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February 23, 2026

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

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

Dear Administrator Oz:

The Center for American Principles (CAP) submits this comment in response to the [proposed "Guarding U.S. Medicare Against Rising Drug Costs"](#) (GUARD) model.

By applying a foreign price-control scheme to Medicare's prescription drug benefit, [Part D](#), CMS would impose a sweeping, unlawful policy that will fail patients on both cost and access and weaken America's global leadership in innovation.

These concerns are central to the work of the Center for American Principles. CAP is a 501(c)(4) nonprofit issue-advocacy organization that advances sound policy solutions based on American core principles and brings attention to the increasing threats facing Americans from government intervention in markets and bureaucratic overreach. Our mission is to protect and promote individual freedoms, free enterprise, limited government, the rule of law, and a strong national defense. The GUARD model directly conflicts with these principles and should be withdrawn.

Congress created the [Center for Medicare and Medicaid Innovation](#) (CMMI) to test limited, voluntary, and narrowly tailored payment and delivery reforms. It did not authorize CMMI to restructure Medicare Part D for a significant share of beneficiaries nationwide through a mandatory, multi-year price control model. The proposed GUARD rule relies on an arbitrary geographic design that randomly selects ZIP-code areas to capture [25%](#) of Part D enrollees. This is a dangerous government overreach in an attempt to induce nationwide market behavior changes not supported by law under the guise of satisfying statutory "test" requirements.

Since its inception, Medicare Part D has relied on private sector competition to deliver broad access and choice for seniors' outpatient prescription drugs. The GUARD model abandons that structure.

Under the proposed model, U.S. prices for certain Part D drugs would be tethered to benchmarks set by government authorities in [19 foreign countries](#), including the United Kingdom, Germany, France, Japan, and Canada -- systems that rely on centralized price-setting. By tying U.S. prices to foreign government decisions, CMS replaces the competitive dynamics that made Part D successful with centralized price administration, contradicting the program's statutory design.

CMS would compel compliance with the model notwithstanding unresolved questions regarding its authority. The model establishes a pricing benchmark based on the lowest prices observed among the reference countries and enforces that benchmark through government-imposed rebates when U.S. prices exceed foreign levels. Manufacturers may avoid this outcome only by "voluntarily" submitting proprietary international pricing data, in which case CMS would instead rely on a foreign-weighted average.

This framework is reinforced by civil monetary penalties equal to [125%](#) of unpaid rebate amounts, amounting to significant coercion on manufacturers, notwithstanding that federal agencies lack the authority to unilaterally create and enforce [punitive financial penalties](#).

The premise underlying the GUARD proposal and other federal price-setting proposals -- that foreign drug prices reflect fair value -- is itself deeply flawed. Most of the countries that CMS proposes to reference rely on rigid [value-assessment frameworks](#) that prioritize budget constraints over patient outcomes, routinely restricting access to new therapies or delaying availability.

Importing these benchmarks risks embedding those same access limitations into Part D and adopting discriminatory valuation tools that override physician judgment. The risk is especially acute because the GUARD model targets drugs that lack generic or biosimilar competition, leaving many patients without clinically appropriate alternatives for serious and chronic conditions.

The model even affects Medicare's six [protected therapeutic classes](#), which are safeguards Congress established to ensure access to treatments for serious conditions like cancer, HIV, and epilepsy. Although formal coverage requirements may remain unchanged, the financial incentives created by proposals like GUARD encourage plans to redesign benefits in ways that effectively restrict access. Plans will be driven to steer patients toward internationally benchmarked drugs and away from other appropriate options, disrupting stable treatment

regimens and undermining physician decision-making for seniors with complex or life-threatening conditions.

Notably, CMS itself concedes that GUARD rebates will [do little](#) to lower out-of-pocket costs. In fact, the GUARD model is estimated to increase Part D premiums and beneficiary cost sharing by approximately [\\$3.6 billion](#). Meanwhile, the true drivers of patient affordability challenges are left unaddressed -- particularly supply chain intermediaries whose fees and rebate structures inflate and obscure costs without improving care.

Beyond failing to deliver patient savings, the GUARD model -- like all federal price-setting schemes -- would carry serious consequences for America's innovation ecosystem. Policies that artificially devalue innovation predictably reduce research investment and delay future breakthroughs. [Independent economic research](#) indicates that importing foreign price-control models could result in the loss of hundreds of future drug treatments over the next decade -- potentially as many as [500 therapies and indications](#) -- as companies are forced to scale back or abandon high-risk research programs.

Federal price-setting proposals like GUARD risk accelerating the migration of early-stage development and production capacity to foreign competitors. At a moment when [China](#) is [aggressively pursuing](#) global leadership in biotechnology, dissociating Medicare Part D services from the market disciplines that enable advanced research, clinical trials, and manufacturing in the United States is a strategic mistake that will bring lasting harm to American patients, jobs, and national security.

The GUARD model is an unlawful restructuring of Medicare Part D. The model replaces market disciplines with foreign price controls, undermines patient-centered care, and fails to deliver cost relief to seniors. For these reasons, CAP strongly urges CMS to withdraw the proposed model.

Sincerely,
Tony Zagotta
Center for American Principles