Public Citizen Comments re: Proposed rules for the Global Benchmark for Efficient Drug Pricing Model (GLOBE Model) and the Guarding U.S. Medicare Against Rising Drug Costs Model (GUARD Model)

Regulationsion.gov ID: CMS-5545-P; CMS-5546-P

Public Citizen is a consumer advocacy organization with more than 1,000,000 members and supporters and a fifty-year history protecting the public's interest before federal agencies, Congress, and the courts. The Access to Medicines program advocates for access to prescription drugs in the United States and internationally. As such, we and our members have a strong interest in improving affordable and stable access to vital medications for U.S. patients.

We commend the Centers for Medicare & Medicaid Services for taking steps to address the high costs of drugs in the United States relative to other comparable countries through the Global Benchmark for Efficient Drug Pricing Model (GLOBE Model) and the Guarding U.S. Medicare Against Rising Drug Costs Model (GUARD Model).[1] The models will test alternative methods for calculating drug manufacturer rebates under the Medicare Part B and Part D inflation rebate program established by the Inflation Reduction Act of 2022. Rebates will be required when the U.S. price exceeds an international reference price benchmark, bringing U.S. prices more in line with the lower costs paid in similar countries.

While we agree it is vital to tackle the high costs of medicines, we have significant concerns about these models' potential to be successful as currently proposed. First, the design and media reports suggest most of the highest cost drugs to the Medicare program are likely to be excluded. Second, the international reference pricing arrangements described in the models contain numerous loopholes that the pharmaceutical industry will use to minimize the impact of the models. Moreover, we are concerned about CMS's own assertions that these demonstrations could weaken critical government efforts to protect Americans from high drug costs such as the Medicare Drug Price Negotiation Program.

In our comments we suggest ways that CMS could improve the model to ensure it is likely to achieve meaningful savings without unintended consequences to vital cost containment programs like the Medicare Drug Price Negotiation Program.

Ultimately Medicare and U.S. patients will be best served by focusing efforts and resources on ensuring the continued success of the Medicare Drug Price Negotiation Program by

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[1] Comparing Prescription Drugs in the U.S. and Other Countries: Prices and Availability [Internet]. Washington (DC): Office of the Assistant Secretary for Planning and Evaluation (ASPE); 2024 Jan 31. Comparing Prescription Drugs in the U.S. and Other Countries: Prices and Availability: Contractor Project Report. 2024 Feb. Available from: https://www.ncbi.nlm.nih.gov/books/NBK611301/

negotiating the lowest maximum fair price for each selected drug, as required by law. GLOBE is expected to result in $11.9 billion in federal savings from 2026 to 2032 and $6.2 billion in Medicare beneficiary out-of-pocket savings from 2026 through 2031. GUARD is estimated to reduce Medicare spending by $14.1 billion from 2028 to 2033. In comparison, the Congressional Budget Office estimated that Medicare drug price negotiations would save the program nearly $100 billion between 2026 and 2031.[2]

1. **Ensure Models Do Not Weaken, Jeopardize Medicare Drug Price Negotiation Program, IRA Inflation Rebate Program**

GLOBE and GUARD should be implemented only if they complement other Medicare efforts to lower drug costs.

CMS must ensure these models do not jeopardize the underlying inflation rebate program it waves to test GUARD and GLOBE. The Congressional Budget Office estimated that program will save Medicare $71 billion over ten years.[3] We appreciate the inclusion of the severability clauses in both models that seek to preserve that program if any part of these models is held invalid or unenforceable and stress the importance of CMS ensuring this IRA program can continue even if legal challenges arise to the CMMI models.

We are also concerned about potential impact to the Medicare Drug Price Negotiation Program. In the regulatory impact analysis for GUARD, CMS assumes that "manufacturers will negotiate more aggressively for upcoming selected drugs in the IRA's Medicare Drug Price Negotiation Program, so that the maximum fair prices would be closer to the ceiling prices specified under the IRA than assumed absent the model." For GUARD, CMMI estimates this will lead to increases in beneficiary cost-sharing and beneficiary premiums, totaling $3.6 billion in additional costs to Medicare recipients. The regulatory impact analysis for GLOBE does not mention such an effect on the Part B drugs selected for the Medicare Drug Price Negotiation program and it's not clear why one of the demonstrations would change negotiation dynamics and not the other.

Overall, it is not clear how these demonstrations would empower a company to achieve a higher maximum fair price (MFP) in the negotiation program. CMS has excluded drugs with a maximum fair price from the GUARD and GLOBE models. And CMS has significant leverage to negotiate the best possible deals in the Medicare drug price negotiation program. The factors CMS must consider by law in negotiating the MFP for selected drugs remain unchanged by the GUARD and GLOBE models as do the high penalties

[2] "Estimated Budgetary Effects of Public Law 117-169, to Provide for Reconciliation Pursuant to Title II of S. Con. Res. 14." Congressional Budget Office, September 7, 2022. https://www.cbo.gov/publication/58455.
[3] Ibid.

manufacturers face for not reaching a pricing agreement with CMS.[4] Thus, CMS can and should ensure its implementation of GLOBE and GUARD do not weaken its achieved prices through the Medicare Drug Price Negotiation Program.

2. GLOBE and GUARD Must Include Manufacturers with White House MFN Deals, New Drugs,

CMS should include drug manufacturers who have negotiated "most-favored nation" (MFN) pricing deals with the White House and newly launched drugs.

The models' current failure to account for how a GLOBE or GUARD Model rebate amount will be calculated for new drugs with no international reference pricing data, along with reports that the administration believes it has excluded certain drugmakers from these demonstrations because they have entered into separate MFN pricing deals with the Trump administration may severely constrict the number of drugs eligible for the model and thus the potential for Medicare to achieve meaningful savings.

2a. Drug Manufacturers with White House MFN Deals

Though it is never explicitly stated in the proposed rules, media reports indicate that drug companies that have agreed to voluntary "most favored nation deals with the Trump administration are exempt from the otherwise mandatory GLOBE and GUARD demos.[5] Additionally, CMS's request for applications for its GENEerating cost Reductions fOr U.S. Medicaid Model (GENEROUS), the formalized demonstration for testing these White House MFN deals, says that "CMS may, at its discretion, waive or modify the applicability of other CMMI models or Model requirements," to ensure that data from the GENEROUS Model can be accurately evaluated and not affected by potential distortions or confounding variables form overlapping participation in other models.[6] While we question whether this process meets the legal standard to exempt manufacturers from otherwise mandatory CMMI

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[4] Cubanski, Juliette. "FAQs about the Inflation Reduction Act's Medicare Drug Price Negotiation Program." KFF. January 25, 2025. https://www.kff.org/medicare/faqs-about-the-inflation-reduction-acts-medicare-drug-price-negotiation-program/?entry=table-of-contents-how-many-and-which-types-of-drugs-qualified-for-price-negotiation-for-2027.

[5] Bayer, Max. "Drugmakers with White House MFN Deals Claim Exemption from Proposed Medicare Pricing Tests." Endpoints News. December 23, 2025. https://endpoints.news/drugmakers-with-white-house-pricing-deals-may-skirt-new-medicare-demos/.

[6] "GENEROUS Model (GENErating Cost Reductions fOr U.S. Medicaid Model) Request for Applications from Applicable Manufacturers." Centers for Medicare & Medicaid Services, December 23, 2025. https://www.cms.gov/priorities/innovation/files/generous-rfa.pdf.

models, the GENEROUS language suggests CMS may envision excluding even more companies than the 16 that have already struck MFN deals with the Trump administration.

Excluding the 16 companies' products from the models would significantly negate their impact.[7] The top 10 drug companies in the world based on 2024 drugs sales would all be excluded.[8] Of the remaining 8 companies who struck MFN deals, only one doesn't crack the top 20 pharmaceutical companies for worldwide sales in 2024. Three-quarters of the 62 drugs CMS identified as potentially subject to reference pricing under the GLOBE Part B demo are made by firms with White House deals.[9] In Part D, the top 14 drugs by Medicare spending in 2023, the most recent year for which Medicare makes data available, are all sold by the 16 companies with MFN deals, potentially excluding them from GUARD.[10] Only two drugs of the top 20 drugs by spend in Medicare Part D in 2023 were made by companies that have not struck MFN deals.[11]

The estimated impacts CMS presents in the proposed rules are contingent on all manufacturers being included in the mandatory model. "If certain manufacturers were excluded due to interactions with other CMS Innovation Center models or for any other reason, the impacts from this proposed demonstration could be significantly less than described in this analysis," both rules say.

The potential for significantly reduced ability to lower drug costs to Medicare beneficiaries and taxpayers necessitates CMS does not exclude drug companies that have struck separate White House MFN deals or participate in GENEROUS. Though much is unknown about the scope and impact of these White House deals due to the confidential nature of

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[7] Lupkin, Sydney. "Trump Struck Deals with 16 Drug Companies. But They're Still Raising Prices This Year." NPR, January 16, 2026. https://www.npr.org/2026/01/16/nx-s1-5678915/trumprx-pharma-drug-price-deals-list-prices.

[8] Christel, Michael. "2025 Pharm Exec Top 50 Companies." PharmExec, June 20, 2025. https://www.pharmexec.com/view/2025-pharm-exec-top-50-companies.

[9] "The GLOBE List: 62 Products Identified By CMS As Potentially Subject To Reference Pricing Under New Model; Three-Quarters Are From Firms With White House Deals." Prevision Policy, January 2, 2026. https://www.previsionpolicy.com/the-globe-list-62-products-identified-by-cms-as-potentially-subject-to-reference-pricing-under-new-model-three-quarters-are-from-firms-with-white-house-deals.

[10] "Medicare Part D Spending by Drug, 2023." Data.CMS.Gov. Centers for Medicare & Medicaid Services, January 2, 2026. https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-d-spending-by-drug.

[11] Ibid.

them, they look likely to be less impactful than GLOBE or GUARD.[12] These White House deals focus on providing MFN pricing to Medicaid, giving Medicaid additional discounts above the current rebates it receives. But because Medicaid already typically receives the best net prices of any U.S. government health program, the benefits of international reference pricing in GENEROUS are anticipated to be modest at best.[13] In some cases, experts worry states could actually be sacrificing larger supplemental rebates they might otherwise be able to obtain by opting into MFN rebates in Medicaid.[14] Most of the drug companies impacted by these White House MFN deals failed to flag a financial impact for them in their latest financial reports, suggesting that these agreements will not have a substantial impact on the finances of drug companies this year.[15] CMS Administrator Oz has also suggested drug manufacturers came out OK under these deals.[16]

The direct-to-consumer pricing deals manufacturers struck with the Trump administration as part of these White House MFN deals also offer minimal to no benefits for Medicare beneficiaries. About 80% of Medicare beneficiaries have Part D retail prescription drug benefits and are expected to get better deals using their insurance benefits than the direct to consumer prices currently available at TrumpRx.[17] More than half of the drugs on TrumpRx have generic versions available that can be purchased at much lower prices.[18]

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[12] "Pfizer Reaches Landmark Agreement with U.S. Government to Lower Drug Costs for American Patients." Pfizer, September 30, 2025. https://www.pfizer.com/news/press-release/press-release-detail/pfizer-reaches-landmark-agreement-us-government-lower-drug.

[13] "A Comparison of Brand-Name Drug Prices Among Selected Federal Programs." Congressional Budget Office, February 18, 2021. https://www.cbo.gov/publication/56978.

[14] Park, Edwin. "A Comparison of Brand-Name Drug Prices Among Selected Federal Programs." Georgetown University McCourt School of Public Policy Center for Children and Families, November 18, 2025. https://ccf.georgetown.edu/2025/11/18/several-key-questions-about-trump-administrations-drug-pricing-deals-and-their-impact-on-medicaid-remain-unaddressed/.

[15] Merrill, Jessica. "Drug Makers Confront Headwinds In 2026, But MFN Doesn't Seem Like A Big One." Scrip, February 11, 2026. https://insights.citeline.com/scrip/drug-pricing/drug-makers-confront-headwinds-in-2026-but-mfn-doesnt-seem-like-a-big-one-YYQBO72NSNCHBE6EBPKF2GSDB4/.

[16] Sullivan, Peter. "Trump Officials Try to Make Peace with Pharma." Axios, February 18, 2026. https://www.axios.com/2026/02/18/trump-drug-prices-fda.

[17] Cubanski, Juliette. "A Current Snapshot of the Medicare Part D Prescription Drug Benefit." KFF, October 7, 2025. https://www.kff.org/medicare/a-current-snapshot-of-the-medicare-part-d-prescription-drug-benefit/.

[18] "TrumpRx Could Cost Families Thousands in Higher Drug Costs." JEC.Senate.Gov. Joint Economic Committee Minority, February 1, 2026. https://www.jec.senate.gov/public/_cache/files/ad634777-aad5-4fdd-ab11-0df48c17f8d7/jec-trump-rx-fact-sheet-final.pdf.

Other commitments made as part of the White House deals like new drug industry investment in U.S.-based manufacturing largely reflect previously made industry commitments.[19]

2b. Newly Launched Drugs

New drugs are typically the most expensive on the market and launch prices continue to rise. In the U.S., median launch prices increased from $2,115 per year in 2008 to $180,007 per year in 2021 with the proportion of drugs priced at $150,000 per year or more rising from 9% in 2008 to 2013 to 47% in 2020-2021.[20]

New drugs are often launched in the U.S. before anywhere else in the world. Between 2018 and 2022, more than half of 287 new drugs launched were marketed first in the U.S. and there was an average lag of about one year between U.S. launch and launch in other high-income Organization for Economic Cooperative and Development markets.[21] Forty-eight of the 287 drugs launched during this period were only sold in the U.S. Based on this analysis, excluding newly launched drugs from the model could mean excluding about 12.8% of U.S. drug spending.

CMS must propose a mechanism to include newly launched drugs without international reference pricing in the model. Absent such a mechanism drug manufacturers may delay launches in other countries to prevent availability of reference pricing. One possibility is for CMS to use the IRA's Medicare Drug Price Negotiation program's approach for calculating a maximum fair price. For drugs included in the model that launch in the United States before reference countries, model pricing can be updated when international pricing information becomes available.

3. Insulate Models From Pharma Gaming

3a. Adjust Method 1 and Method 2 design

CMS could take further steps to improve the model by insulating it from pharmaceutical company gaming.

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[19] Panda, Sushmita, and Aakash Babu. "Big Promises, Long Timelines – Trump'S US Pharma Investment Push." Scrip, February 18, 2026. https://insights.citeline.com/scrip/perspectives/big-promises-long-timelines-trumps-us-pharma-investment-push-YQA56HA2QJAIPBDMIW7JJHOXDY/.

[20] Rome BN, Egilman AC, Kesselheim AS. Trends in Prescription Drug Launch Prices, 2008-2021. *JAMA*. 2022;327(21):2145–2147. doi:10.1001/jama.2022.5542

[21] Mulcahy, Andrew W., Comparing New Prescription Drug Availability and Launch Timing in the United States and Other OECD Countries. Santa Monica, CA: RAND Corporation, 2024. https://www.rand.org/pubs/research_reports/RRA788-4.html.

In both models CMS proposes using two methods to calculate an international drug pricing benchmark and proposes to select as the international benchmark the price that is the greater of the two. The first method for calculating the international price benchmark involves using international drug pricing data from a set of economically similar countries with CMS ultimately selecting the lowest among a set of country-level average prices, adjusting for the reference country's specific gross domestic product (GDP) and purchasing power parity (PPP) and an additional percentage adjustment to account for the difference between the U.S, market and markets in the reference countries. In the second method, CMS will rely on manufacturers to voluntarily report data on their net prices and use an across-country average net price, also adjusted by GDP and PPP and an additional percentage adjustment to account for differences between the U.S. and the selected international comparators.

There are several problems with this process of determining an international pricing benchmark. Method 1 is likely to overestimate the prices paid in other countries as it involves using available sources of international data that, as CMS acknowledges, do not include confidential manufacturer rebates to payers and other discounts. Use of list prices also provides drug companies with the ability to minimize impact of the models. Drug companies may simply raise their list prices internationally; while also increasing their confidential discounts and rebates to ensure they take a more limited hit in the GLOBE and GUARD models. CMS's own analysis assumes that manufacturers will increase list prices in other countries in response to the models. Further, given CMS's decision to only calculate a Method 1 pricing benchmark once during the entire model period, pharmaceutical companies could strategically keep list prices higher overseas until the model prices are set and then lower them. While CMS argues that identifying the Method 1 benchmark once, protects from other drug industry gaming, such as companies raising international list prices during the model and offering greater rebates abroad, CMS could protect against this possibility by proposing to update the Model 1 benchmark only if the benchmark drops below the benchmark at the time the drug enters the model. CMS indicates it contemplated this possibility in the proposed rule but said it elected not to proceed with this due to "increased operational complexity," and concern it could interfere with manufacturers desire to voluntarily submit international new pricing data for the Method 2 benchmark.

However, the structure of the model is designed so manufacturers will only be incentivized to voluntarily submit data if they are relatively confident that their voluntary data provides them with a favorable benchmark, i.e. more than the Method 1 benchmark. And the Method 2 international benchmarks can be adjusted each year.

Overall, it is not clear what benefit Medicare and beneficiaries achieve form encouraging manufacturer submission of data via Method 2. CMS's own estimates of the impact of the models assumes that manufacturers will, as the model years go on, report their international net price data to CMS in cases where that data show higher prices than the Method 1 benchmark, limiting savings from the demonstrations. "Our estimate assumes that manufacturer reporting would reduce the total GLOBE model rebate amount by 35 percent by the end of the model test period," CMS says. In GUARD, CMS assumes that manufacturer reporting would reduce the level of total GUARD model rebates by 30 percent by the end of the model test period.

Given the limited benefits of encouraging manufacturer voluntary submission of net pricing data, it seems prudent for CMS to simply calculate the international benchmark price using only Method I, while implementing additional strategies to adjust for pharmaceutical price gaming throughout the entire length of the demonstration. To improve the potential for international reference pricing-based efforts to lower drug prices the United States should pursue agreements to promote transparency of net drug prices. The Trump administration previously supported countries sharing net pricing information through a 2019 World Health Assembly resolution on "improving the transparency of markets for medicines, vaccines, and other health products."[22]

3b. Align Inclusion Criteria with IRA Price Negotiation Program

In GLOBE, CMS proposes selecting Part B rebateable drugs with greater than $100 million in total Medicare Part B fee-for-service allowed charges during a consecutive 12-month period, using HCPCS Level II codes (J codes). In GUARD, CMS proposes using NDC-9 codes to select Part D rebateable drugs that have an application-level total gross covered drug cost above $69 million and adjusted for inflation annually.

Using HCPCS Level II codes and NDC-9 codes, means that different strengths and dosage forms of the same active moiety/active ingredient from the same holder of a new drug application (NDA) will not be lumped together.

To avoid gaming, we suggest the models use an inclusion criterion that aligns with how drugs are selected in the Medicare Prescription Drug Price Negotiation Program. In this program, CMS defines a qualifying single source drug to include all dosage forms and strengths of the drug with the same active moiety and the same holder of a NDA, inclusive of products that are marketed pursuant to different NDAs. In guidance for this program

[22] Fletcher, Elaine. "World Health Assembly Approves Milestone Resolution On Price Transparency." Health Policy Watch, May 28, 2019. https://healthpolicy-watch.news/world-health-assembly-approves-milestone-resolution-on-price-transparency/.

CMS notes this "will decrease incentives for pharmaceutical manufacturers to engage in 'product hopping,'" or shifting use of products away from those with a maximum fair price to those without a maximum fair prices based on modest or minor modifications.[23] In the GUARD and GLOBE models, following the Medicare Drug Price Negotiation Program's example would avoid manufacturers trying to shift utilization of drugs so that products do not hit the $69 million of $100 million thresholds to be included in models and should ensure more drugs are included in the demonstrations.

4. Demonstration Population: Adjust Randomization Strategy

To obtain a better estimate of how the models impact Medicare beneficiaries care, we suggest CMS consider adjusting its randomization strategy.

CMS proposes to test these models in about 25 percent of Medicare beneficiaries, by randomly selecting 25 percent of zip code tabulation areas (ZCTAs). All beneficiaries in the selected ZCTAs area would be included in the test population and the rest of the country would comprise the comparison group. Given the influence of social determinants of health on U.S. health outcomes, the demonstrations will likely offer a more accurate comparison of the models' ability to preserve or enhance the quality of care furnished to beneficiaries if people within the same ZCTA's are randomized either to the model or to the comparison group.[24]

5. GLOBE-Specific Comments

5a. Include Cell and Gene Therapy Products In GLOBE

CMS suggests it is considering excluding cell and gene therapies from the GLOBE model. Cell and gene therapies are amongst the most expensive medicines available on the market today with U.S. prices typically exceeding those in other wealthy countries and thus should not be automatically excluded.[25] If international countries are achieving lower price

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[23] Seshamani, Meena. "Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026." Centers for Medicare & Medicaid Services, June 30, 2023. https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf.

[24] Healthy People 2030, U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. Retrieved [date graphic was accessed], from https://health.gov/healthypeople/objectives-and-data/social-determinants-health

[25] Shukla V, Seoane-Vazquez E, Fawaz S, Brown LM, Rodriguez-Monguio R. The landscape of cellular and gene therapy products: Cost, approvals, and discontinuations. *Hum Gene Ther Clin Dev*. 2020;30(3):102-113 https://doi.org/10.1089/humc.2018.201

points on these treatments, Medicare and its beneficiaries would stand to benefit by including these products in the models.

For example, there are six FDA-approved chimeric antigen receptor (CAR) T-cell therapies indicated for a variety of hematological malignancies with average wholesale prices starting at nearly $400,000, price points that far exceed the median launch price for cancer drugs in the U.S. of about $155,000 per year.[26] Currently, only a fraction of eligible U.S. patients are reported to receive the treatments with cost being one of the primary reasons for access challenges.[27] For some indications CAR-Ts are seen as needing significant price reductions on the order of 50% to be deemed priced in line with their clinical benefit.[28] And even in cases where analyses have found CAR-T therapies are priced in alignment with their clinical benefit for individual patients and their particular malignancy, the total health care costs are seen as difficult for the U.S. health system to absorb.[29]

Gene therapies tend to be even higher priced than cell therapies like CAR-T, often starting at more than $1 million for a one-time treatment. A recent study estimated that average annual spending on gene therapy in the U.S. will be about $20.4 billion between 2020 through 2034 with about one-third of that being attributed to Medicare.[30] Medicare is estimated to need to increase its annual budget by up to $7.89 billion to cover this cost.[31] Even though these therapies are often used by relatively small populations, their high price point and their potential to proliferate for many more diseases as the technology advances necessitates they are included in the government's drug pricing cost containment efforts.

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[26] Edward R. Scheffer Cliff et al. High Cost of Chimeric Antigen Receptor T-Cells: Challenges and Solutions. *Am Soc Clin Oncol Educ Book* **43**, e397912(2023). DOI:10.1200/EDBK_397912

[27] Andrea P. Chung, Jason T. Shafrin, Sachin Vadgama, Kristen Hurley, Miguel-Angel Perales, Leonard C. Alsfeld, Sanjana Muthukrishnan, Anik R. Patel, Gunjan L. Shah, Richard T. Maziarz; Inequalities in CAR T-cell therapy access for US patients with relapsed/refractory DLBCL: a SEER-Medicare data analysis. *Blood Adv* 2025; 9 (18): 4727–4735. doi: https://doi.org/10.1182/bloodadvances.2024015634

[28] "Anti B-Cell Maturation Antigen CAR T-cell and Antibody Drug Conjugate Therapy for Heavily Pretreated Relapsed and Refractory Multiple Myeloma." Institute For Clinical and Economic Review, November 22, 2022. https://icer.org/wp-content/uploads/2020/10/ICER_Multiple-Myeloma_Final-Report_Unredacted_112222.pdf.

[29] "Chimeric Antigen Receptor T-Cell Therapy for BCell Cancers: Effectiveness and Value." Institute For Clinical and Economic Review, March 23, 2018. https://icer.org/wp-content/uploads/2020/10/ICER_CAR_T_Final_Evidence_Report_032318.pdf.

[30] Wong CH, Li D, Wang N, Gruber J, Lo AW, Conti RM. The estimated annual financial impact of gene therapy in the United States. Gene Ther. 2023 Nov;30(10-11):761-773. doi: 10.1038/s41434-023-00419-9. Epub 2023 Nov 8. PMID: 37935855; PMCID: PMC10678302.

[31] Ibid.

5b. Concern with Making Providers Whole

The GLOBE model is designed so that providers will not experience significant financial impact when prescribing medicines to Medicare beneficiaries who are in the GLOBE model. If an international benchmark leads to a reduced price and reduced beneficiary coinsurance, CMS is proposing to adjust the Medicare Part B payment to the provider to make up for this change. This raises questions about how CMS could move forward and try to more permanently and fully operationalize this model if successful since presumably a permanent implementation of the international reference pricing concept would not involve having to calculate the reimbursement rates a provider would receive under the old norms.

By keeping providers whole, as well as Part B's average sales price plus 6 percent payment system where Medicare pays providers the average price realized by a manufacture for its sales plus an added fee, the demonstration also by design perpetuates a fundamental flaw in the Part B drug pricing reimbursement program that incentivizes providers to use high cost drugs when less expensive alternatives are available.

6. GUARD-Specific Comments

6a. Beneficiaries Should Not Be Harmed

The GUARD demonstration offers no guaranteed benefit to Medicare beneficiaries as all savings from the model go to the government. Part D beneficiary copays, coinsurance and premiums are not directly impacted by the international benchmark price points.

And while we are skeptical of CMS's logic, the proposed rule estimates that Part D beneficiary cost-sharing and premiums will actually increase due to resulting changes in how drug companies negotiate maximum fair prices for products in the Medicare Drug Price Negotiation Program.

Beneficiaries should receive some financial benefit from using the drugs in the GUARD model, otherwise it is difficult to imagine a way that this model could possibly improve beneficiaries' health.

CMS argues that the GUARD model may address deficits in care indirectly because manufacturers may decrease launch prices for GUARD model drugs to reduce liability under the GUARD model leading to potential "cascading shifts" in Part D plan benefit design and offerings that could increase access and/or reduce cost for drugs included in the model. Similarly, CMS argues that manufacturers might respond to GUARD by reducing

list prices of these drugs to reduce their rebate liability in GUARD and this might lead to a reduction in the out-of-pocket costs paid by Part D enrollees who take these drugs.

However, it seems unlikely that these scenarios CMS proposes will materialize as companies are unlikely to lower their price points to avoid liability in a demonstration that captures only 25% of beneficiaries if it would cause them to lose more money due to the price change impacting the other 75% of beneficiaries.

Conclusion

We commend CMS for its interest in lowering the cost of drug prices in the U.S. and bringing them into closer alignment with prices charged by prescription drug corporations in other high-income countries. The high cost of prescription drugs is a barrier to patient access and improved health. In GUARD, CMS estimates international benchmarks are about 49 percent below estimated Medicare Part D prices and in GLOBE, CMS estimates international benchmarks are about 71 percent below Part B average sale prices. Americans should not be expected to pay significantly more than citizens of other comparable countries for prescription drugs.

International reference pricing can help Medicare lower drug prices. However, to ensure Medicare and its beneficiaries stand the best chance of achieving savings and health benefits from these models, changes are needed to make certain Medicare will not exclude the costliest drugs and to close loopholes the pharmaceutical industry will exploit that will reduce the savings from these models.

CMS must also make sure that these models complement, not weaken, its other efforts to reduce drug prices. The Medicare Drug Price Negotiation Program and inflation rebates have successfully reduced the prices of drugs in Medicare and are much further reaching than what these models envision. GLOBE and GUARD should only be implemented if the demonstrations will lead to net savings for Medicare and beneficiaries when impacts to these other cost containment programs are accounted. Further, GLOBE and GUARD must be structured so that the models don’t risk Medicare’s ability to continue implementing the Medicare inflation rebate program if legal challenges to the models arise.