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 Dr. Oz,

On behalf of the Partnership for Part D Access (the Partnership), we appreciate the opportunity to comment on the proposed model, Guarding the U.S. Against Rising Drug Costs (GUARD). The Partnership is a coalition of patient advocacy organizations, clinician groups, and aligned stakeholders committed to protecting patient access to the full range of available medications within Medicare Part D's six protected classes (6PC). As a patient-centered coalition focused on access to clinically appropriate therapies, we support the Administration's goal of improving affordability to expand access and improve health outcomes. That said, in its current form, the model moves in the opposite direction by increasing financial burden for Medicare beneficiaries and taking no steps to address existing access barriers to medications for many of the most serious conditions. The GUARD Model calls into question the administration's commitment to statutory protections that have long assured that vulnerable patients receive medications in the 6PC that meet their heterogeneous treatment needs.

The Partnership opposes the GUARD Model in its entirety. In order to provide full context for this opposition, our comment letter first outlines the purpose of the 6PC, including how it impacts patient outcomes and quality of life, and then applies those understandings to the GUARD Model.

Our concerns center on the following key points:

1. The GUARD Model weakens 6PC protections through its proposed Medicare drug pricing changes, which could lead to worsening patient health outcomes and increased costs.
2. We believe the GUARD Model will also:
    - Increase costs to patients (based on the economic analysis in the proposed rule, stating that it will cause an increase of $3.6B in out-of-pocket costs).
    - Worsen already-declining access to medications by undercutting incentives for innovation in areas of high unmet need.
    - Worsen perceived "deficits of care" faced by patients taking 6PC drugs -- the very deficits that the 6PC were designed to address.
    - Import other countries' rationing approach to coverage.

While we share the Administration's goal of addressing patient challenges accessing affordable care, we nevertheless oppose the GUARD Model and respectfully urge CMS to withdraw it and work with the patient community, including the Partnership for Part D Access, on alternative solutions that will have a tangible impact on patients in Part D.

Background on Medicare's Trusted Six Protected Classes Policy

The 6PC policy was originally created by the Centers for Medicare and Medicaid Services (CMS). During implementation of the Medicare Modernization Act (MMA), which created the Medicare Part D drug program in 2003, CMS issued guidance directing prescription drug plans to cover "all or substantially all" medications within six classes and categories that the agency identified. These categories included: anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants. To demonstrate strong support and address uneven plan compliance, bipartisan leaders in Congress codified the policy in 2008 as part of the Medicare Improvements for Patients and Providers Act. Subsequently, as a part of the Affordable Care Act (ACA), Congress provided the Secretary of Health and Human Services (HHS) with authority to "identify, as appropriate, categories and classes of drugs for which the Secretary determines are of clinical concern." It added that the Secretary shall have the authority to develop the criteria used to make the designation. However, the ACA reiterated the codification of the six existing protected classes and categories by name and expanded coverage to include drugs within these six classes and categories until such time as the Secretary makes changes. Congress has repeatedly been clear in its intent and support for the six identified classes of medications to maintain protected status.

The policy has been so widely supported because it is rooted in patient-centered care and clinical evidence. The six classes represent conditions where medication choice and

access are critical to outcomes. Patients protected by the policy include individuals living with conditions such as human immunodeficiency virus (HIV), cancer, epilepsy, mental illness, and recipients of organ transplants. Therapies that treat these and other serious covered conditions are not interchangeable, and sometimes patients may spend years working with their clinicians before finding a regimen that is right for them. When they do, continuity of access is essential. The 6PC policy serves this purpose by ensuring beneficiaries can access the specific therapy determined by their health care provider to be medically necessary.

Since the 6PC policy was codified by Congress, the health care ecosystem has become even more complicated and expensive for patients to navigate. Managing lifelong, complex, and chronic conditions can involve a series of complicated decision-making and engagement spanning years within the healthcare system. Today, the protections guaranteed by the policy are even more important to the patients who rely on them.

Medicare beneficiaries pay Part D premiums each month in exchange for the knowledge that their coverage will function as promised, without having to contest coverage decisions, navigate new, unexpected barriers, or be turned away at the pharmacy counter. Part D includes a statutory requirement that beneficiaries not be substantially discouraged from enrolling in any Part D plan, regardless of their health conditions or medication needs -- thus upholding the non-discrimination clause. Patients have both a financial and physical stake in maintaining their coverage, and they reasonably expect that the protections embedded in the Part D program, including the six protected classes, will be honored.

The 6PC policy leaves ample room for Part D plans to mitigate rising costs and ensure fiscal responsibility within Medicare. For example, generic utilization within the 6 PC remains high -- by one estimate, in fact, generics are 93% of prescribed 6PC drugs.[1]

The Patient Impact of the Six Protected Classes Policy

The 6PC policy has resulted in meaningful gains for patients, including increased life expectancy for people living with HIV and ensuring cancer patients' access to medications remains undisrupted.[2] [3] The Partnership believes that the 6PC policy must be upheld in its

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[1] Brantley, K., Young, J. (Nov. 20, 2018). Patients Use Generics More Frequently than Brands in Medicare's Protected Drug Classes. *Avalere Health*. https://advisory.avalerehealth.com/insights/patients-use-generics-more-frequently-than-brands-in-medicares-protected-drug-classes.

[2] Mental Health America. Position Statements: Access to Medication. https://mhanational.org/position-statements/access-to-medications/.

[3] Cancer Action Network. (Jul. 20, 2018). Six Protected Classes Explained. https://www.fightcancer.org/sites/default/files/Medicare%20Six%20Protected%20Classes%20Fact%20Sheet%2007202018.pdf.

entirety and would be concerned by any policy changes -- whether the GUARD Model or otherwise -- that would potentially erode access.

In fact, CMS has agreed with this position and has demonstrated a commitment to uphold the 6PC protections. For example, in the FY 2025 Part D Redesign Program Instructions, CMS stated: "Our current formulary review process includes evaluation of the placement of drugs in the Part D six protected classes, and CMS will continue to ensure that these drugs remain accessible to all enrollees who need them." Even though CMS has considered enacting changes to the 6PC in the past, it has never ultimately chosen to do so, which highlights an understanding of the value the protections provide to patients who need access to these drugs. Notably, in the final CY 2020 drug pricing rule, CMS stated in its decision not to finalize proposed changes to the 6PC that "the risks associated with inappropriately interrupting therapy for stabilized patients…outweighs the potential cost savings that would accompany additional formulary management flexibility;[4] in other words, nothing should impact a patient's ability to access 6PC drugs, including the potential for government savings.

The Partnership has heard from many patients and clinicians whose experiences exemplify why the 6PC policy is vital. One clinician specialist shared the experience of her patient, J.S., who is impoverished and lives with a seizure disorder. After a suicide attempt and inpatient treatment, J.S. lacked a clear plan for continuing care for both his seizure disorder and mental health conditions post-discharge. The 6PC policy guaranteed him access to his needed medications, and his care team was able to ensure that he continued to receive the prescription drugs that have continued to keep his conditions stable.[5]

Hundreds of thousands of patients rely on the 6PC policy like J.S. does. Among countless other examples of patient impact are experiences like these:

- A kidney and pancreas transplant patient takes a personalized combination of immunosuppressants and other medications that keep her new organs healthy and functional. Because the six protected classes policy requires that "all or substantially all" immunosuppressants be covered by her Part D plan, she knows she is protected from forced switching that occurs when plans drop coverage. Before she was on Medicare and covered by this policy, forced switching required

[4] Centers for Medicare & Medicaid Services. (2024). Final CY 2025 Part D Redesign Program Instructions. *U.S. Department of Health and Human Services*. https://www.cms.gov/files/document/final-cy-2025-part-d-redesign-program-instructions.pdf.

her to undergo numerous costly tests in the hospital, and she faced the risk of her transplant being rejected.[6] The 6PC means this will not happen again.[7]

- An epilepsy patient went from 5-6 seizures per week to only 1 a month under her Medicare Part D-covered medication.[8] Because "all or substantially all" anticonvulsant drugs are covered by Medicare, and the plan cannot drop coverage, she will continue to have access to her life-changing medication.
- A kidney transplant patient requires immunosuppressant medications for the rest of her life. The six protected classes policy ensures that no matter what Part D plan she chooses, she will be able to have access to a wide range of drugs that could work for her.[9]

It is also important to note that many patients protected by the 6PC policy are chronically ill and living with one or more comorbidities. For example, a patient might be living with HIV *and* a mental health condition, or epilepsy *and* severe pain. Managing multiple illnesses can make it challenging to find a medication regimen that works, but the 6PC ensures that once a patient finds a successful medication, they can stay on it for as long as needed.

On the other hand, when patients lose access to their chosen drug regimen, the consequences to their health can be serious and create additional costs for both the patient and Medicare. Patients often face negative consequences from alternative medications rather than what was selected by their care team; their care gets more expensive, including the possibility of hospitalization; and they can experience life-threatening complications.

Published national data demonstrates how quickly these types of costs can escalate. According to the Agency for Healthcare Research and Quality (AHRQ), the average Medicare payment for an emergency department visit is approximately $1,153 per visit.[10] For patients whose conditions deteriorate further, costs rise substantially. A recent analysis published in *Health Affairs* found that the average ICU spending during hospitalizations

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[6] The cost to Medicare for re-transplantation of only a kidney could reach $123,084 according to analysis by Cheng, et al and adjusted for inflation. https://pmc.ncbi.nlm.nih.gov/articles/PMC8914579/.
[7] Copperman, I. (Mar. 14, 2024). Part D Redesign Could Threaten Organ Transplant Recipients' Second Lease on Life. *The Well News*. https://www.thewellnews.com/opinions/part-d-redesign-could-threaten-organ-transplant-recipients-second-lease-on-life/.
[8] Partnership for Part D Access. Epilepsy One-Pager. https://www.partdpartnership.org/uploads/8/4/2/1/8421729/epilepsy___6pc.pdf.
[9] Jones, D. Navigating Genetic Waters: A Black Man's Perspective on Kidney Health and Medication Access. *Partnership for Part D Access*. https://www.partdpartnership.org/community-perspectives.html.
[10] Roemer M. (Sep. 2024) Costs of Treat-and-Release Emergency Department Visits in the United States, 2021. HCUP Statistical Brief #311. *Rockville, MD: Agency for Healthcare Research and Quality*. https://hcup-us.ahrq.gov/reports/statbriefs/sb311-ED-visit-costs-2021.pdf

was approximately $15,799 per stay, with total hospitalization spending averaging more than $81,000.[11]

For organ transplant recipients, the financial implications are even more significant. Peer-reviewed research published in *JAMA* estimates that medical costs associated with kidney transplantation exceed $100,000 per transplant episode, and graft failure requiring re-transplantation or dialysis can impose even greater cumulative costs over time.[12] Interruptions in access to immunosuppressive therapy increase the risk of rejection, exposing both patients and Medicare to substantial downstream expenditures that far exceed the cost of maintaining stable medication access. These economic realities are relevant because loss of access to medication can cause many negative health effects, leading to possible hospitalization, surgery, and more.

These figures underscore a critical concern: policies that increase financial or administrative barriers to all protected class therapies risk shifting costs from pharmacy spending to far more expensive acute and inpatient care settings.

To further evaluate the potential implications of reduced access to therapies within the six protected classes that could result from any interruption to 6PC protected medication access, the Partnership engaged independent health economics experts to analyze publicly available CMS data and peer-reviewed literature and assess the potential impact. Initial modelling of the financial and clinical consequences associated with disruptions in access to protected class medications shows that across all six classes, both patients and Medicare would experience increased financial burdens.

For a patient already in a vulnerable financial situation, these avoidable economic costs could be catastrophic -- not even taking into account potential downstream impacts like job loss due to absenteeism while in the hospital, housing access issues, and food insecurity. And extrapolated across many Medicare patients who may face similar realities should they be forced to discontinue successful medications, the cost to the federal government could be substantial.

The Partnership's Concerns about the GUARD Model

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[11] Kannan S, Song Z. (Feb. 27 2024). Surprise billing in intensive care unit (ICU) hospitalizations. He*alth Aff Sch; 2(3): qxae025*. doi: 10.1093/haschl/qxae025. PMID: 38486789; PMCID: PMC10932732.

[12] Cheng XS, Han J, Braggs-Gresham JL, Held PJ, Busque S, Roberts JP, Tan JC, Scandling JD, Chertow GM, Dor A. (Mar. 1 2022). Trends in Cost Attributable to Kidney Transplantation Evaluation and Waiting List Management in the United States, 2012-2017. *JAMA Netw Open. 5(3): e221847*. doi: 10.1001/jamanetworkopen.2022.1847. PMID: 35267033; PMCID: PMC8914579.

1. **The GUARD Model will exacerbate existing and worsening access challenges for 6PC medications.**

In its proposed rule, CMS acknowledges that Part D plan sponsors may respond to the GUARD Model by changing their formularies or revising their plan benefit designs, among other unintended consequences of CMS's proposal. Because CMS's proposal would affect Medicare beneficiaries in a fraction of the country, while Part D plans typically cover regions that are much larger than individual zip code areas, the uncertainty posed by potential plan changes represents a risk that Medicare patients cannot accept when it comes to the amount of disruption they may face. Moreover, there is a risk of care disruption for Medicare patients even if they are not included in CMS's proposed selected zip codes. Reduction to the protections provided by the 6PC policy risks inadvertently creating health and quality of life impacts on patients *and* increased economic costs to Medicare and the health care system.

During a recent patient roundtable convened by the Partnership, advocates representing multiple disease areas shared consistent concerns that access to medications within the 6PC has already become more difficult in recent years. Specifically, we understand that over the past several years, health plans have faced increased financial obligations because of Part D market policy changes (e.g., Part D redesign). This has already resulted in higher costs for patients through increased coinsurance and monthly premiums. Unfortunately, the GUARD Model does not address these concerns and may inadvertently exacerbate them.

Across conditions, participants reported instances in which therapies that were previously covered under their Part D formularies were no longer available or were subject to new restrictions, forcing patients and providers to navigate additional barriers to maintain continuity of care. Such disruptions can be destabilizing and dangerous.

Importantly, many of these challenges are occurring under the current Part D framework, before implementation of the GUARD Model. Patients and providers are already working to navigate formulary exclusions, utilization management requirements, and coverage changes that strain care delivery and undermine treatment stability. Rather than addressing these existing access issues, the GUARD Model risks layering additional financial and administrative pressure on a system that is already showing signs of stress.

CMS has an ability to focus on strengthening and stabilizing access for 6PC patients. However, introducing a model that may intensify existing access challenges, without first addressing current gaps, risks compounding harm for the very beneficiaries the 6PC policy was designed to protect.

2. The GUARD Model will result in increased costs for patients.

While the GUARD Model is framed as an effort to reduce out-of-pocket costs to patients, CMS itself states in the proposed model that "we do not expect the GUARD rebates to be visible to beneficiaries at the point of sale." In other words, rebates paid by manufacturers under the model would not translate into lower costs for beneficiaries. In actuality, it would fail to address the perceived deficits in care upon which CMS's rationale for the model rests.

By CMS's own analysis, rather than decreasing financial burdens for patients, the GUARD Model would result in an estimated $3.6 billion *increase* in cost sharing for beneficiaries over the model years.[13] CMS attributes this increase to projected higher point-of-sale drug prices in the pilot's initial year, as well as increases in beneficiary premiums, which have already increased due to other Part D policy changes currently in effect. Taken together, CMS's own economic analysis demonstrates that the GUARD Model, in practice, would increase the financial burden faced by Medicare beneficiaries, which directly contradicts the model's stated goals.

For patients who rely on medications within the 6PC, any increase in out-of-pocket costs can have significant and immediate consequences. These patients often live with serious, chronic, or life-threatening conditions and already face substantial financial obligations related to their care. Many patients in Medicare are on fixed incomes, and those who are able to work but who live with one or more of the conditions covered by the 6PC policy are likely to be able to do so only on a very limited basis. Increased cost burden can force patients to make difficult, financially driven trade-offs, such as delaying care, rationing treatment, or going without medically necessary therapies altogether. The Partnership is concerned that the GUARD Model would further exacerbate these existing cost pressures. Furthermore, CMS has more effective tools at its disposal, which, unlike GUARD, would directly improve affordability, like the Medicare Prescription Payment Plan (MPPP), which allows beneficiaries to spread their out-of-pocket costs over the plan year and maximizes the advantages of the recently implemented $2,100 out-of-pocket maximum for appropriate beneficiaries.

In addition to being detrimental to patient outcomes and quality of life, disruptions in treatment for the serious conditions covered by the 6PC can result in higher costs to Medicare and the broader health care system. When patients are unable to adhere to prescribed treatment regimens, conditions that are otherwise manageable can worsen,

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[13] Centers for Medicare & Medicaid Services. (Dec. 23, 2025). Table CS: Impacts to Medicare Part D enrollees ($ billions), in Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model. *Federal Register*, (90 Fed. Reg. 60411) (Proposed rule). https://www.govinfo.gov/content/pkg/FR-2025-12-23/pdf/2025-23705.pdf.

often leading to avoidable emergency department visits, hospitalizations, and the need for more intensive and costly care. While the importance of adherence can clearly be seen across all the classes, it is particularly apparent in the treatment of HIV.

HIV is a uniquely challenging virus to treat, given that it aggressively replicates at a rate of one billion new viral particles per day, overwhelming and simultaneously destroying the immune system by targeting the cells needed for a proper immune response.[14] Effectively targeting viral replication requires combining multiple drugs with different mechanisms of action, and this highly individualized approach has been critical to transforming a once-deadly disease into a manageable, chronic condition with minimal impact on life expectancy.[15] When individuals take their medication as prescribed, such adherence prevents HIV from multiplying, which suppresses the HIV virus.[16] Viral suppression stops HIV infection from progressing, helping people living with HIV stay healthy and live longer, and maintaining an undetectable viral load also effectively eliminates the risk of sexually transmitting the virus to an HIV negative partner.[17] Additionally, effectively managing HIV infection requires vigilance to avoid creating treatment-resistant mutations, which reduce the efficacy of antiretroviral therapies (ARTs). Mutations are more likely to develop in patients with suboptimal adherence to the treatment regimen, including patients whose access to treatment is disrupted by policy interventions. Delays in access to these medications can have major life-threatening consequences for patients; increase the likelihood of costly hospitalizations and emergency room visits; and adversely impact a person's ability to achieve and sustain viral suppression. These consequences are not only potentially devastating to patient health outcomes, but can also become very expensive.

3. **The GUARD Model would only worsen any perceived "deficits of care" faced by patients taking 6PC drugs.**

When proposing models to test, CMMI is required by law to identify and define specific populations who are experiencing "deficits of care," such that any potential payment and care delivery intervention may be specifically designed to test ways to improve their care

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[14] Center for Substance Abuse Treatment. Substance Abuse Treatment for Persons With HIV/AIDS. Treatment Improvement Protocol (TIP) Series, No. 37. 2000. No. (SMA) 12-4137. *Rockville, MD: Substance Abuse and Mental Health Services Administration*.

[15] National Institutes of Health Panel on Antiretroviral Guidelines for Adults and Adolescents. (Dec. 6, 2023). Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. De*partment of Health and Human Services*. https://clinicalinfo.hiv-stage.od.nih.gov/sites/default/files/guidelines/archive/adult-adolescent-arv-2023-12-06.pdf.

[16] HIVinfo. (Jan. 13, 2025). HIV Treatment Adherence. *National Institutes of Health*. https://hivinfo.nih.gov/understanding-hiv/fact-sheets/hiv-treatment-adherence.

[17] Eisinger, R. W., Dieffenbach, C. W., & Fauci, A. S. (2019). HIV Viral Load and Transmissibility of HIV Infection: Undetectable Equals Untransmittable. *JAMA, 321(5), 451–452*. https://doi.org/10.1001/jama.2018.21167.

and health outcomes. CMMI does not describe any specific challenges experienced by Medicare patients who rely on drugs covered under the 6PC, nor does CMMI propose ways to address any of the existing challenges that patients currently face in accessing their treatment, notwithstanding the 6PC policy being in place. While the 6PC policy was created to promote and enable the stability and other benefits that come from finding and adhering to a clinically appropriate medication regimen, it is well known that some barriers to access still remain.[18] Some of these very real barriers include delays in accessing a medical provider, the lack of appropriate and timely diagnosis and treatment, and care coordination challenges. Sadly, this model does not support addressing those real deficits in care that we do see today.

Additionally, for many patients, switching medications can destabilize previously controlled diseases, leading to treatment discontinuation, increased hospital or emergency care, and higher overall healthcare costs that outweigh any drug-level savings. For example, one epilepsy patient reported having to try numerous different anti-convulsant medications over several years before finally finding a regimen that effectively controlled her seizures and allowed her to regain stability in her daily life.[19]

4. **The GUARD Model imports other countries' use of metrics for discriminatory health care rationing.**
    a. **The reliance on formulas like Quality-Adjusted Life Years is inappropriate**

This model would tie Medicare payments to the prices in certain other countries, where governments often make determinations of value using metrics like Quality-Adjusted Life Years (QALYs). Those approaches are biased against older adults and people with disabilities. As Congress has recognized in its various prohibitions against the use of QALYs and similar measures in federal health programs, America's health care system should protect medically frail and seriously ill patients, not make it harder for them to get the care they need.

CMS is proposing to subject Medicare patients to foreign policies that conflict with long-standing U.S. disability protections, effectively categorizing seniors and medically frail patients as less worthy of treatment. We urge CMS to protect patient access, keep QALY-based metrics out of Medicare decision-making, allow meaningful public input, and work with stakeholders on alternatives that lower costs without restricting care.

Perhaps most importantly, the Inflation Reduction Act specifically prohibits the use of QALY-like measures in the implementation of the Medicare Drug Price Negotiation Program

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[18] Baum, S. J. (Feb. 7, 2023). Non-medical switching an unmitigated threat to patient care. *American Journal of Preventive Cardiology,* 13, Article 100470. https://doi.org/10.1016/j.ajpc.2023.100470.
[19] Brittney's Story. *CURE Epilepsy*. https://www.cureepilepsy.org/personal-stories/brittneys-story-2/.

(MDPNP). In CMS guidance, it specifically states "CMS will not, per section 1194(e)(2) of the Act, use evidence from comparative effectiveness research in a manner that treats extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, non-disabled, or not terminally ill, and will not, per section 1182(e) of the Act, use QALYs."[20] Given this stance, the Partnership believes it would be inappropriate to apply QALYs or QALY-like metrics in this model.

b. International reference pricing is not an appropriate comparison tool given the differences in system payment structures

The Partnership is concerned that comparing drug prices in the United States against other countries with entirely different health care systems -- for example, those that operate under single-payer or fully government-funded health care payment systems -- creates false equivalencies. Those systems set prices through fundamentally different financing, access, and coverage structures than the U.S. market. Moreover, foreign markets often fail to recognize the value of innovation and appropriately pay their fair share for the new and emerging treatment options. Treating those prices as a direct corollary for U.S. policy decisions risks importing conclusions that don't translate to our fragmented multi-payer system, and could unintentionally undermine patient access, provider stability, and incentives for future innovation.

Some of the specific reference countries chosen are troubling in that their health systems are not easily compared to the United States, and in fact, the United States has benefits that these other systems do not. One of these main benefits is the increased access patients have to innovative medications in the US. Specifically, the 6PC policy supports clinician flexibility in prescribing and ensures patient access to the medications that they need, leading to broad coverage within the classes in the US. On the other hand, many of the reference countries operate very differently. For example, Germany has far fewer novel antipsychotics available for patients than the United States; formularies in Germany tend to be stricter, and reimbursement can be limited as compared to Medicare, where we see broad availability across brands and formulations.

Therefore, the Partnership urges CMS to focus on solutions specific to the United States that are tailored to the needs of our patients and relevant to our payment system, instead of proposing policies that are driven by false equivalent international comparison. CMS has more actionable, patient-centered levers available, like focusing on reducing patient out-

[20] Inflation Reduction Act of 2022, Pub. L. No. 117-169, § 1194(e)(2), 136 Stat. 1818 (2022). https://www.govinfo.gov/app/details/PLAW-117publ169?utm.com.

of-pocket costs, improving benefit design, and increasing price transparency across the supply chain that can be utilized to improve patient access to medicines.

5. **The GUARD Model will stifle innovation.**

Patients protected by the 6PC benefit directly from innovation in drug development. For example, innovation in the HIV space has transformed the disease from a near-certain fatal diagnosis to one that can be successfully managed through antiretroviral medication regimens -- often only one pill per day or, thanks to innovation, a long-acting injection, with longer-acting treatments in the pipeline. Patients can experience a high quality of life, working, caring for family, and even preventing HIV transmission due to the medications they take.

We are concerned that the GUARD Model will disincentivize the scientific innovation that patients rely on by destabilizing the health care marketplace. While impacting everyone, this could be especially catastrophic for small- and mid-size innovators. The development of new treatments and cures depends on long-term planning and takes decades of sustained research investment. When policies reduce incentives to innovate, fewer new therapies get developed and fewer reach patients -- especially in high-risk/high-reward areas like the 6PC. That means people wait longer for better options, have fewer choices when current treatments do not work, and miss out on next-generation therapies that could improve or extend their lives, or cure them of their illness, as has been done for hepatitis C.

We recognize the importance of addressing rising health costs for both patients and the Medicare program, and we support thoughtful, evidence-based efforts to promote fiscal responsibility. At the same time, policies designed to control spending must be carefully evaluated to ensure they achieve their intended goals rather than shifting costs elsewhere or creating unintended consequences for beneficiaries. CMS must ensure that the 6PC policy is not compromised. As proposed, the GUARD Model does not provide this assurance and presents meaningful risks to patient cost sharing and well-being.

The Partnership urges CMS to rescind the GUARD Model fully and work with stakeholders to develop more appropriate and patient-centered approaches to health care affordability. We appreciate the opportunity to provide our feedback on the model through this comment and welcome continued discussion with you. Should you have any questions for us, please reach out to Michelle Seger at mseger@vennstrategies.com.

Sincerely,

The Partnership for Part D Access