February 23, 2026

The Honorable Dr. Mehmet Oz
Administrator
The Centers for Medicare & Medicaid Services
Department of Health and Human Services

Re: Global Benchmark for Efficient Drug Pricing (GLOBE) Model [CMS-5545-P]; RIN 0938-AV66

Dear Administrator Oz,

Thank you for the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed Global Benchmark for Efficient Drug Pricing ("GLOBE") and Guarding U.S. Medicare Against Rising Drug Costs ("GUARD") Models. This group of experts writes to provide comments on several areas of the proposed rules. We have submitted separate comment documents for each model. This comment, submitted in response to the GLOBE Model, first addresses issues raised only in the GLOBE Model, then addresses issues raised in both models. Please refer to our additional comment on GUARD for our discussion of issues raised only in the GUARD Model.

GLOBE-specific Comments:

Alternative approaches for reporting, invoicing, and reconciliation/suggestion of error

In the GLOBE model proposed rule, CMS presents two approaches for how it will provide rebate reports and reconciliation rebate reports to GLOBE model participants—a combined approach and an incremental approach—and request comment on which approach to finalize.[1] Under the "combined approach" CMS would delay the Medicare Part B Drug Inflation Rebate Program Preliminary Rebate Reports for all manufacturers by up to two months and would provide a combined report to all manufacturers of Part B rebatable drugs for both the Medicare Part B Drug Inflation Rebate Program and the GLOBE Model. In effect, this would provide one report for both the Inflation Reduction Act (IRA) rebates and the GLOBE Model rebates. Under the "incremental approach," CMS would provide the Medicare Part B Drug Inflation Rebate Program Preliminary Rebate per the IRA and separately provide GLOBE Model reports under a different timeline as to not disrupt the existing Medicare Part B Drug Inflation Rebate Program processes and timelines.

We strongly recommend that CMS adopt the incremental approach for reporting, reconciling, and invoicing in the GLOBE Model, for several reasons. First, it reinforces and complements the proposed severability policies, which would ensure continued operations of the Medicare Part B

[1] Ctrs. for Medicare & Medicaid Servs., *Global Benchmark for Efficient Drug Pricing (GLOBE) Model*, 90 Fed. Reg. 60,244, 60,299 (Dec. 23, 2025) (hereinafter "*GLOBE Model*").

Drug Inflation Rebate Program regardless of what happens to the GLOBE Model.[2] Second, we agree with CMS that the incremental approach would be operationally more favorable than the combined approach by providing administrative efficiencies for CMS and manufacturers alike. Third, the GLOBE model does not include all rebatable drugs, and likely not all manufacturers who receive a Medicare Part B Drug Inflation Rebate Program Rebate Report would be subject to GLOBE rebates. Finalizing the incremental approach with a separate report and suggestion of error process could avoid unnecessary confusion for both CMS and the manufacturers that would likely arise with a combined approach.

Audit, record access, record retention, and model termination parameters for GLOBE Model manufacturers

The Notice of Proposed Rulemaking proposes deviating from the Standard Provisions for Innovation Center models by implementing GLOBE-specific requirements to provide CMS "regulatory specificity and flexibility to effectively test and evaluate" this model.[3] While CMS may want to propose specific requirements in order to test and evaluate the model, the proposed requirements need further clarification. CMS should clarify how the proposal at § 513.100(d)(1) to provide the federal government with "comprehensive oversight authority" is different than the authority under 42 CFR part 512(a), and why any such deviation is necessary.

Similarly, the standard provision at 42 CFR § 512.135(c) requires that records be retained for six years after the last payment determination of the model; CMS proposes to deviate from that standard in the proposed rule under § 513.100(d)(3), but it is unclear what date CMS intends to serve as the date of the "last GLOBE model rebate payment" that would substitute for the "last payment determination" under the model (e.g., preliminary rebate report, rebate report, or Reconciliation Rebate Report).

The GLOBE-specific requirements are vague and appear to be very similar to the Standard Provisions. Further clarification of the GLOBE-specific requirements and why they are needed explicitly to test and evaluate the model should be provided in the final rule.

Applying the 6% add-on

Continuing the add-on serves to continue the incentive for providers to choose the highest cost drug to administer to their patients. The proposed rule claims that the approach to the 6% add-on is similar to how the add-on applies in the inflation rebate program. But this is misleading.

In the IRA's inflation rebate program, the add-on is only affected by the difference between the manufacturer's price increase and the change in CPI-U. The decision to incorporate International Reference Prices (IRPs) into the inflation rebate program means that there are three components of the rebate calculation. The first is a price level change in the benchmark from a product's Average Sales Price (ASP) to the new benchmark. The second is the difference between the ASP and the observed price net of the IRA's relative to the CPI-U. And the third is the difference between the new IRP-based benchmark and the observed price relative to CPI-U. These three components form the total rebate to be paid by a manufacturer.

[2] *Id.* at 60,246.
[3] *Id.* at 60,263.

Thus, the add-on works quite differently because of the large effect of the level change in the benchmark. Since the rule proposes to hold providers harmless, the initial prescribing pattern would likely be little altered. The alternative presented would not include the add-on in the benchmark calculation, which would, in turn, increase savings.

The Part B add-on and the total payment are made by the provider—thus the mechanism would need to be specified as an alternative to ensure that the manufacturer's revenues would fall by the add-on amount. CMS should also clarify the treatment of add-on payments in the out years after the model expires, or how these payments would be treated if the model were to become permanent. If CMS intends that the 6% add-on payment would continue to be applied to the pre-model prices going forward, it should clarify its intent to do so.

Comments on both GLOBE and GUARD:

Establishment and updating of benchmark

In both GLOBE and GUARD, CMS should provide additional details regarding the agency's understanding of potential fallback rules. For example, consider a situation in which a drug has been launched in the United States first, such that by the time it becomes eligible for GLOBE or GUARD, it does not have any international reference pricing data available.

The extent of this challenge is significant. Because of the relative prices across nations and other regulatory factors, new drugs frequently launch first in the U.S. Only about 15% of new drugs are estimated to be launched first outside of the U.S.,[4] meaning that 85% of new products could be launched without the ability to calculate a benchmark IRP. Given recent rates of new drug launches in the U.S., estimating 212 new products approved over 5 years (averaging just over 42 per year),[5] we might therefore expect that 36 drugs per year would be launched without the ability to calculate benchmark IRP, effectively excluding them. Because roughly 30% of high-cost new drugs have been Part B drugs,[6] 10 or fewer new Part B drugs would likely not have prices available to calculate the GLOBE benchmark IRP. Roughly 26 or more new Part D drugs would not have prices available to calculate the GUARD IRP benchmark. This is not the only scenario[7] in which a fallback would need to be contemplated. It is not clear from the proposed rules what procedures CMS would follow in this and similar situations, and CMS should clarify the potential fallback rules. For example, CMS might consider estimating the ratio of the IRP price to the U.S. price for existing eligible products in the therapeutic class and applying that ratio to the U.S. price of the relevant product to establish a benchmark.

New drug launches pose a further risk of gaming in applying Method I. Under Method I, companies can affect the benchmark price for drugs newly launched in the U.S. that do not have established prices in comparator nations. They can delay new launches in countries with low prices for brand-

[4] Andrew W. Mulcahy, Daniel Schwam, & Susan L. Lovejoy, *International Prescription Drug Price Comparisons*, RAND (Feb. 1, 2024).

[5] Ass't Sec'y for Planning & Evaluation, *Comparing New Prescription Drug Availability and Launch Timing in the United States and Other OECD Countries* (Feb. 2024), https://aspe.hhs.gov/sites/default/files/documents/430a3e61c234f06270b04414e797ad3a/new-drug-availability-launch-timing.pdf.

[6] Gov't Accountability Office, *Medicare Part B: Expenditures for New Drugs Concentrated among a Few Drugs, and Most Were Costly for Beneficiaries* (Oct. 23, 2015), https://www.gao.gov/products/gao-16-12 (noting that 83 out of 250 drugs approved from 2006 through 2013 were Part B drugs).

[7] See also comment below, discussing the updating of the GDP/PPP figures.

name prescription drugs in favor of launching in countries with higher prices. Alternatively, they can announce high list prices and negotiate lower net prices privately. In both cases, the result would be upward pressure on the benchmark price under Method I and a compression of the differential between the U.S. and the benchmark that is supposed to represent the international comparator price, without actual substantive pricing relief in the U.S.

Relatedly, at present, CMS has proposed in both GLOBE and GUARD not to revise or update the benchmark price over time (and as a result proposes no method for doing so). Although CMS may face operational challenges in performing such updating, we believe it is important to consider revising or updating the benchmark to account for strategic behavior by manufacturers to avoid paying rebates under the models. If a manufacturer launches a drug in the United States first (or even markets the drug in some reference countries but only where the list price matches the United States list price), an analysis using the initially available data would conclude that the manufacturer owed no GLOBE/GUARD rebate. The manufacturer could then later market the drug at a lower list price in other countries, but because CMS has proposed not to revise the benchmark over time, that lower price would not be captured in CMS' analysis.

We suggest that CMS adopt for both models one of the alternative approaches to calculating the default international benchmark identified in GUARD: "updating said benchmark each performance year if a subsequent performance year's calculation resulted in a lower benchmark."[8] CMS' stated reason for not adopting this alternative at the proposed rule stage—"to ensure that data availability did not result in some GUARD Model drug's being updated and others not"—fails to account for this known concern regarding manufacturers' strategic behavior.

Relatedly, the Purchasing Power Parity (PPP) is recalculated by OECD in most years, and therefore, the benchmarks may need to be adjusted for that reason in addition to the lagged market entry circumstance described previously. The updated PPP further complicates the approaches proposed by CMS, and the authors have additional comments related to the use of PPP in a follow-on section.[9] If CMS retains its existing approaches, CMS should explain why it would be of concern for some benchmarks to be updated and others not.

Approach to selection of geographic areas

Both GLOBE and GUARD aim to test their approaches on a sample of approximately 25% of eligible Medicare beneficiaries, operationalized through selection at the Zonal Improvement Plan Code Tabulation Area (ZCTA) level. The proposed models offer highly similar justifications for adopting this ZCTA-based geographic restriction, with GLOBE (for example) noting that this restriction "fosters a stable and consistent model cohort and comparison group."[10] In other respects, however, the proposed models differ regarding alternatives considered.

GLOBE explicitly notes that CMS "considered selecting the entire country as the model geographic area"[11] but concluded that "limiting geographies would facilitate the identification of a representative comparison group."[12] But this conclusion is incomplete and does not fully account

[8] Ctrs. for Medicare & Medicaid Servs., *Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model*, 90 Fed. Reg. 60,338, 60,385 (Dec. 23, 2025) (hereinafter "*GUARD Model*").
[9] See also comment below.
[10] *GLOBE Model*, 90 Fed. Reg. at 60,262.
[11] *GLOBE Model*, 90 Fed. Reg. at 60,265.
[12] *Id.*

for the reasons for and against adopting a nationwide policy, which the agency has previously done as recently as 2020.

In 2020, CMS issued an interim final rule establishing a model for most-favored-nation (MFN) pricing in Part B.[13] CMS envisioned that the model would have a nationwide scope.[14] Although some of the 2020 model's explanations for a nationwide approach related to the role of providers within that model, some related to the role of beneficiaries, with the model stating that "a nationwide model geographic area allows all eligible beneficiaries who receive an MFN Model drug from an MFN participant where separate payment is allowed to benefit from the cost-sharing reductions under the MFN Model."[15]

In the proposed rule for GLOBE, CMS does not explain why other features of the model (such as its inclusion and exclusion of specific therapeutic classes or drugs) could not be used to establish a comparison group. In GUARD, by contrast, CMS did not appear to consider the possibility of a nationwide model at all, stating only that CMS considered "initiating the model with a greater number of geographic areas to include up to approximately 50 percent of Part D beneficiaries."[16]

Given that CMS knew how to consider the possibility of a nationwide model (as was contemplated in both the 2020 model and in GLOBE), CMS should explain why it did not consider such a model for GUARD. Particularly because both models contemplate the possibility for manufacturers and providers to attempt to shift utilization between Part B and Part D,[17] CMS must explain why the geographic alternatives considered differ between the two proposed models.

Mandatory manufacturer participation and inclusion/exclusion criteria

The proposed rules request comment on whether participation for manufacturers ought to be mandatory, as proposed. We agree with CMS' proposal to make manufacturer participation mandatory, as manufacturers are unlikely to participate voluntarily in a model that is projected to result in significant savings to the Medicare program.

More generally, we are largely in agreement with CMS' proposed inclusion/exclusion criterion for model drugs. We particularly agree with CMS' decision to include protected class drugs within the GUARD model. To the extent that CMS' decisions about which drugs to include are driven at least in part by existing deficits in care, there is evidence that the protected class rules contribute to higher overall prices[18] and that patients may have greater difficulty affording these products in particular.[19] However, it is not apparent why GUARD operationalizes the minimum spend threshold as an exclusion criterion and GLOBE operationalizes the minimum spend threshold as an inclusion criterion. It may be that standardizing approaches to inclusion/exclusion criteria could

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[13] Ctrs. for Medicare & Medicaid Servs., Most Favored Nation (MFN) Model, 85 Fed. Reg. 76,180 (Nov. 27, 2020).
[14] *Id.* at 76,188.
[15] *Id.*
[16] *GUARD Model*, 90 Fed. Reg. at 60,358.
[17] *GLOBE Model*, 90 Fed. Reg. at 60,313 (anticipating "the increased use of white-bagging" to shift utilization to Part D to avoid a GLOBE rebate); *GUARD Model*, 90 Fed. Reg. at 60,410 (anticipating "the increased use of brown-bagging" to shift utilization to Part B to avoid a GUARD rebate).
[18] Pragya Kakani, Michael Anne Kyle, Amitabh Chandra, & Luca Maini, *Medicare Part D Protected-Class Policy Is Associated With Lower Drug Rebates*, 43 HEALTH AFFAIRS 1420 (2024).
[19] Stacie B. Dusetzina et al., *Many Medicare Beneficiaries Do Not Fill High-Price Specialty Drug Prescriptions*, 41 HEALTH AFF. 487, 487 (2022).

lead to operational efficiencies for both manufacturers and CMS, and CMS should consider whether such procedural standardization may be appropriate in the final rule.

Although not formally proposed or otherwise discussed in the preamble to either proposed rule, we are aware of public reporting stating that manufacturers who have signed agreements with the Trump Administration believe that they will be exempt from inclusion in GLOBE and GUARD.[20] CMS should take the opportunity in the final GLOBE and GUARD rules to clarify that 1) there is no basis in either GLOBE or GUARD for manufacturers to make such a claim and 2) manufacturers signing such agreements will not be exempt from GLOBE and GUARD. The proposed inclusion and exclusion criteria for the models and the associated comment solicitations do not offer the signing of a voluntary agreement as a basis for model exclusion or as one of the alternatives considered, and the public thus has not had an opportunity to comment on any such policy proposal.

We raise this issue because the consequences of exclusions stemming from the signed agreements with the Administration would be quantitatively significant and would call into question CMS' ability to conduct a meaningful test, as required under 42 U.S.C. § 1315a(b)(4). Based on the limited information available publicly, we estimate that such exclusions would reduce the number of proposed GLOBE drugs by 55% to 64%.[21] Because there was no specific list of drugs published likely to meet GUARD model criteria for inclusion, we cannot provide exclusion estimates linked to deals with precision.

In addition to this significant reduction in model drugs, the potential to exclude 16 or more manufacturers from a mandatory Medicare model as a result of confidential agreements could bias the playing field against the manufacturers who were not presented with a request to sign an agreement and are therefore required to participate. The reported exemptions from the two models and the reported tariff relief for the 16 firms that have announced agreements would serve to alter competitive dynamics in the market for prescription drugs. The reported exemptions would create a relative price advantage for firms signing agreements related to all other market participants. This is potentially especially harmful to smaller/newer firms that have been the source of many new products launched in the U.S. Thus, the exemptions serve to tilt the playing field and, in so doing, penalize arguably the most innovative segment of the market.

These are just some of the concerns that we, and likely other commenters, would raise if CMS had proposed to exclude manufacturers from GLOBE and GUARD based on what has been reported on the confidential agreements with the Administration. But CMS has not proposed such a policy, and thus we have not had a meaningful opportunity to comment on any such proposal. Given the

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[20] *See, e.g.*, John Wilkerson & Elaine Chen, *Major Pharma Companies May Avoid Medicare Experiments' Forced Price Cuts*, STAT (Dec. 23, 2025), https://www.statnews.com/2025/12/23/trump-drug-pricing-deals-medicare-most-favored-nation-demos/.

[21] This calculation is based on our analysis and public reporting. Had CMS formally proposed such an exclusion, the agency would have had to perform and publicly disclose its own analysis, which we would have had the opportunity to comment on. Because CMS did not do so, we offer this brief overview of our methodology. To estimate the exclusions for GLOBE, analyzing only the drugs included in Table 4 of the GLOBE rule and removing the products manufactured by the firms that have announced agreements with the Administration results in the removal of 64% of the listed drugs. To the extent that Table 4 is illustrative rather than complete, however, we conducted a broader analysis that resulted in the removal of 55% of drugs. We have no way of knowing if the Administration has entered into agreements with other manufacturers, further underscoring limits on our ability to meaningfully comment on exclusion criteria that have not been formally proposed in the models.

number of legal, substantive, and operational details CMS would need to specify in order to exempt these manufacturers, to say nothing of offering a plausible policy reason for exempting them, because CMS did not propose or even solicit comment on such a policy in the proposed rules, it could not properly be included in any final rule. If CMS wishes to create such exemptions now or in the future, the agency must pursue an additional round of notice-and-comment rulemaking to make modifications or adjustments to GLOBE and GUARD.

Proposed severability policies

Both GLOBE and GUARD include proposed severability policies. The effect of these severability policies is to clarify that "should the proposed alternate rebate calculation payment methodology in this proposed rule be deemed invalid or unenforceable, the underlying obligation under current statute will continue."[22] We agree with CMS' proposed policies, which make clear that the inflation rebate program on which GLOBE and GUARD are based is separate from the proposed models, and that if there were to be a ruling adverse to the provisions of GLOBE and GUARD, it would not obviate CMS' continued enforcement of the IRA's Medicare Part B and D inflation rebate program and manufacturers would continue to owe rebates under the IRA program as they had previously.

CMS should, however, consider standardizing the form in which the severability policies appear and clarifying that they are meant to function in the same way. For example, although the GLOBE proposed rule states CMS' intention to create a § 513.800 including the relevant severability provision,[23] the text of § 513.800 appears to be focused on civil monetary penalties and the severability provision is instead found in § 513.1(d).[24] The text of § 513.1(d) differs slightly from the text of GLOBE's § 514.900 (creating a severability provision). We recommend that CMS either standardize the regulatory organization and text appearing in these two provisions or at least clarify that they are intended to function in the same way.

As discussed more fully in the first comment above,[25] this relates to our recommendation that CMS should finalize the incremental approach under the GLOBE model for invoicing rebates consistent with and in support of the severability policies. We strongly agree with the agency that the models are separate from the underlying IRA inflation rebate program on which they are based and the agency should make every effort to ensure that CMS can continue operations of the IRA inflation rebate program in the event there is an adverse ruling on either GLOBE or GUARD.

Measurement of International Reference Prices

Establishing a uniform approach to calculating comparable prices across national regulatory regimes, differential insurance and reimbursement processes and cost structures is highly complicated. It is notable that the CMS guidance document for establishing ASP reporting (a potentially less complicated task) runs about 80 pages.[26] CMS must develop at least an outline of the procedures CMS will follow to calculate the relevant comparable prices from the comparator

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[22] *GLOBE Model*, 90 Fed. Reg. at 60,246; *GUARD Model*, 90 Fed. Reg. at 60,407.
[23] *GLOBE Model*, 90 Fed. Reg. at 60,246.
[24] *Id.* at 60,322.
[25] See comment above.
[26] Ctrs. for Medicare & Medicaid Servs., *Medicare Part B Average Sales Price (ASP) Module Submitter User Guide Version 2.1* (Aug. 29, 2025), https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing-items/cms-10110.

nations and allow for public comment on the issue. Since the proposed rule includes no details, more complete and robust guidance on the procedures that would be followed in making prices comparable is called for so that judgments can be made about the lowest-cost product or the weighted average prices.

Consider as just one example of this complexity the rules' inclusion of the requirement that eligible drugs be comparable to international benchmark products based on active pharmaceutical ingredient (API), dosage and form of administration. These requirements make gaming of inclusion criteria very easy. That is, U.S. launches could be designed so that they fail on one dimension of the inclusion criteria, thereby excluding many products that are comparable in principle. Instead, a focus on defining a product according to its API with adjustments for comparability, like those found in the guidance for the Medicare Drug Price Negotiation Program (MDPNP), would be preferred.

CMS should expect that manufacturers choosing to report net prices from the comparator countries will report prices in ways that are advantageous to their financial circumstances. Cross-national prices are very complex. Although CMS sets out a Verification of the Submission process, given the granularity of the definition of a drug product, the reported prices will be difficult and costly, if not impossible to verify. The data sources cited by CMS are unlikely to offer complete ability to verify company and product-specific reporting of net prices. For example, SEC filings at best offer a broad approximation of net prices.[27] The decision by CMS to allow a great deal of leeway in reporting by manufacturers will likely result in reduced savings relative to a more directive approach.

Solicitation on PPP and GDP adjustments in the benchmark price process

Method I in both GLOBE and GUARD relies on publicly available comparator country price data. In establishing the benchmark, it uses data from countries with similar GDP per capita, calculates individual country prices for reference products and adjusts for PPP and GDP per capita, then chooses the lowest price as the benchmark. The adjustments to price data and calculations appear to all be implemented by CMS, but CMS should clarify that it is its intent to do so and also how it intends to operationalize those procedures. Method II calls for companies to voluntarily report net sales and volume data for relevant reference products. The companies would then make the GDP and PPP adjustments. The benchmark price under this method would be the weighted average net price across comparator countries.

Adjusting for PPP serves to control for the general cost of living across nations. It reflects affordability and not nominal prices. But note that PPP is highly correlated with GDP per capita.[28] As a result, adjusting a second time for GDP per capita is likely to "over correct" and thereby compress price differences by too much, if the disparity between U.S. and international prices does relate to policy decisions rather than affordability of comparable countries, as the President has

[27] Benedic Ippolito & Joseph Levy, *Best Practices Using SSR Health Net Drug Pricing Data*, HEALTH AFFAIRS FOREFRONT (March 10, 2022), https://www.healthaffairs.org/content/forefront/best-practices-using-ssr-health-net-drug-pricing-data.

[28] Note that the International Comparison Program conducts a large scale survey to construct PPP rates every 3-4 years, with the last one in 2021. OECD conducts more limited data collection and analyses more frequently, every 1-2 years. The rule should note which data will be relied upon by CMS.

stated.[29] The second GDP adjustment should be eliminated. So, in sum, the benchmark procedure minimizes U.S.–OECD price differences, makes the U.S. prices less exceptional, and misleadingly over-weights the role of income in explaining price differences. The Regulatory Impact Analysis (RIA) reports that the PPP and multiple GDP assessments account for a 35% reduction in potential savings, the largest factors by far. The basis for this large an adjustment is inconsistent with the introductions to the two rules.

We would also note that, since the publication of the proposed rules, the CIA has announced that the CIA World Factbook is ending.[30] Given the models' proposed reliance on that database (in some cases using the data as it existed on October 1, 2025, but in others doing so prospectively, such as for the applicable calendar quarters),[31] CMS should identify an additional data source which could be used for this purpose.

Conflicting assumptions in the RIAs and assessing claims that the models will promote more aggressive industry negotiation, lower launch prices, and shift utilization

The GLOBE and GUARD RIAs appear to conflict in their assumptions leading to different potential impacts and outcomes for each model. CMS should provide a rationale for why they made different underlying assumptions in each model when the policies they are testing should have a similar effect on the market and market participants. We want to specifically raise conflicting statements related to how manufacturers will respond during Medicare negotiations for selected drugs and statements on the use of "white-bagging" in the Part B program and "brown-bagging" in the Part D program.

With respect to the MDPNP, the GUARD RIA suggests that manufacturers involved in the model may bargain harder for drugs selected for negotiation. The mechanisms leading to that conclusion are unclear. It is unclear why a company would have left un-used bargaining leverage "on the table" prior to the new models. In fact, this conjecture is inconsistent with the positions taken by the Administration with respect to cost shifting into the private sector stemming from the IRA.

There is also a claim made that manufacturers would reduce launch prices. Given that many, if not most, new launches will not have international reference product prices at the time of launch, resulting in an incentive to boost list prices under benchmark Method I, CMS should reconsider this analysis and provide much stronger support for this claim. This matters because the RIA "score" appears to include savings from lower launch prices that appear to be unlikely given the timing and location of product launches.

Furthermore, in the GLOBE RIA the agency assumes that manufacturers participating in the MDPNP would be "less inclined to give discounts below the statutorily specified ceiling price," but that there would only be a small effect due to the ceiling established by the IRA for Part B drugs. This appears to be a different assumption regarding regulatory impacts than those made in the GUARD IRA. Because both Part B and Part D drugs selected for the negotiation program are subject to the same ceiling calculation, it is unclear what CMS is referring to when it says "ceiling

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[29] White House, *Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients* (May 12, 2025), https://www.whitehouse.gov/presidential-actions/2025/05/delivering-most-favored-nation-prescription-drug-pricing-to-american-patients/.

[30] Central Intelligence Agency, *Spotlighting the World Factbook as We Bid a Fond Farewell* (Feb. 4, 2026), https://www.cia.gov/stories/story/spotlighting-the-world-factbook-as-we-bid-a-fond-farewell/.

[31] *GLOBE Model*, 90 Fed. Reg. at 60,292.

prices specified … for Part B drugs." CMS should clarify their rationale for the difference in assumption related to the effects on the MDPNP, as well as provide stronger support for why it believes Part B drugs would be impacted differently.

The GUARD and GLOBE RIAs appear to contain conflicting statements regarding white- and brown-bagging. That is, GLOBE anticipates "the increased use of white-bagging" to shift utilization to Part D to avoid a GLOBE rebate,[32] while GUARD anticipates "the increased use of brown-bagging" to shift utilization to Part B to avoid a GUARD rebate.[33] Both assumptions are quite plausible given that the price concessions are large. But as these assumptions are somewhat in conflict, CMS should clarify the potential interaction between them. For example, since the Part D eligible classes are large in number compared to the GLOBE classes, it may be that CMS anticipates the GUARD effect to be larger and to overcome the GLOBE effect.

Conclusion

We thank CMS for the opportunity to provide comments on these proposed models and are available to discuss these issues at any time.

Sincerely,

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[32] *Id.* at 60,313.
[33] *GUARD Model*, 90 Fed. Reg. at 60,410.