COUNCIL FOR AFFORDABLE
HEALTH COVERAGE

The Honorable Robert F. Kennedy, Jr.
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS–5545–P; Proposed Global Benchmark for Efficient Drug Pricing (GLOBE) Model

Submitted electronically to regulations.gov

Dear Secretary Kennedy:

On behalf of the Coalition for Affordable Health Coverage (CAHC), we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed Global Benchmark for Efficient Drug Pricing (GLOBE) 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 at the point of sale.

We share the goal of lowering prescription drug spending for Medicare beneficiaries. We are concerned that the GLOBE model undermines the principles outlined above. By taxing innovators through a mandatory rebate model, we are concerned that the GLOBE model will not achieve significant cost savings because it encourages higher prices to offset increased rebate liability. The proposed GLOBE Model also raises significant legal and evidentiary concerns under the statutory framework governing the Center for Medicare and Medicaid Innovation (CMMI). CAHC believes the models create problems with fatal flaws, including:

1. Lowers costs for government without a corresponding preservation or improvement in patient care quality;
2. Expands the scope of CMMI models beyond the scope envisioned in the law;
3. Increases regulatory burden through overlapping and conflicting intersections with other CMMI models and
4. Presupposes lower net prices in ex-US countries without evidence.

[1] CMS-5545-P

We encourage HHS to rescind the CMMI model and work with concerned citizens to address these problems before moving forward with any mandatory rebate model. Our concerns are outlined below.

I. The GLOBE Model, as proposed, exceeds CMMI's statutory authority under 42 U.S.C. § 1315a.

Section 1115A of the Social Security Act authorizes the Innovation Center to test "innovative payment and service delivery models" that are expected to either: (1) reduce program expenditures while preserving or enhancing the quality of care, or (2) improve quality without increasing program expenditures.[2]

The statutory framework and legislative history make clear that CMMI is intended to test changes in care delivery systems, payment methodologies, or provider incentives, such as value-based purchasing arrangements, integrated care models, or alternative payment methodologies that realign incentives around quality and coordination.

The proposed GLOBE Model does not meaningfully test payment or service delivery innovation. Instead, it establishes a mandatory rebate obligation for manufacturers of certain high-spend, single-source Part B drugs without generic or biosimilar competition when U.S. prices exceed a benchmark derived from prices in selected foreign countries. Mandatory rebates are taxes levied on manufacturers.

CMMI's statutory authority does not extend to imposing broad new taxes or price controls untethered to a demonstrable test of payment or service delivery reform. A model that functions primarily as a mechanism to extract manufacturer rebates based on foreign pricing does not fall within the plain meaning of "testing innovative payment and service delivery models" under § 1115A. Accordingly, the GLOBE Model exceeds CMMI's statutory authority.

II. The GLOBE Model's expected cost effects and quality impacts are inadequately supported.

Section 1115A requires that CMMI models either reduce spending without reducing quality or improve quality without increasing spending.[3] CMS states that GLOBE is expected to reduce costs for Medicare and "preserve or enhance" the quality of care for beneficiaries.

However, the proposed rule lacks adequate empirical support demonstrating that:

- the international pricing benchmark will reliably result in lower total costs net of manufacturer price concessions, and
- the quality of care will be preserved or improved, especially considering possible shifts in provider prescribing behavior or drug availability.

[2] 42 U.S.C. §1315a(a)(1) and (b)(2)(A)
[3] 42 U.S.C. § 1315a(b)(2)(A)

The cost-saving projections depend heavily on the assumption that tying rebates to an international benchmark will lower net Part B drug spending. Because the model relies on a benchmark that may be set at the lowest price among reference countries (if manufacturers do not submit net price data), the resulting rebate obligations could be substantial and may alter market dynamics in ways that increase costs.

CMS states Part B drug coinsurance for GLOBE beneficiaries will be lowered proportionately to the GLOBE model benchmark amount, but 87% of Part B Fee-for-Service (FFS) beneficiaries already have supplemental insurance.[4]

Consequently, the projected coinsurance reductions are unlikely to translate into meaningful out-of-pocket (OOP) savings for most beneficiaries, as evidenced by a recent analysis that found that over 99% of sampled Part B FFS beneficiaries would see no reduction in OOP costs.[5] Instead, lowering supplemental carrier obligations will lower costs for insurers and act as yet another industry subsidy.

In the absence of robust evidence that such international reference pricing benchmarks will translate into lower net costs or sustained quality of care in the U.S. context, CMS has not met its burden to show that GLOBE is expected to achieve the statutory cost/quality criteria.

III. Inconsistency between GLOBE and GUARD benchmarks undermines the evidence base.

CMS's parallel GLOBE and GUARD proposals employ different benchmarks and methods for incorporating international pricing information into rebate calculations for Part B and Part D drugs, respectively. GLOBE overlays an international benchmark onto the existing ASP-based Part B system without clearly explaining how these two pricing constructs will interact over time. In a given calendar quarter, providers are reimbursed based on all market sales net of price concessions, which is a market-derived price. The GLOBE rebate would be calculated against a simultaneous international benchmark, which is derived by government set prices.

The complex hierarchical structure for data used in calculating an assumed net price, and a differential benchmark offered to manufacturers who submit net pricing data, shows that CMMI is assuming international net prices are less than the U.S. ASP-based methodology. HHS is thus predicating all its models on a data assumption that has yet to be proven. CMS has not provided affirmative evidence that international prices for Part B drugs are lower, and so its already flawed premise for launching this model becomes further dubious. This inconsistency suggests that CMS does not have sufficient evidence to justify the assumed superiority of international price benchmarks and lacks a consistent framework for how such benchmarks relate to quality, affordability, and U.S. market dynamics.

[4] https://www.kff.org/medicare/a-snapshot-of-sources-of-coverage-among-medicare-beneficiaries/
[5] https://advisory.avalerehealth.com/insights/how-mfn-pricing-in-part-b-may-affect-beneficiary-oop-costs

Under §1115A, CMMI must test models grounded in evidence and sound assumptions. Designing a model based on unresolved or inconsistent international price assumptions undermines the ability to evaluate whether the model satisfies the statutory criteria.

IV. The GLOBE Model offers no direct beneficiary protections or access improvements.

The proposed GLOBE Model focuses on manufacturer-to-government rebates. It does not impose requirements on providers, does not modify supplemental insurer obligations, and explicitly excludes 340B units from rebate calculations. The rebate obligation is structured to minimize direct operational changes for other stakeholders, including providers, whose reimbursement under Part B remains based on ASP plus the statutory add-on.

While CMS states that beneficiary coinsurance will be reduced proportionately to the benchmark, this provision offers limited practical benefit given the prevalence of supplemental coverage among Part B beneficiaries. The proposal does not include additional beneficiary protections, such as mandatory safeguards against access disruptions, enhanced transparency for patients, or targeted protections for beneficiaries who lack supplemental coverage.

For CMMI models involving financial consequences to manufacturers, the statute contemplates tests that meaningfully redesign care incentives or improve outcomes. CMMI has not outlined how new government revenues might be used to improve beneficiary engagement, care plan adherence, improve clinical outcomes, or any other benefit to patients. Considering CMMI proposes to increase taxes and not use new revenue to test any quality-enhancing activities, it is not aligned with the Center's statutory goals or Congressional intent.

V. The GLOBE Model should isolate its effects from overlapping CMMI initiatives.

Section 1115A requires rigorous evaluation of model performance.[6] To assess whether a model reduces spending while preserving or enhancing quality, CMS must be able to attribute observed effects to the model itself. The proposed GLOBE rule, however, does not clearly exclude drugs or manufacturers that may be participating in other CMMI initiatives or federal pricing programs.

CMS acknowledges in the proposed rule that interactions with other models may occur and suggests that future "modifications or adjustments" could be made if necessary for purposes of testing. This open-ended approach introduces substantial uncertainty and risks the evaluation of GLOBE's independent effects.

Since CMS does not separate the GLOBE model from overlapping initiatives, it poses program integrity issues and makes it untenable for CMS to accurately measure the impacts of the model.

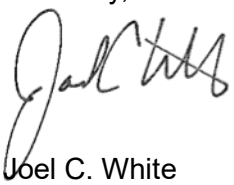
[6] 42 U.S.C. § 1315a(b)(4)

Conclusion

CAHC urges CMS to withdraw the GLOBE Model. Under section 1115A, CMMI is authorized to test truly innovative payment and service delivery models expected to reduce costs or improve quality for beneficiaries. As proposed, GLOBE contemplates a new tax without any patient benefit, does not clearly satisfy statutory criteria, and risks modeling frameworks that lack evidentiary support and measurable beneficiary benefit.

Thank you for the opportunity to comment. We look forward to engaging further on proposals that genuinely advance affordability, access, and quality for Medicare beneficiaries.

Sincerely,



Joel C. White
President