

February 23, 2026

Robert F. Kennedy Jr.
Secretary
U.S. Department of Health and Human
Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Request for Public Comment on the Proposed GUARD Model [CMS-5546-P]

Dear Secretary Kennedy and Dr. Oz,

The undersigned organizations appreciate the opportunity to share their concerns regarding the proposed Guarding U.S. Medicare Against Rising Drug Costs (GUARD) model. As advocacy organizations representing older adults, caregivers, people with disabilities, and individuals living with chronic illness, we share CMS's interest in policies that improve affordability while ensuring timely access to medically necessary treatments.

The GUARD model, however, would not advance these shared objectives.

While framed as a "demonstration," the model ties Medicare Part D drug prices to prices set by foreign governments, using benchmarks derived from a group of OECD countries with government-run health systems. Although GUARD relies on manufacturer rebates rather than explicit price caps, it applies a Most Favored Nation (MFN) approach to Medicare Part D pricing.

Like prior MFN proposals, GUARD would risk restricting access to medicines that older patients rely on and undermining medical innovation -- without delivering meaningful reductions in beneficiaries' out-of-pocket costs. In fact, the proposed rule itself estimates that beneficiaries will see an additional \$3.6 billion in increased costs due to rising Part D premiums and cost-sharing obligations. For these reasons, the undersigned organizations urge CMS to withdraw the proposal and instead pursue reforms that directly improve patient affordability.

Medicare Part D disproportionately covers medicines used to treat chronic, progressive, and age-related conditions. Although CMS asserts that GUARD would not alter coverage or formulary placement, Part D plans retain broad discretion to manage access through prior authorization, step therapy, quantity limits, and tiering changes.

In practice, plans are likely to respond to foreign reference pricing by favoring drugs that align with the benchmark while increasing access barriers for those that do not. As a result, older adults -- nearly 95 percent of whom live with at least one chronic condition -- could experience reduced access to therapies prescribed by their physicians.

GUARD also raises serious concerns about access because MFN-style policies are designed primarily to generate savings for the government through reduced utilization. According to CMS's own analysis from its November 2020 MFN proposed rule, the model assumed a 9 to 19 percent reduction in patient utilization.¹ CMS further acknowledged that many affected medications lacked comparable therapeutic alternatives, meaning some beneficiaries would have been left without access to treatment.

These access restrictions reflect the value assessment frameworks embedded in government-set price controls. Many foreign governments rely on Quality-Adjusted Life Years (QALYs) to determine coverage and pricing decisions. QALYs systematically devalue care for older adults, people with disabilities, and individuals living with chronic illness by assigning lower value to additional years of life or improvements in quality of life.

In the United Kingdom, for example, health authorities have declined to recommend routine use of new Alzheimer's treatments after those therapies failed to meet QALY-based cost-effectiveness thresholds.²

Federal law reflects a clear judgment that Medicare should not rely on cost-effectiveness tools that assign a lower value to the lives of older adults or people with disabilities. That is why Congress explicitly prohibited the use of QALYs in Medicare coverage and reimbursement decisions.³ A 2019 report from the National Council on Disability (NCD) further warned that countries relying on QALY-based assessments often impose access restrictions and delays that worsen patient outcomes, and urged policymakers and insurers in the United States to reject such metrics.⁴ By tethering Medicare prices to countries that rely on these frameworks, the GUARD model would effectively import discriminatory value judgments into Medicare, undermining longstanding statutory protections for older adults and people with disabilities.

GUARD would also weaken incentives for the long-term, high-risk research necessary to develop new therapies for Alzheimer's disease, Parkinson's disease, cancer, and rare neurological disorders. Analysis from researchers at the University of Chicago estimates that MFN pricing would result in 210 fewer new drug approvals over a ten-year period.⁵ Older adults would bear the greatest burden of slowed medical innovation.

The undersigned organizations are also concerned that GUARD exceeds the statutory authority of the Center for Medicare and Medicaid Innovation. GUARD would operate as a functionally mandatory, nationwide program with the potential to fundamentally reshape

¹ <https://www.federalregister.gov/documents/2020/11/27/2020-26037/most-favored-nation-mfn-model#page-76244>

² https://www.alzheimer-europe.org/news/nice-publishes-final-guidance-recommending-against-routine-nhs-use-donanemab-and-lecanemab?language_content_entity=en#

³ https://www.ssa.gov/OP_Home/ssact/title11/1182.htm

⁴ <https://www.ncd.gov/report/quality-adjusted-life-years-and-the-devaluation-of-life-with-a-disability/>

⁵ <https://ecchc.economics.uchicago.edu/2025/09/29/policy-brief-the-impact-on-patient-health-of-most-favored-nation-pricing-of-already-marketed-drugs/>

Part D plan design. The Innovation Center was not intended to serve as a vehicle for imposing de facto price controls or restructuring Medicare Part D through administrative action. CMS should not rely on demonstration authority to achieve outcomes that Congress has not authorized.

Finally, GUARD fails to address the structural factors that actually drive patient costs in the U.S. health care system. Under the model, only drug manufacturers would be required to pay rebates to the government, while pharmacies, insurers, and other intermediaries are excluded -- despite extensive evidence that rebate practices, utilization management, and supply-chain distortions contribute significantly to affordability challenges. For example, 340B hospital discounts and pharmacy benefit manager fees for common brand-name drugs can exceed the total cost of those same medicines in OECD countries.⁶

Policymakers should instead focus on reforms that address misaligned incentives and practices among health insurers and ensure that safety-net programs, including the 340B Drug Pricing Program, operate with appropriate transparency and oversight to effectively support patients. Rationing medicines through foreign reference pricing does nothing to address these distortions and risks further harming beneficiaries.

The undersigned organizations support CMS's goal of ensuring that foreign governments contribute more fairly to global biomedical innovation. Medicare beneficiaries, however, should not be used as leverage in international pricing disputes. For these reasons, we urge CMS to rescind the GUARD proposal and pursue reforms that lower costs while protecting access to care and preserving the incentives for innovation that older adults depend on.

Sincerely,

Alliance for Aging Research
ADAP Advocacy Association
Alliance for Patient Access
Alpha-1 Foundation
ALS Association
ASCP (The American Society of
Consultant Pharmacists)
Association of Black Cardiologists
Biomarker Collaborative
Caregiver Action Network
Children with Diabetes
Chronic Care Policy Alliance
Davis Phinney Foundation for Parkinson's
Exon 20 Group
Global Coalition on Aging

Global Colon Cancer Association
Global Healthy Living Foundation
Haystack Project
HIV+Hepatitis Policy Institute
Hypertrophic Cardiomyopathy
Association
ICAN, International Cancer Advocacy
Network
International Pemphigus and Pemphigoid
Foundation
Justice in Aging
Lupus and Allied Diseases Association,
Inc.
MET Crusaders
National Association of Hispanic Nurses

⁶ <https://www.pacificresearch.org/the-340b-discounts-hospitals-receive-will-often-exceed-total-drug-prices-in-europe/>

National Minority Quality Forum
Neuropathy Action Foundation
NRG1 Energizers
Organic Acidemia Association
Partnership to Fight Chronic Disease

Patients Rising
PDL1 Amplifieds
Schizophrenia Policy Action Network
Second Wind Dreams, Inc.
SSVA