicare beneficiaries. By moving forward with a framework that acknowledges multibillion-dollar cost increases for patients and relies on a retrospective monitoring system, CMS leaves those who depend on continuous, life-sustaining treatment without meaningful protection from harm. We urge CMS to withdraw this proposal and instead pursue alternative reforms that offer immediate, point-of-sale affordability without jeopardizing treatment access, destabilizing essential safety nets, or undermining the research and development necessary to reach future therapeutic advances and cures.

We appreciate the opportunity to provide our feedback to the model through this comment and welcome continued discussion with you. Should you have any questions for us, please reach out to Carl Schmid at [cschmid@hivhep.org](mailto:cschmid@hivhep.org).

Sincerely,



Carl E. Schmid II  
Executive Director

---

<sup>1</sup> Hyle EP, Ang L, Luu G, et al. Costs associated with increasing numbers of Medicare beneficiaries with HIV aged 65 years and older from 2026 to 2035. medRxiv. Published online December 27, 2025. doi:10.64898/2025.12.19.25342703

<sup>2</sup> Society of Actuaries, *Health Care Cost Trends for the Medicare Population Living with HIV*, June 2025.

<sup>3</sup> Health Resources and Services Administration (HRSA), *340B Drug Pricing Program: Covered Entity Purchases*, 2024.

<sup>4</sup> Kristi Martin, “What Pharmacy Benefit Managers Do, and How They Contribute to Drug Spending” (explainer), Commonwealth Fund, Mar. 17, 2025. <https://doi.org/10.26099/fsgq-y980>

<sup>5</sup> National Alliance of State and Territorial AIDS Directors. 2025. 2025 National RWHAP Part B ADAP Monitoring Project Annual Report: Table 18, Major FY2024 ADAP Budget Categories Compared with FY2023. 2026. <https://nastad.org/sites/default/files/2026-02/2026-adap-report-table-18.pdf> .

---

<sup>6</sup> IQVIA Institute for Human Data Science, *The Use of Medicines in the United States 2024*.

<sup>7</sup> Funders Concerned About AIDS. 2026. Philanthropy's Response to HIV and AIDS: 2024 Grantmaking. February 2026. [https://www.fcaids.org/wp-content/uploads/2026/02/FCAASupportReport24\\_v4-abb.pdf](https://www.fcaids.org/wp-content/uploads/2026/02/FCAASupportReport24_v4-abb.pdf).

<sup>8</sup> National Council on Disability. (2019). *Quality adjusted life years and disability discrimination: An analysis of the disabilities addendum to the life-years lost methodology* (Report).

[https://www.ncd.gov/assets/uploads/reports/2019/ncd\\_quality\\_adjusted\\_life\\_report\\_508.pdf](https://www.ncd.gov/assets/uploads/reports/2019/ncd_quality_adjusted_life_report_508.pdf)

<sup>9</sup> Yahoo Finance UK. 2025. "Bread Price Shock: What Brits Pay Compared to Other Countries." February 25, 2025. <https://uk.finance.yahoo.com/news/bread-price-shock-brits-pay-130000802.html>.

<sup>10</sup> 90 FR 60411

<sup>11</sup> 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.

<sup>12</sup> Greenwalt, L. (2021, November 30). Understanding the impact of cost sharing in pharma: Cost is a powerful control of patient behavior. IQVIA. <https://www.iqvia.com/locations/united-states/blogs/2021/11/understanding-the-impact-of-cost-sharing-in-pharma>

<sup>13</sup> 90 FR 60412

<sup>14</sup> 90 FR 60403