COUNCIL FOR AFFORDABLE
HEALTH COVERAGE

February 23, 2026

The Honorable Mehmet Oz, M.D.
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS–5546–P; Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model Proposed Rule

Dear Administrator Oz:

On behalf of the Council for Affordable Health Coverage (CAHC), we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model.[1]

CAHC (www.cahc.net) is a broad-based alliance with a singular focus: ensuring all Americans have access to affordable coverage. We are pro-patient, pro-competition, and pro-innovation. Our member organizations include employers, medical providers, patient groups, agents and brokers, technology companies, and pharmaceutical manufacturers. CAHC has long supported market-based reforms that lower drug costs, promote greater access to drug therapies, and foster innovation to help treat and cure disease. Government price controls can reduce access to needed therapies, weaken incentives for innovation, and shift costs within the system rather than lower them. Durable affordability is more effectively achieved through market-based reforms that promote competition, increase transparency, and ensure savings are delivered directly to patients.

We share the goal of lowering prescription drug spending for Medicare beneficiaries. We are concerned, however, that the proposed GUARD Model undermines the principles described above, exceeds CMMI's statutory authority and risks increasing patient costs without testing meaningful innovations in care delivery or payment and should therefore be rescinded.

As structured, the GUARD Model functions as a pricing intervention rather than a test of delivery system reform. This Administration to date has made a clear point to lead the country away from socialist economic policy, yet this model copies those exact ill-conceived government-first policies. CMMI's statutory authority is intended to evaluate innovative payment and care delivery models – not to impose broad price-setting mechanisms. The mandatory nature of the Model raises additional concerns, as Congress authorized a regulatory agency, CMMI, to test time-limited demonstrations, not to replace Congress by implementing sweeping, compulsory policy changes that operate as de facto nationwide pricing reform law.

[1] CMS–5546–P

While the program saves the government money, it would increase costs for patients by more than $3 billion, which directly contradicts the President's April 15 Executive Order[2]. A clearer and more direct benefit to patients would be to remove bureaucratic barriers that prevent TrumpRx[3] discounts from counting towards patients' deductibles and out-of-pocket costs in Medicare and other federal programs. Moreover, because nearly half of every dollar spent on brand-name drugs flows to entities that did not develop or manufacture them[4], policymakers should prioritize reforms that address supply chain inefficiencies and ensure negotiated savings reach patients directly. Absent such safeguards, the GUARD Model risks redistributing costs rather than reducing them, potentially increasing premiums or limiting access without generating sustainable system-wide savings.

The following sections detail CAHC's concerns with the GUARD Model:

I. GUARD does not test an "innovative payment or service delivery model" as required by statute.

Section 1115A of the Social Security Act authorizes CMMI to test "innovative payment and service delivery models" that are expected to either (1) reduce program expenditures while preserving or enhancing quality of care, or (2) improve quality of care without increasing expenditures.[5] Legislative history confirms that Congress intended CMMI to test changes in how care is delivered and paid for, such as care coordination, provider accountability, benefit design, and incentives that improve outcomes and efficiency – not to create new revenue mechanisms disconnected from patient care.

The GUARD Model does not test changes to clinical practice, prescribing behavior, benefit design, care coordination, or provider incentives. Instead, the core mechanism of the model is an increase in mandatory manufacturer payments to the federal government through additional rebates. CMS does not explain how these payments are expected to alter care delivery, improve quality, or change beneficiary behavior. As proposed, GUARD functions as a fiscal policy tool rather than a test of an innovative payment or service delivery model. Because GUARD neither tests a change in care delivery nor evaluates a novel payment methodology tied to patient care, it falls outside the statutory authority Congress granted CMMI under Section 1115A.

II. CMS acknowledges GUARD may increase patient costs, undermining compliance with section 1115A.

CMMI models must either reduce spending without reducing quality or improve quality without increasing spending.[6] In the GUARD proposed rule, CMS estimates that the model would increase beneficiary cost sharing by $0.6 billion and increase premiums by $3 billion as plans

[2] https://www.whitehouse.gov/presidential-actions/2025/04/lowering-drug-prices-by-once-again-putting-americans-first/
[3] https://trumprx.gov/
[4] https://media.thinkbrg.com/wp-content/uploads/2025/01/06161850/PhRMA_Supply-Chain-2013-2023_White-Paper.pdf
[5] 42 U.S.C. §1315a(a)(1) and (b)(2)(A)
[6] 42 U.S.C. § 1315a(b)(2)(A)

respond to manufacturer behavior changes resulting from mandatory rebates.[7] CMS also acknowledges potential negative effects on utilization and access. This means that CMS predicts patients will be financially worse off.

A model that affirmatively contemplates increased patient costs – particularly for prescription drugs – does not satisfy section 1115A's statutory requirements. As the regulatory preamble indicates, higher beneficiary costs increase medication non-adherence that leads to poorer health outcomes, especially for beneficiaries with chronic and complex conditions. CMS does not identify a plausible pathway by which GUARD could meet the statute's cost or quality standards given these acknowledged impacts. Absent a credible argument that the model will reduce total program expenditures while preserving or enhancing quality, GUARD cannot lawfully proceed under Section 1115A.

III. Any manufacturer assessment should directly benefit patients through affordability and access protections.

The GUARD model should not move forward as proposed. Section 1115A authorizes CMMI to test models that improve beneficiary outcomes, not impose revenue-generating assessments untethered to meaningful patient relief. GUARD does not require affected drugs to be placed on lower formulary tiers, does not limit utilization management, and does not require reductions in patient cost sharing. As a result, there is no assurance that increased manufacturer payments will benefit patients at all.

Any model implemented under Section 1115A must deliver clear, measurable benefits to beneficiaries – not merely increase federal revenue or alter manufacturer payment obligations. GUARD does not demonstrate such patient-centered improvements.

Rather than advancing a model that risks raising beneficiary costs, CMS should pursue reforms that directly improve affordability and access. For example, CMS could allow Medicare enrollees to use voluntary price reductions available on TrumpRx and apply those cash purchases against Medicare plan cost sharing obligations by waiving the 2005 and subsequent OIG rulings related to Patient Assistance Programs.[8]

Enabling Medicare beneficiaries to access most favored nation (MFN)- based prices through TrumpRx while still meeting their deductible and maximum out-of-pocket requirements would provide immediate, patient-centered savings. Unlike GUARD, this approach would lower prescription drug costs rather than increase financial burdens on beneficiaries.

IV. Inconsistent international price benchmarks between GUARD and GLOBE reveal insufficient evidentiary support.

CMS relies heavily on international reference pricing to justify both the GUARD[9] and GLOBE[10] Models yet applies differing benchmark methodologies across the two contemporaneous

[7] 90 Fed Reg. No. 244. Page 60341
[8] OIG Special Advisory Bulletin on PAPs
[9] CMS-5546-P
[10] CMS-5545-P

proposals without adequately explaining the basis for those differences. In GLOBE, CMS proposes a defined international benchmark tied to prices in a specified set of economically comparable countries for certain Part B drugs. In GUARD, CMS adopts a separate benchmarking framework for Part D drugs that relies on a different calculation methodology.

These divergent approaches raise serious questions about CMS's analytical foundation. If international prices are appropriate and reliable comparators for U.S. drug prices, CMS should be able to articulate a consistent methodological framework or clearly explain why distinct approaches are warranted. The absence of a transparent, data-driven rationale for the divergent benchmark designs raises concerns regarding analytical rigor and reasoned decision-making.

Section 1115A requires CMMI to test models grounded in evidence and data-driven hypotheses. Rather than presuming that international prices are lower, appropriate, or transferable to the U.S. market context, CMS should first collect and analyze empirical data demonstrating that international net prices meaningfully differ from U.S. prices in comparable ways and that such differences translate into improved patient outcomes or lower total program costs. Designing large-scale, mandatory models around unresolved methodological assumptions risks producing invalid or inconclusive results and undermines the integrity of the CMMI testing framework.

V. CMS must isolate GUARD's effects from other CMMI models.

CMS acknowledges potential interaction between GUARD and other CMMI models but does not explicitly exclude GUARD drugs from participation in those models. Overlapping participation risks confounding results and makes it impossible to determine whether observed effects are attributable to GUARD or to other models.

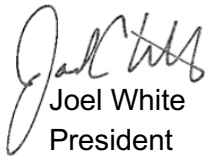
Section 1115A requires rigorous evaluation of model performance. To meet this obligation, CMS should explicitly isolate GUARD's effects by excluding affected drugs from other CMMI models or otherwise preventing overlapping participation.

Conclusion

For the reasons outlined above, CAHC urges CMS to rescind the current GUARD Model as proposed and offer a new model based on TrumpRx. CMMI's statutory authority under section 1115A is limited to testing innovative payment and service delivery models that improve quality and/or reduce costs for beneficiaries. GUARD, as proposed, does not meet these requirements and risks increasing patient costs without delivering meaningful improvements in care or access.

CAHC welcomes continued engagement to improve affordability for patients and to lower drug costs. We stand ready to work with CMS on alternative approaches that better align with CMMI's statutory mission and the needs of patients.

Sincerely,



Joel White
President