Arnold Ventures

February 20, 2026

Dr. Mehmet Oz, Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Comments on the proposed rule to implement the Global Benchmark for Efficient Drug Pricing Model [File code CMS-5545-P]

Dear Administrator Oz,

Thank you for the opportunity to provide comments to the Centers for Medicare and Medicaid Services (CMS) on the proposed rule to implement the Global Benchmark for Efficient Drug Pricing Model ("GLOBE Model") published in the Federal Register on December 23, 2025.

Arnold Ventures (AV) is a philanthropy dedicated to investing in evidence-based policy solutions that maximize opportunity and minimize injustice. As a philanthropy, we do not accept funding from industry or have a financial stake in policy outcomes. Our work within the health care sector is driven by the recognition that the system costs too much and fails to adequately care for the people it serves. Our work spans a range of issues including commercial-sector prices, provider payment incentives, prescription drug prices, FDA accountability, Medicare sustainability, and Medicaid.

We applaud CMS staff for your efforts to lower prescription drug prices for patients and taxpayers. Arnold Ventures supports the GLOBE Model to test a framework for lowering the prices of high-cost brand-name drugs purchased by Medicare, which could create savings for taxpayers and Medicare beneficiaries. We support using inflation penalties to lower drug prices for patients and taxpayers and **we support CMMI leveraging that mechanism to lower spending in Medicare Part B if the model is severable from the Medicare inflation penalties created by the Inflation Reduction Act.** We ask that CMS clarify whether participation in other CMMI models or Most Favored Nation deals would allow manufacturers to opt out of the GLOBE Model. Understanding this key detail will help stakeholders assess the true impact of GLOBE on patients and taxpayers.

This letter provides comments on the following sections of the proposed rule:

- *A.2.f. Proposed Model Waivers*
- *B.3 and B.4. Summary of GLOBE Model Drug Inclusion and Exclusion and Alternatives Considered*
- *E.1. Proposed Mandatory Participation of Manufacturers of GLOBE Model Drugs*
- *G.1.d. Proposed Voluntary Submission of International Drug Net Pricing Data*
- *G.2.b. Proposed Methodology for Identifying the Per Unit Method II GLOBE Model Benchmark Using Manufacturer Submitted Data*
- *G.3. Proposed Methodology for Identifying the Per Unit GLOBE Model Benchmark Amount for an Applicable Calendar Quarter*
- *G.7. Proposed GLOBE Model Beneficiary Coinsurance Adjustment and Adjusted Medicare Payment for GLOBE Model Drugs*
- *N.3.b. Medicare Advantage*

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OVERVIEW OF THE PROPOSED GLOBE MODEL

One quarter of Medicare Part B Fee-for-Service (FFS) beneficiaries would be randomly selected to participate in the GLOBE Model.

- Single source brand-name drugs with over $100 million in Medicare Part B FFS sales in seven specific therapeutic categories that largely fall within oncology, rheumatology, immunology, ophthalmology and endocrinology would qualify as GLOBE Model drugs.
- When administered to GLOBE Model beneficiaries, manufacturers would have to increase the Part B inflation rebate for GLOBE Model drugs to the difference between the Medicare Part B payment rate and the benchmark amount, which uses international prices.
- Out-of-pocket (OOP) costs for beneficiaries would be lowered to 20% of the GLOBE Model benchmark amount. Providers would be made whole as the amount they are paid for administering Part B GLOBE Model drugs would remain unchanged. (Payments from the federal government to providers would increase to offset lower beneficiary OOP costs).
- The higher Medicare Part B inflation rebate payments under the GLOBE Model would be paid to the SMI Trust Fund which would both reduce Medicare costs and lower premiums for all Part B beneficiaries.

COMMENTS ON SELECT SECTIONS OF THE PROPOSED GLOBE MODEL

A.2.f. Proposed Model Waivers

AV supports CMS's decision to make the GLOBE Model severable from the Medicare inflation rebate, should some part of the model be deemed invalid or unenforceable. The inflation rebate is a core part of the Inflation Reduction Act's (IRA) Medicare reforms, limiting the price increases in Part B and Part D drugs to the rate of inflation. Without these severability provisions in the proposed rule, this model could invite more litigation from manufacturers aiming to dismantle the IRA.

B.3 and B.4. Summary of GLOBE Model Drug Inclusion and Exclusion and Alternatives Considered

AV supports adjusting the $100 million sales threshold by the CPI-U. Not updating this threshold for inflation would be disregarding the purpose of the threshold to capture the highest cost Part B drugs. Without the inflation index, the process would be administratively burdensome and inefficient by pulling in lower cost drugs that may not be posing affordability issues for taxpayers and patients.

AV supports CMS's use of a publicly available drug classification list, such as USP DC, to identify the categories of drugs of interest. AV also supports the USP DC categories that CMS has selected as high-cost therapeutic areas.

E.1. Proposed Mandatory Participation of Manufacturers of GLOBE Model Drugs

AV supports the mandatory participation of all manufacturers in the Model. CMS states that requiring participation allows for observation of the experiences of "manufacturers of drugs with diverse characteristics." We agree and consider broad participation to be an important factor as well, especially since the model uses a sales threshold to decide which drugs would be subject to the model. If CMS decides

that there should be some exception for small biotech manufacturers, AV recommends that CMS address this by raising the sales threshold for drugs to qualify for the Model.

G.1.d. Proposed Voluntary Submission of International Drug Net Pricing Data

AV recommends the following method to verify the net pricing data submitted to CMS by manufacturers, which are used to calculate the Method II GLOBE Model benchmark. As a first step for verification, CMS can estimate a volume weighted benchmark across the reference countries at ex-manufacturer prices using a data source such as IQVIA. The Method II GLOBE Model benchmark estimated from the voluntarily submitted data by manufacturers should be less than the calculated amount because it is based on net prices rather than the higher ex-manufacturer prices that do not account for discounts and rebates.

As an additional method of checking the Method II GLOBE Model benchmark, CMS could adjust downward the volume weighted ex-manufacturer pricing benchmark discussed above by approximating the ratio of net sales to sales at ex-manufacturer prices for GLOBE Model drugs in a way that would take advantage of data sources similar to those used by SSR Health to estimate net prices for brand-name drugs sold in the US.[1] The adjustment calculation would generate the ratio of worldwide net sales of the GLOBE Model drug in non-US countries compared to worldwide sales at ex-manufacturer prices in non-US countries.

- The numerator would be based on net US and net worldwide sales of the GLOBE Model drug published in financial reports of publicly traded companies.[2]
- Worldwide net sales for non-US countries would be equal to worldwide net sales of the GLOBE Model drug less US net sales of the GLOBE Model drug.
- The non-US net sales amount could then be divided by the non-US worldwide sales of the drug valued at ex-manufacturer prices estimated using a data source such as IQVIA.
- The ratio of net sales across countries outside the US divided by sales at ex-manufacturer prices across the same countries would approximate the non-US net to ex-manufacturer price sales adjustment for countries outside the US.
- That ratio could be multiplied by the volume weighted ex-manufacturer pricing benchmark mentioned above which is based on ex-manufacturer prices across the reference countries to obtain an estimate that is a benchmark like the Method II GLOBE Model benchmark.
- A key difference from the Method II GLOBE Model benchmark would be that the net to ex manufacturer sales adjustment would be estimated across a broader set of countries, not just the reference countries, under this alternative approach.

This approach could be used as a point of comparison to evaluate the reasonableness of the Method II GLOBE Model benchmark calculated based on data voluntarily submitted by the manufacturer. This method is a potential approach for estimating a benchmark that approximates a volume weighted net price benchmark for GLOBE Model drugs in cases where manufacturers choose not to voluntarily submit net pricing data to CMS.

AV also recommends that the assumptions that manufacturers use when reporting net sales of GLOBE Model drugs in reference countries to CMS be consistent with the methods that manufacturers use to report net sales in financial reports filed by publicly traded companies in the US.

G.2.b. Proposed Methodology for Identifying the Per Unit Method II GLOBE Model Benchmark Using Manufacturer Submitted Data

AV recommends that CMS standardize pricing measures across dosage forms, routes of administration and strengths (such as using a 30 day supply or price per course of treatment). That approach would enable the prices of the drug in all reference countries where the GLOBE Model drug is available to be included in the calculation of the GLOBE Model benchmark. It would also help to prevent manufacturers from circumventing the ability of CMS to estimate the average net price at which the GLOBE Model drug is available in other reference countries by introducing dosage forms in reference countries that differ from those in the US.

G.3. Proposed Methodology for Identifying the Per Unit GLOBE Model Benchmark Amount for an Applicable Calendar Quarter

CMS requested comments on potential alternative approaches that would closely align the GLOBE Model benchmark amount with the net pricing in various international markets. AV recommended an alternative benchmark in this comment letter under section G.1.d. The advantage of this alternative benchmark is that it would be based on data that could be purchased by CMS and would not rely on data reported voluntarily by manufacturers.

Both the Method II GLOBE Model benchmark as well as the alternative benchmark proposed above have advantages over a benchmark that is based on the lowest price across the reference countries because the latter approach (Method I) is more vulnerable to manipulation by manufacturers. While the Method I GLOBE Model benchmark is fixed over time which helps prevent its manipulation for existing drugs, concerns would remain for new drugs launched after the demonstration begins. One alternative would be for the benchmark proposed in section G.1.d. of this letter to be the default benchmark if manufacturers choose not to submit data rather than the Method I benchmark.

G.7. Proposed GLOBE Model Beneficiary Coinsurance Adjustment and Adjusted Medicare Payment for GLOBE Model Drugs

AV supports the proposed methods to lower OOP costs for GLOBE Model beneficiaries without affecting the total payments to providers for GLOBE Model drugs. GLOBE Model beneficiaries would pay out of pocket costs equal to 20 percent of the GLOBE Model benchmark (rather than 20 percent of a higher Medicare FFS payment rate). Federal payments to providers for GLOBE Model drugs administered to GLOBE Model beneficiaries would increase (above 80% of the Medicare FFS payment rate) to offset the lower OOP costs so that the total amount paid to providers for GLOBE Model drugs would remain unchanged.

N.3.b. Medicare Advantage

AV recommends that CMS revisit its guidance on inflation rebates under the IRA to include physician administered drugs administered to beneficiaries in Medicare Advantage (MA) plans. Further, upon completing the demonstration, should CMS decide to extend the GLOBE Model framework to all Medicare FFS beneficiaries, AV recommends that MA beneficiaries be included as well and that mechanisms be explored to share the savings on purchases of GLOBE Model drugs with MA plans and

beneficiaries. Since the GLOBE Model relies on the inflation rebate mechanism for Part B drugs under the IRA and that penalty does not extend to sales in Medicare Advantage (MA) plans, MA beneficiaries would be excluded from the GLOBE Model. Still, the extent to which FFS payments are lowered through lower payments for GLOBE Model drugs would be considered by CMS in determining the historical FFS claims experience for calculating the payment rates for MA plan service areas. Therefore, this model as currently proposed would be lowering payments to MA plans without lowering MA plans costs.

CONCLUSION

Arnold Ventures is prepared to assist with any additional information needed. Comments were prepared by Anna Anderson-Cook, PhD, Senior Fellow at Arnold Ventures and Kate Young, MA, Director of Health Care at Arnold Ventures, with assistance from Andrea Noda, MPP, Vice President of Health Care at Arnold Ventures, and Mark E. Miller, PhD, Executive Vice President of Health Care at Arnold Ventures. Please contact Andrea Noda at anoda@arnoldventures.org or Mark E. Miller at mmiller@arnoldventures.org with any questions.

Sincerely,

Andrea Noda
Vice President of Health Care
Arnold Ventures

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[1] See Ippolito, B and Levy, J. (2022). Best Practices Using SSR Health Net Pricing Data. AEI.
[2] This approach could not be used for companies that are not publicly traded. SSR Health relies on this type of net sales data reported by publicly traded companies and is able to estimate net prices for most top selling brand-name drugs in the US.