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CMS Releases Mandatory Most-Favored Nation Pricing Models for Medicare Part B and Part D

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The Big Picture

On December 19, 2025, the Centers for Medicare & Medicaid Services (CMS) issued two proposed rules to establish two new Center for Medicare and Medicaid Innovation (CMMI) models:

- The [Global Benchmark for Efficient Drug Pricing \(GLOBE\) Model](#), a mandatory most-favored nation (MFN) pricing model for certain Medicare Part B drugs in select geographic areas; and
- The [Guarding U.S. Medicare Against Rising Drug Costs \(GUARD\) Model](#), a mandatory MFN pricing model for certain Medicare Part D drugs in select geographic areas.

Public comments on both proposed rules are due by February 23.

While necessarily different, the models take similar approaches and adopt many of the same definitions, geographic scopes, inclusions, exclusions, and benchmarks:

- **Basic Implementation of Reference Price.** Both models rely on the existing Inflation Rebate Programs for Part B and Part D drugs created under the Inflation Reduction Act (IRA) as a mechanism for manufacturers to rebate the difference between current Medicare net prices and an international benchmark price back to the Medicare program.
- **Basic Definition of Included Drugs.** Across both models, included drugs are defined with reference to eligibility for the existing Part B or Part D (as relevant) Inflation Rebate Programs, including single-source drugs and biologicals (excluding multi-source products, but potentially including authorized generics and unbranded biologics). 340B drugs are excluded from both models, as 340B drugs are already excluded from the Part B and Part D Inflation Rebate Programs.
- **Reference Pricing Calculation.** Both models share the same set of countries from which reference prices will be drawn, and both models propose two alternative methods for calculating a reference price that will be used to calculate a manufacturer's rebate

owed—one method based on the lowest of prices from publicly available pricing information across the basket of countries and one method based on manufacturer-reported, volume-weighted net pricing information across those countries. Both models incorporate a concept of “international analogs” for model drugs, intending to capture drugs in other countries that may be effectively the same as a model drug (e.g., same active ingredient) but with only minor differences (e.g., slightly different name).

- **Selection of Beneficiaries.** Both models follow broadly the same method by which beneficiaries will be assigned to the model, with Medicare beneficiaries in the model being beneficiaries in pre-identified ZIP code tabulation areas (ZCTA) that include approximately 25 percent of the Medicare population.
- **Time Frames.** The models would each be implemented for five “performance years,” with GLOBE beginning October 1, 2026 and GUARD beginning January 1, 2027.

Notable differences between the models include:

- **Beneficiary Cost Sharing.** GLOBE would reduce beneficiaries’ cost sharing for GLOBE drugs in a similar way as the existing Part B inflation rebate program (i.e., would calculate a beneficiary’s coinsurance based on the lower, post-rebate amount), while GUARD does not incorporate a method to reduce cost sharing based on GUARD rebates.
- **Differences in Drug Inclusion.**
 - Different minimum spend thresholds for exclusions: While both models use a threshold for annual Medicare drug spending to determine whether a drug is included in the model, GLOBE uses a slightly higher threshold, at \$100 million, compared to \$69 million for GUARD.
 - Scope of included therapeutic categories: CMS defines drugs included in each model by reference to U.S. Pharmacopeia (USP) categories, with GLOBE based on USP Drug Classification categories and GUARD using USP Medicare Model Guideline categories. The models include some of the same categories (specifically, the overlapping categories are antineoplastics, central nervous system drugs, metabolic bone disease agents, immunological agents, and ophthalmic agents), but GUARD includes substantially more categories than GLOBE, including all Part D protected classes.
- **Scope of Payers Covered.** GLOBE applies generally only to Part B fee-for-service (FFS) beneficiaries and not to Medicare Advantage (MA) beneficiaries (although CMS notes that reductions in Part B FFS payments may reduce MA payments), while GUARD applies to all eligible Part D beneficiaries, including both Part D and MA-PD enrollees.

Notably, and contrary to rumors that had been circulated, the models do not appear to include exemptions for participation in the [GENERating cost Reductions for U.S. Medicaid \(GENEROUS\) model](#), nor do the models explicitly reference any of the agreements entered into to date between individual pharmaceutical manufacturers and the White House. The models also do not discuss coverage of anti-obesity medications included in the voluntary [Better Approaches to Lifestyle and Nutrition for Comprehensive hEalth \(BALANCE\) Model](#), announced December 23, 2025.¹ (For more on the [GENEROUS](#) and [BALANCE](#) models, see the *Manatt on Health* analyses.)

GLOBE Model

Under the [GLOBE Model](#), manufacturers of GLOBE Model drugs would pay GLOBE Model rebates to the Medicare Trust Fund when GLOBE Model drugs are furnished to Medicare FFS beneficiaries who are in the model cohort (i.e., reside in a GLOBE Model geographic area). CMS would modify the calculation of the existing Medicare Part B Drug Inflation Rebate Program Rebate Amount using a benchmark derived from international pricing information, instead of the domestic benchmark. The benchmark would be based on the greater of either manufacturer-reported international pricing information (updated throughout the model's duration) or publicly available information for countries with a real gross domestic product (GDP) per capita that is at least 60 percent of the United States' and with a minimum real economy size of \$400 billion (with these publicly available reference prices **not** updated throughout the model). Key details of the model are described below.

Authority. Section 1115A of the Social Security Act (42 U.S.C. 1315a).

Model Timeline. The proposed model includes a seven-year test period with five performance years (October 1, 2026–September 30, 2031), during which the GLOBE Model beneficiary coinsurance and adjusted payments to providers and suppliers could apply and monitoring activities would occur. It also includes seven payment years (October 1, 2026–September 30, 2033), during which CMS would calculate, invoice, collect, and reconcile GLOBE Model rebates for each performance year.

Included Drugs. GLOBE Model drugs would include a subset of Part B rebatable drugs, namely those that meet all of the following criteria:

- (1) Are single-source drugs and sole-source biological products (i.e., not generic or biosimilar products²;
- (2) Are used to treat conditions in select USP Drug Classification categories (antigout agents, antineoplastics, blood products and modifiers, central nervous system agents,

¹ The two most prominent products that may be covered by BALANCE, tirzepatide and semaglutide, are included in a Medicare Model Guidelines (MMG) category, Blood Glucose Regulators, that is included in GUARD.

² Once a drug becomes multi-source, as of the following quarter, it is no longer included.

immunological agents, metabolic bone disease agents, or ophthalmic agents), with CMS explaining that these are the categories in which Part B spending is highest and care deficits may, therefore, be more likely due to high costs;

- (3) Have Medicare Part B FFS spending greater than \$100 million over a 12-month period, defined by Healthcare Common Procedure Coding System (HCPCS) Level II code; and
- (4) Are not excluded (see [below](#)).

CMS would identify GLOBE Model drugs and add them to the GLOBE Model Drug List that would be made available on the GLOBE Model [webpage](#). The GLOBE Model Drug List would be maintained quarterly to add and remove drugs as appropriate in accordance with the inclusion criteria.

The \$100 million threshold would be assessed over a 12-month period ending six months prior to the start of an applicable calendar quarter. However, once a product has met the \$100 million threshold over one such 12-month period, it will continue to be included in GLOBE throughout the model.

The model would generally include authorized generic drugs and unbranded biologics. The agency explains that, since these products are directly or indirectly sponsored by the original manufacturer, these products would be included in GLOBE in the same way they are included in the Part B Inflation Rebate Program.

Excluded Drugs. The GLOBE Model would exclude:

- A Part B rebatable drug for which a maximum fair price (MFP) under the Medicare Drug Price Negotiation Program is in effect (the earliest date for which is January 1, 2028—15 months after the model is proposed to start);
- A Part B rebatable drug during the quarters prior to the first calendar quarter for which CMS calculates a Part B inflation rebate (generally, the first two quarters a product is marketed); and
- 340B units, as well as units of discarded drugs.

CMS seeks comments regarding whether cell and gene therapies (which have complex supply chains) and plasma-derived products (which are more likely to experience shortages) should also be excluded.

If there is no international pricing data available for a product—e.g., if the product is not sold outside the U.S.—then CMS states that it will not calculate or impose a GLOBE rebate in a given quarter.

Model Participants. The proposed GLOBE Model would require mandatory participation for all manufacturers of rebatable Part B drugs that are included in GLOBE (see [Included](#) and [Excluded](#) Drugs). A manufacturer that has no sales of a GLOBE drug would not be a participant in GLOBE, and participation in other federal programs does not impact participation in GLOBE.

Beneficiaries would not be model participants but could see reduced cost sharing as a result of the model. The model would not affect payment to providers and suppliers that furnish GLOBE Model drugs, who similarly would not be considered model participants. However, when the GLOBE Model reduces beneficiary coinsurance to units of GLOBE Model drugs furnished to beneficiaries in the GLOBE Model beneficiary cohort, the provider or supplier would reduce the amount of coinsurance charged to the beneficiary, and the portion of the Medicare Part B allowed amount that would be payable by Medicare Part B would be adjusted upwards.

In the required regulatory impact analysis for small entities, CMS states that it considered several approaches to limiting impact on small manufacturers, including phased compliance dates or a higher spending threshold for a drug to be included. A higher threshold for inclusion in the model, the agency explains, would remove more small manufacturers from the model (a \$186 million threshold, as opposed to a \$100 million threshold, would exclude all manufacturers classified as small businesses, defined by the Small Business Administration as having fewer than 1,300 employees). The agency seeks comments on these options and “other factors that could be considered to mitigate the impact on small manufacturers.”

Geographic Selection. CMS proposes a randomized design in which the GLOBE Model geographic reach would be determined by selection of geographic areas—specifically, ZCTA, a geographic area used by the Census—where approximately 25 percent of Medicare Part B FFS beneficiaries have an address of record within CMS’s Medicare Beneficiary Database. Model test geographic areas would be randomly selected to balance the Medicare beneficiary population and Medicare expenditures nationwide.

Included Beneficiaries. GLOBE Model rebates will be due for units of GLOBE Model drugs furnished to Medicare beneficiaries who are:

- Enrolled in Medicare Part B;
- Have Traditional Medicare Part B as their primary payer (i.e., not be enrolled in an MA plan, Section 1876 cost plan, or Section 1833 health care prepayment plan, and not have other group health coverage, such as employer coverage, that is a primary payer); and
- Have an address of record within the GLOBE Model geographic areas.

CMS would identify the eligible beneficiaries code no later than 30 days before the model start date. CMS would then maintain and periodically update the GLOBE Model Eligible Beneficiary

List, not more than weekly, using available Medicare program administrative information as determined by CMS. A beneficiary in an included area who becomes eligible under the coverage criteria (e.g., loses employer coverage and Part B becomes their primary payer) during the course of the model would then become part of the model upon CMS' next update of the beneficiary list, but a beneficiary moving into a GLOBE geographic area during the course of the model would not.

Pricing Benchmark Countries. CMS would identify reference countries based on the following criteria:

- Members of the Organization for Economic Cooperation and Development (OECD);
- A real GDP per capita that is at least 60 percent of the U.S. real GDP per capita based on purchasing power parity (PPP); and
- An annual real GDP that is at least \$400 billion (as measured in U.S. dollars) based on PPP.

Based on these criteria, CMS identified the following potential set of reference countries: Australia, Austria, Belgium, Canada, Czech Republic, Denmark, France, Germany, Ireland, Israel, Italy, Japan, the Netherlands, Norway, South Korea, Spain, Sweden, Switzerland, and the United Kingdom.

CMS would identify countries meeting these requirements based on the CIA World Factbook as of October 1, 2025; the agency considered adjusting the list over time to account for GDP changes but rejected the idea because it may introduce more uncertainty. The adjustments to the reference price based on other countries' GDP vs. U.S. GDP for pricing, however, will be updated with countries' changing GDPs over time.

Benchmark Price Calculation. The agency will use as the "GLOBE Model applicable international benchmark" the greater of the prices from one of two benchmark calculations, with Method I being a CMS-calculated benchmark price based on the lowest of prices from the GLOBE countries, or Method II, in which manufacturer-submitted data will be used to create a volume-weighted benchmark price from across GLOBE countries.

Importantly, the Method I benchmark price would not change once it is set within the model, while Method II would involve ongoing reporting by manufacturers to update the benchmark price. As the agency explains, "for each Part B rebatable drug that becomes a GLOBE Model drug during the performance period, CMS would identify the per unit Method I GLOBE Model benchmark for the first applicable calendar quarter for which the drug is a GLOBE Model drug and that benchmark would remain in place for the remaining applicable calendar quarters until the end of the model." The agency explains that it considered adjusting the Method I

benchmark for inflation, but it was not clear how to do so given differing inflation rates across countries and different countries being used to determine the Method I benchmark.

The two methods would be implemented as follows:

- *Method I: CMS-sourced data.* Method I would use what CMS finds to be the lowest estimated GDP-adjusted country-level price for the product among GLOBE comparator countries.
 - Data Sources of International Drug Pricing Data. The agency states that it expects to rely on existing pricing databases, specifically discussing IQVIA MIDAS, GlobalData Pharmaceutical Prices (POLI), and Eversana NAVLIN, to produce international pricing data. The agency expects that these databases “would likely provide adequate information [...] for the vast majority of proposed GLOBE Model drugs,” and plans only to use databases that can provide data within 90 days of the end of a given calendar quarter. The agency solicits comment on whether there are other sources of available data that could be used.
 - The agency acknowledges that “[c]onfidential manufacturer rebates would not likely be accounted for within these available data sources” and, therefore, these “existing sources for international drug sales data may overstate actual prices realized by manufacturers.”
 - CMS proposes a detailed hierarchy of how it will use sources in cases where a given source does not provide data on all of the reference countries, essentially relying on a source that has the greatest number of countries available, and then using wholesaler data (i.e., ex-manufacturer or list price data) as a last resort. CMS plans to use pricing data in U.S. dollars but seeks comment on whether it could also use local currency prices.
 - To avoid potential pricing errors or mistaken identification of drugs, the agency proposes to remove any country-level average prices for a drug where the price at the dosage form and strength level is less than 5 percent of the U.S. price (i.e., is more than 95 percent lower than the U.S. price). Although, as mentioned above, the GLOBE benchmark would not be revised over time, the agency notes that it considered an option where CMS would revise the benchmark quarterly, only if the new benchmark was lower than the existing Method I benchmark, but stated that it did not pursue this option because of “unnecessary complexity” and “the potential for confounding events” during the model’s test.
- *Method II: “Updated International Benchmark” (manufacturer-submitted data).* Under Method II, CMS would rely on a volume-weighted, GDP-adjusted average net

international price across GLOBE countries submitted by a manufacturer in compliance with CMS instructions and methodology.

- Manufacturers would execute a data agreement with CMS obligating them to report this information throughout the whole test to prevent “manufacturers choosing to report only if the Method II benchmark would be higher than the Method I benchmark.” However, CMS states that manufacturers could choose to report data for “one or more” GLOBE drugs, suggesting that manufacturers may be permitted to submit Method II data for some GLOBE drugs but not others. Manufacturers would submit the Method II data within 30 days after the end of each calendar quarter. CMS notes that, in some cases, multiple manufacturers (e.g., repackagers) may submit data for a given drug. Manufacturers may submit data on “one or more” GLOBE drugs, suggesting that a manufacturer may be able to submit Method II data for one GLOBE drug, but not other GLOBE drugs the manufacturer sells.
- CMS states that they expect the pricing under Method II to be somewhat higher than Method I, because it is a volume-weighted price across GLOBE countries, rather than the lowest-price method used under Method I, but expects that Method II pricing, as net prices, would incorporate more rebates and discounts offered in GLOBE countries than Method I.
- CMS proposes two potential methods for manufacturers to submit this cross-country pricing data:
 - A “streamlined” approach, in which a manufacturer would report certain data for every reference country where at least one international product was sold during the relevant performance year—including gross sales and net sales (i.e., exclusive of price concessions such as rebates, chargebacks, etc.) and sales volume—all at the net price level (i.e., separate reporting for each “net price” within a country, where the number of “net price levels” will depend on the number of different prices offered to purchasers in the reference country). The manufacturer would also report the average net-to-gross ratio, a country-level volume-weighted average net price for the product, the exchange rate for currency conversion, the GDP (PPP) adjuster, and the across-country average price in U.S. dollars.
 - A “limited” approach, under which manufacturers would submit data that is more aggregated in nature for each country. Specifically, manufacturers would submit *total* gross sales, net sales, and sales volume (i.e., not broken down by net price level), as well as average net-

to-gross ratio, the exchange rate for currency conversion, the country-level average price, and the GDP (PPP) adjuster.

- In converting local currency pricing to U.S. dollars, CMS suggest several sources of currency conversion rates (including the World Bank Atlas, required to be used under GUARD) but would simply require that manufacturers use a consistent source across products and years.
- For manufacturer pricing information submitted to implement Method II, CMS states that it will “not disclose manufacturer-submitted international net pricing information in a form which discloses the identity of a specific manufacturer and their international net pricing and sales data except as CMS determines to be necessary to carry out” the model.
- *Adjustment of the Applicable International Benchmark.*
 - In calculating the reference price used to determine the rebate amount, CMS would multiply the benchmark by an “applicable threshold percentage” on top of the calculated benchmark price, depending on the method used to calculate the benchmark (multiplying a Method I benchmark by 102 percent and a Method II benchmark by 105 percent).
 - CMS notes that the difference in percentage is intended to account for the fact that Method I prices likely understate price concessions given by manufacturers and, therefore, overestimate prices, while the agency wishes to provide an incentive for manufacturers to provide Method II pricing information, which more fully reflects discounts offered.

Role of International Analogs. In the pricing benchmark calculation, pricing will be included for GLOBE drugs and “international analogs,” defined as “a non-U.S. analog whose scientific or nonproprietary name, dosage form, and route of administration (if applicable) align with a GLOBE Model drug” (but not including international biosimilar or generic products as defined by the relevant foreign authority). In other words, international analogues are drugs that are essentially the same products as a Part B GLOBE product, at the level of HCPCS Level II detail, with differences between a Part B product and an international analog potentially including, for instance, slightly different names or different descriptions of the same packaging, such as single-use vs. disposable vial. For both Method I and Method II calculations, CMS will perform data checks (explained in detail in the proposed model) to ensure that international analogs do in fact align with the GLOBE drug.

CMS discusses concerns manufacturers may have around situations in which a manufacturer selling a drug in the U.S. does not have responsibility for its sales or pricing outside of the U.S. but does not provide any exceptions or special provisions for such situations. The agency

explains that it “considered excluding manufacturers where the U.S. manufacturer may not be the same entity that is responsible for sales in other countries,” though also explained that it is “concerned about the possibility of manufacturers transferring responsibilities to other entities to avoid model participation.” The agency also considered an “application process” for manufacturers that do not have responsibility for sales outside of the U.S. to seek exclusions, but is concerned that this type of exclusion “might potentially be too broad.”

Rebate Calculation. Under the GLOBE Model, manufacturers would be required to pay a rebate based on the difference between an international price benchmark and the existing Part B payment amount, to the extent that this rebate exceeds the rebate owed under the existing Part B inflation rebate program. For each GLOBE Model drug and calendar quarter, CMS would calculate a per-unit GLOBE rebate equal to the greater of:

- (1) The difference between the drug’s standard average sales price (ASP)-based (or otherwise determined) payment amount, inclusive of the typical Part B add-on payment (6 percent typically) and a GDP-adjusted international benchmark price derived from comparable countries; or
- (2) The difference between the ASP-based (or otherwise determined) payment amount, including the add-on payment and the inflation-adjusted payment amount under current Part B inflation rebate rules, with negative values set to zero.

The portion of this amount that exceeds the standard Part B inflation rebate is treated as an incremental GLOBE rebate, ensuring manufacturers never pay less than they would under existing law while avoiding double counting. CMS then applies that per-unit rebate only to the drugs actually given to GLOBE-eligible beneficiaries, multiplies it by the number of doses used, and invoices the manufacturer for the total rebate amount for a given quarter, with adjustments if a drug is in shortage or has a severe supply chain disruption. Specifically, in the event that a product is in shortage or experiences a severe supply chain disruption, as defined by the existing Part B inflation rebate program, CMS would reduce the GLOBE rebate amount by the same percentages that it would reduce inflation rebates.

Reports of Rebate Amounts, Reconciliation, Suggestion of Error, and Payments. The agency proposes and requests comment on two potential ways in which it could implement the GLOBE rebate as a practical matter, including the reporting of rebate amounts, reconciliation, suggestion of error, and rebate payments, with both using existing standards from the Part B Inflation Rebate Program but in different ways:

- A “combined approach,” in which the agency would delay the current Part B Drug Inflation Rebate Program invoicing for all manufacturers by up to two months and would provide a combined invoice to all manufacturers that would contain their combined rebate (i.e., inflation rebate and GLOBE incremental rebate), although this invoice would still inform manufacturers about the breakdown of the inflation rebate vs.

the GLOBE incremental rebate. Under the combined approach, manufacturers would have a single opportunity to raise any potential errors in both the inflation rebate and GLOBE incremental rebate calculation.

- An “incremental approach,” in which the agency would provide manufacturers with a “preliminary” report regarding their expected GLOBE rebate owed approximately one month after the current Medicare Part B Drug Inflation Rebate Program reports, and then provide the actual GLOBE incremental rebate invoice approximately two months after the inflation rebate invoice.

Processes for suggestion of error and paying rebates under either approach would use the deadlines and processes for the existing inflation rebates.

Beneficiary Cost Sharing. CMS would calculate beneficiary coinsurance using essentially the same methodology under GLOBE that it uses under the Part B statutory Inflation Rebate Program—instead of a beneficiary’s cost sharing being calculated based on the inflation-adjusted payment amount under Part B, it would be calculated based on the GLOBE benchmark amount.

CMS estimates the cost sharing reductions would amount to between \$100 and \$300 million per year in reduced coinsurance for FFS beneficiaries (Table 14 of the proposed rule).

Provider Payments. The model does not affect the basic structure of Part B drug payments to providers under the “buy and bill” model. CMS would adjust the Medicare payment to the provider or supplier for a separately payable GLOBE Model drug claim in the same manner as under the Medicare Part B Drug Inflation Rebate Program—in other words, adjust the Medicare payment upward to account for the lower cost sharing paid.

Enforcement of Manufacturer Payment of Rebate. CMS proposes to use Civil Monetary Penalties (CMPs) under its general CMP authority in Section 1128 of the Social Security Act. CMPs may be up to 125 percent of incremental GLOBE rebate amount for failure to pay GLOBE rebates, and the agency may also impose CMPs for false data, false representations, fraud, or potential False Claims Act issues.

Quality and Monitoring Strategy. CMS outlines, at a high level, how it will assess quality improvements and reactions to the model, specifically citing drug utilization, prescribing levels, out-of-pocket (OOP) costs, changes in site of service, and downstream health care resource utilization. The agency states that it will consider using surveys to assess impacts on beneficiaries but plans to use existing surveys and data sources where possible. The agency notes that it does not expect changes in prescribing of higher cost drugs, because the add-on payment for prescribers (typically ASP plus six percent) would remain the same between GLOBE and non-GLOBE drugs.

Beneficiary Access Protections. To monitor and protect beneficiary access to GLOBE drugs, CMS plans to implement a reporting system for beneficiaries or providers to report instances where a drug has become harder to obtain. The agency states that it considered the possibility of a beneficiary opt-out provision but decided not to include such an option to improve the rigor of the demonstration and avoid selection bias.

Impact on Other Programs. CMS suggests that the model's impact on other CMS programs will primarily be indirect. Because the pricing reductions would be implemented through rebates, it would not affect the calculation of Medicaid Best Price or Average Manufacturer Price (AMP), although the agency notes that it could indirectly affect Best Price or AMP if manufacturers lower list prices to avoid paying rebates or other payers seek lower prices based on "awareness" of GLOBE.

Because units submitted with a 340B modifier would be excluded from GLOBE, CMS also does not expect direct effects on 340B ceiling prices, although any effects on Best Price and AMP from decreases in price manufacturers pursue because of the model could lower the 340B ceiling price.

For MA, because lower net spending on Part B drugs would lower overall Part B FFS spending, the per capita rates paid by CMS to MA plans would drop, with CMS estimating approximately a \$10 billion reduction in payments to MA plans over the course of the model. The agency suggests that this reduction in MA payments "may reduce supplemental benefits and increase MA beneficiary out-of-pocket costs."

Included Waivers. CMS will waive the Medicare Part B inflation rebate calculation provisions, the timing requirements for manufacturer rebate reports issued by CMS, and beneficiary cost sharing requirements.

Model Savings Estimate. CMS estimates that the GLOBE Model would result in overall savings of \$11.9 billion in Medicare Part B net spending during the seven-year model—\$8.4 billion in Part B FFS savings and \$7.5 billion in MA savings (produced because lower FFS Part B payments would reduce the payment made to MA plans), minus \$4 billion in offsetting premium impacts. Additionally, the agency estimates \$1 billion in Medicaid savings through reductions in premiums and cost sharing paid by Medicaid on behalf of dual eligibles covered by the model.

CMS Assumptions Regarding Stakeholder Impact and Response. Regarding potential reactions to the model from providers, CMS expects some increase in the use of white bagging (dispensing of a drug through Part D for providers to administer), because this would allow a manufacturer to avoid a GLOBE rebate. (The agency does not discuss that a manufacturer may owe a rebate for such a drug under the GUARD model.)

The agency states that its modeling suggests a slight increase in utilization of drugs (1.2 percent on total gross Part B drug spending in the first year for GLOBE beneficiaries) due to decreased cost sharing for beneficiaries.

CMS projects several potential reactions from drug manufacturers. The agency expects that manufacturers negotiating MFPs under the IRA would be “less inclined to give discounts below the statutorily specified ceiling price,” but does not quantify this difference or explain how manufacturers would accomplish this. CMS also expects that manufacturers may wish to “change their pricing to become eligible” for MFP negotiation sooner, although it states that this would likely be difficult to achieve. CMS also expects manufacturers may try to incentivize utilization of 340B units of GLOBE drugs, but states that most GLOBE drugs “have a relatively low proportion of 340B units currently” and the degree of savings from 340B pricing versus GLOBE pricing is currently “unknown.” Because MA reimbursement for drugs would not be directly affected by GLOBE, CMS also expects that drug manufacturers may wish to encourage beneficiaries to enroll in MA plans rather than Medicare FFS.

The agency also expects that manufacturers may attempt to raise list prices across all payers to counteract revenue losses from GLOBE, especially for products with relatively higher utilization outside of Medicare, and solicits comment on the “probability and magnitude” of this response.

While conducting a required analysis of the model’s impact on small rural hospitals, CMS states that it does not expect the model to have a significant impact on providers, except for the previously-described impact on white-bagging.

GUARD Model

The [GUARD Model](#) will be a new mandatory CMMI model to test whether changing how Part D inflationary rebates are calculated can reduce costs for the Medicare program while preserving or enhancing quality of care. Under the model, manufacturers of specified drugs would be required to pay a rebate back to the Medicare program to the extent the Medicare net price for their product is greater than the GUARD Model applicable international benchmark, as in the GLOBE Model. Similar to the GLOBE model, the GUARD model would be operated on a limited geographic basis, with approximately 25 percent of Medicare beneficiaries assigned to the model based on a random sample of ZIP code areas.

Authority. Section 1115A of the Social Security Act (42 USC 1315a).

Model Timeline. CMS proposes a seven-year test period consisting of a five-year performance period for the model (January 1, 2027–December 31, 2031) and a seven-year payment period for the model (January 1, 2027–December 31, 2033), during which CMS will calculate, invoice, collect, and reconcile the GUARD Model rebates for a performance year, unless the model is terminated sooner. CMS notes that this time horizon would allow the agency to observe the

short-, intermediate-, and long-term impact of the GUARD Model, such as manufacturer and other stakeholder responses and changes in cost sharing for beneficiaries.

Included Drugs. The GUARD Model will test a subset of Part D rebatable drugs that are included in the existing Part D Inflation Rebate Program, and which meet the following criteria (which contain some overlap but some differences with GLOBE):

- (1) Are sole-source drugs or sole-source biological products.³
- (2) Are used to treat conditions in specific therapeutic categories selected by CMS, including all Medicare Part D Protected Classes, using the most recent USP Medicare Model Guidelines to identify the categories, and based on CMS's determination that beneficiaries using these drugs have conditions for which deficits in care exist, and that these drugs account for a meaningful share of Part D spending.
 - a. Relative to GLOBE, the GUARD Model includes a broader scope of therapeutic categories:
 - i. Analgesics; anticonvulsants; antidepressants; antimigraine agents; antineoplastics; antipsychotics; antivirals; bipolar agents; blood glucose regulators; cardiovascular agents; central nervous system agents; gastrointestinal agents; genetic or enzyme or protein director replacement, modifiers, or treatment; immunological agents; metabolic bone disease agents; ophthalmic agents; and respiratory tract/pulmonary agents.
- (3) Have Part D application-level total gross covered prescription drug costs above a minimum spend threshold of \$69 million (increased by Consumer Price Index for All Urban Consumers for future performance years).⁴
 - a. Notably, this is lower than GLOBE's \$100 million threshold.
- (4) Are not excluded (see [below](#)).

Once CMS has identified the drug or biological product's category, it will remain in the category for the entire GUARD Model performance period. Moreover, any change to CMS's definition of "Medicare Protected Classes" would be carried over and apply to the GUARD Model.

³ If a sole-source drug or biological product becomes multi-source at any point during the performance year, it will only be subject to the GUARD Model for the period of the performance year during which it was sole-source.

⁴ CMS defines "application-level total gross covered prescription drug costs" as the sum of total gross covered prescription drug costs from Medicare Part D PDE data for all rebatable Part D drugs belonging to the same Food and Drug Administration application. CMS states that it is using "application-level" costs to address any risk of manufacturer "gaming."

Identification of drugs and biological products will be at the NDC-9 level, which CMS will use to identify the drugs in the Medicare Part D Prescription Drug Event (PDE) data.

Once a GUARD Model drug has exceeded the GUARD Model minimum spend threshold for a model performance year, it would no longer qualify for the minimum spend threshold moving forward, even if minimum spend in a future performance year is below the threshold (i.e., CMS will not check a GUARD Model drug's minimum spend annually).

Similar to the approach taken in GLOBE, CMS notes that since both authorized generics and unbranded biological products are, directly or indirectly, sponsored by the original manufacturer, if their NDC-9 is included in the Part D Inflation Rebate Program, these products will also be included in the GUARD Model.

Excluded Drugs. Like in the GLOBE Model, the GUARD Model will exclude:

- Generics and biosimilar biological products;
- Drugs subject to a negotiated MFP during the price applicability period⁵; and
- Drug units for which payment is subject to an agreement under 340B.

Model Participants. The GUARD Model would require mandatory participation of all manufacturers of Part D rebatable drugs that qualify as GUARD Model drugs. These manufacturers would be the only “participants” in the model.

Geographic Selection. Like GLOBE, the proposed rule authorizes CMS to randomly select geographic areas to test the GUARD Model to balance the Part D population and Medicare expenditures nationwide. CMS will select geographic areas based on ZCTAs; however, unlike GLOBE, the geographic areas selected must include 25 percent of the general population (CMS notes that “a simple random selection of 25 percent of ZCTAs would result in the selection of approximately 25 percent of Medicare Part D enrollees representing approximately 25 percent of Medicare spending”).

Included Beneficiaries. A GUARD Model beneficiary would be a Part D enrollee (standalone Part D plan or MA-PD plan) who resides within a GUARD Model geographic area, meaning that the beneficiary's home address is within the set of ZIP Codes linked to ZCTAs selected for the GUARD Model geographic areas (CMS notes that this is intended to limit beneficiary incentives to switch pharmacies). Relevant exclusions include individuals residing in U.S. territories, those who do not have Medicare as their primary payer, and those enrolled in an employer group waiver plan.

⁵ Should a drug no longer have a negotiated MFP in effect, but is still covered under Medicare, to the extent it continues to meet GUARD Model inclusion requirements, the drug will be included in the GUARD Model.

Included beneficiaries will be the “initial model cohort.” The model’s “comparison group” will consist of Part D beneficiaries who do not have an address of record within the GUARD Model geographic areas selected for inclusion in the model.

Thirty calendar days before the start of the model, CMS will identify a beneficiary as a GUARD Model beneficiary. GUARD Model beneficiaries would be aligned to the model until the model ends, or the beneficiary is no longer enrolled in Part D (even if the beneficiary experiences an address change to an area that is not a GUARD Model geographic area).

CMS will periodically (but no more than weekly) identify additional eligible GUARD Model beneficiaries. This “updated cohort” will consist of Part D beneficiaries that meet the criteria but have not yet been included in the model cohort, and that have not been in the comparison group.

Pricing Benchmark Countries. The model requires the selection of reference countries according to the same criteria as GLOBE—the country, using data available as of October 1, 2025 in the CIA World Factbook, must:

- Be included as an OECD country;
- Have a minimum of 60 percent of the U.S. PPP GDP; and
- Have a minimum \$400 billion PPP GDP.

The reference countries for the GUARD Model according to these criteria are the same as the GLOBE Model (see [above](#)).

Benchmark Price Calculation. Like in the GLOBE Model, the GUARD Model will adopt as the “GUARD Model applicable international benchmark” ***the greater of*** the prices from the following two benchmark calculations, unless there is only a Default International Benchmark under Method I (in which case it would become the GUARD Model applicable international benchmark). Importantly, the Method I benchmark price will not change once it is established within the model for a particular model drug, whereas Method II would involve ongoing reporting by manufacturers to update the benchmark price.

- *Method I: “Default International Benchmark” (CMS-sourced data).* Under Method I, CMS would select the lowest **country-level average price** among the set of average prices for each reference country, adjusted by the country-specific GDP based on PPP, where an international product that is part of a GUARD Model drug’s set of international analogs is sold. “Country-level average price” would mean the average or weighted-average price for the international products sold in the specific reference country that are part of a GUARD Model drug’s set of international analogs, where the unit is the lowest dispensable amount of the GUARD Model drug expressed in terms of National Council for Prescription Drug Program units.

- Data Sources for International Drug Pricing Data. As in GLOBE, CMS proposes to use existing data sources as available to the agency that contain international drug pricing data for purposes of determining the GUARD Model default international benchmark under Method I, including coordinated prices and volume data, coordinated sales and volume data, or only prices. CMS notes that existing sources for international drug sales data may differ from net prices realized by manufacturers but believes that these sources are nonetheless adequate for purposes of identifying country-level average prices.
 - As in GLOBE, CMS specifically cites three data sources of international drug pricing data for purposes of the GUARD Model, including 1) IQVIA MIDAS, 2) POLI data, and 3) Eversana NAVLIN's Price & Access database.
 - CMS acknowledges, however, that it is possible other data sources may be utilized for the determination of the GUARD Model default international benchmark.
 - CMS proposes certain criteria that such data sources must meet in order to be used in the GUARD Model, including using a standardized approach based on country-specific regulatory approval pathways that, at a minimum, distinguishes international generic and international biosimilar biological products, as well as a requirement that the data source(s) limit the lag inherent in data to no more than 90 calendar days from the end of the period for which drug pricing data is compiled to the time that the relevant organization makes data updates available to users of the data source.
 - CMS also proposes a hierarchy framework that the agency will use to determine which data sources to use for a specific GUARD Model drug's set of international analogs, which slightly differs from the approach taken in the GLOBE Model.
 - Under the GUARD Model, the highest level in the hierarchy will be a data source with coordinated *sales* and volume data for the set of international analogs in the highest number of reference countries, followed by a data source with coordinated *prices* and volume data in the highest number of reference countries.
 - In cases where multiple data sources are all equal in the above-described hierarchy, CMS proposes to select a single data source based on "an assessment of the relative reliability and generalizability of the data from each available data source."

- As under the GLOBE Model, CMS will determine a GUARD Model default international benchmark just once in the performance period for the relevant model drug, ***meaning that the GUARD Model default international benchmark would not be revised over time with more recent international pricing data.***
- Notably, CMS considered but is not proposing to adopt an exclusion of country-level average prices that are less than five percent of the performance year Medicare net price (GLOBE does include such proposal), finding that including all available data increases accuracy and precision.
- ***Method II: “Updated International Benchmark” (manufacturer-submitted data).*** As in the GLOBE Model, as an alternative to Method I, CMS will permit manufacturers to submit international drug “net pricing” data for the set of reference countries where international products that are part of a GUARD Model drug’s set of international analogs are sold, including the ***across-country average net price.***
 - Manufacturers would execute a data agreement with CMS for every performance year.
 - Under this Method II, CMS will use these submissions to determine the alternative GUARD Model “updated international benchmark.” The updated international benchmark for a GUARD Model drug will be the across-country average net price, which is a volume-weighted average across all reference countries where an international product that is part of the set of international analogs is sold, adjusted by the reference country’s specific GDP (PPP) adjuster. Like the GLOBE model, it appears that a manufacturer has discretion to submit data on “one or more” model drugs—i.e., is not required to submit Method II data on all of its GUARD drugs just because it submits data on one or more.
 - Under this alternative approach, each manufacturer submission is only used by CMS for a specific corresponding performance year—i.e., any subsequent performance year would need a separate submission.
 - 90 calendar days prior to each submission, the manufacturer is required to execute a new data agreement with CMS that establishes the terms, conditions, and requirements related to the international drug pricing data to be reported.
 - As for the actual submission, the manufacturer must include data that corresponds to the same timeframe as the performance year for which it will be used.
 - Manufacturers must submit this data within 180 calendar days of the end of the performance year.

- As under GLOBE, CMS proposes two options for manufacturers who elect to submit international drug net pricing data under Method II:
 - A “streamlined” option under which manufacturers would be required to submit data for every reference country where at least one international product was sold during the relevant performance year—including gross sales and net sales (i.e., exclusive of price concessions), and sales volume—all at the net price level (i.e., separate reporting for each “net price” within a country, where the number of “net price levels” will depend on the number of different price offered to purchasers in the reference country). The manufacturer would also report average net-to-gross ratio, a country-level volume-weighted average net price for the product, the exchange rate for currency conversion, the GDP (PPP) adjuster, and the across-country average price in U.S. dollars.
 - A “limited” option, under which manufacturers would submit data that is more aggregated in nature for each country. Specifically, manufacturers would submit *total* gross sales, net sales, and sales volume (i.e., not broken down by net price level), as well as average net-to-gross ratio, the exchange rate for currency conversion, the country-level average price, and the GDP PPP adjuster.
- For purposes of converting local-current pricing to U.S. dollars, CMS states that the exchange rate will come from the World Bank Atlas.
- CMS notes it will issue supplementary guidance to manufacturers with information regarding these submissions, including the data elements, how they must be submitted, and guidelines to facilitate identification of the international products that are part of the set of international analogs for the corresponding GUARD Model drug.
- In the case where a GUARD Model drug has a GUARD Model updated international benchmark for a performance year but CMS does not receive an applicable submission for the next performance year, CMS proposes to utilize the default international benchmark (Method I) for the next performance year and any subsequent performance years where there is no applicable submission.
- For manufacturer pricing information, CMS proposes to maintain confidentiality of information submitted to the extent permitted by law and in accordance with applicable privacy and security requirements. CMS also proposes that the data

submission process would occur through Health Plan Management System (which is currently used for the Manufacturer Discount Program and the Medicare Drug Price Negotiation program reporting), or another existing CMS data system would be adapted for this purpose.

- *Adjustment of the Applicable International Benchmark.*
 - Like the GLOBE model, when the GUARD Model applicable international benchmark is based on the GUARD Model Method I default international benchmark, CMS will apply an adjustment factor of 102 percent and, if the applicable international benchmark is based on the Method II updated international benchmark, CMS will apply an adjustment factor of 105 percent.
 - CMS notes that these adjustments are intended to further account for potential differences between the U.S. markets and reference country markets (in addition to GDP PPP adjustments already included). Moreover, CMS notes that the higher adjustment for the updated international benchmark is intended to incentivize manufacturers to submit their own international net pricing data under the updated international benchmark approach.

Role of International Analogs. As under the GLOBE Model, in securing international drug pricing data for a specific GUARD Model drug, CMS will look to that drug's set of "international analogs" defined as an "international product" that is aligned across the drug's identifying characteristics, which include active ingredient(s), route of administration, dosage form, and strength. According to CMS, this approach allows for adjustments that do not materially modify the nature of the drug but account for country-specific differences, such as differences due to language, units of measurement, labeling standards, or differences in dosage form or strength.

- CMS notes that it considered only requesting data for the set of international analogs that correspond to a GUARD Model drug that are sold directly by the manufacturer and not by any other subsidiary or company in the reference countries, as well as an option where manufacturers would only submit the data for the set of international analogs that they directly sell in the reference countries. *However, CMS states that it believes manufacturers have relationships with subsidiaries, wholesalers, and other businesses involved in selling the set of international analogs in the reference countries and can obtain the data that is requested under this option.* CMS solicits feedback on this issue.
- However, CMS does propose to exclude any international products identified in the selected data source as being an international generic or international biosimilar biological product according to the reference country's regulatory framework.

- In other words, if the international product has sales in multiple reference countries, the data for the reference countries where it is classified in the data source as an international generic or an international biosimilar biological product based on the own-country's regulatory system would be excluded.

Rebate Calculation. Manufacturers of GUARD Model drugs would be required to make a rebate payment if the Medicare net price (wholesale acquisition cost minus manufacturer direct and indirect remuneration and discounts paid under the Manufacturer Discount Program) *is greater than the GUARD Model's applicable international benchmark*, calculated on a per unit basis for the total number of units dispensed under Part D during the performance year (the "per unit Guard Model rebate amount").

- When the per unit GUARD Model rebate amount exceeds the performance year per unit Part D inflation rebate amount,⁶ CMS will waive the Part D inflation rebate amount that is established pursuant to statute to operationalize rebates under the GUARD Model.
- When CMS waives the Part D inflation rebate amount, and instead applies the GUARD Model rebate amount, the GUARD Model rebate amount for a performance year will be invoiced to manufacturers in two stages:
 - CMS will invoice the Part D inflation rebate amounts otherwise owed pursuant to the Part D Inflation Rebate Program; and
 - CMS will subsequently reconcile the amounts invoiced via the Part D Inflation Rebate Program against the GUARD Model rebate amount via an additional invoice that is specific to the GUARD Model (rebate invoice process described in more detail below).
 - The amount reflected in the model-specific invoice would be the "Total Incremental Guard Model rebate amount."
 - This amount is the product of the incremental per unit GUARD rebate amount and the total units dispensed during the performance year for the GUARD Model drug to GUARD Model beneficiaries.

⁶ While the per unit GUARD Model rebate amount is calculated on a calendar year basis, the per unit Part D inflation rebate amount is calculated on a fiscal year basis. As such, CMS is proposing to calculate *the performance year* per unit Part D inflation rebate amount by computing the weighted sum of the per unit Part D inflation rebate amount for the first applicable period that overlaps with the first three quarters of the performance year and the per unit Part D inflation rebate amount for the second applicable period that overlaps with the last quarter of same performance year.

- The “incremental per unit GUARD rebate amount” is equal to the difference between a) the per unit GUARD rebate amount and b) the performance year per unit Part D inflation rebate amount (both described above).
- CMS will reduce the Total Incremental GUARD Model rebate owed for a drug that is currently in shortage at any point during a performance year.
- Rebate funds would be deposited into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.

Reports of Rebate Amounts, Reconciliation, Suggestion of Error, and Payments.

- *Preliminary GUARD Model Rebate Report.* CMS will provide each manufacturer of a GUARD Model drug with the preliminary Total Incremental GUARD Model rebate amount through a “Preliminary GUARD Model Rebate Report” **at least one month prior** to the issuance of the GUARD Model Rebate Report described below (per CMS, for Performance Year 1, this preliminary report would be sent to manufacturers no later than August 2029).
 - This preliminary report is intended to provide manufacturers an opportunity to review the report for mathematical errors that could be corrected before official invoicing (i.e., a manufacturer’s opportunity for “suggestion of error”).
 - Manufacturers will have ten calendar days after receipt of the Preliminary GUARD Model Rebate Report to make such “suggestions of error” to CMS.
 - This suggestion of error process would be limited to **mathematical steps** involved in determining the total GUARD Model rebate amount and Total Incremental Guard Model rebate amount.
 - CMS notes that it is not providing an administrative dispute resolution process in this context.
- *GUARD Model Rebate Report.* CMS will then invoice the Total Incremental GUARD Model rebate amount to the manufacturer through the “GUARD Model Rebate Report” no later than 22 months after the end of each performance year.
 - Manufacturers will be required to pay the Total Incremental GUARD Model rebate amount within 30 calendar days from the date of receipt of the GUARD Model Rebate Report.

- Manufacturers would submit GUARD Model rebate payments using the online portal used for the Part D Inflation Rebate Program (i.e., the Manufacturer Payment Portal).
- *Reconciliation of the Total Incremental GUARD Model Rebate Amount.*
 - CMS will also use a reconciliation process for each performance year, by which the agency recalculates the GUARD Model rebate amount for each performance year at regular intervals.
 - CMS will send manufacturers reconciliation reports reflecting the difference, if any, between the rebate amount due as specified in the GUARD Model Rebate Report and the reconciled Total Incremental GUARD Model rebate amount (where the reconciled amount reflects updates in the underlying data identified since the prior rebate report) as follows:
 - No later than 12 months after receipt of the GUARD Model Rebate Report for the relevant performance year.
 - No later than 36 months after receipt of the GUARD Model Rebate Report for the relevant performance year.
 - CMS will issue *preliminary* reconciliation reports in both instances, 60 days prior to the issuance of each reconciliation report, to allow manufacturers to review and provide “suggestions of error” to CMS. Manufacturers must make such suggestions of error within ten calendar days after date of receipt of the preliminary reconciliation report.
 - CMS also proposes a separate reconciliation process in cases where CMS identifies either agency error (up to five years after receipt of GUARD Model Rebate Report) or manufacturer misreporting (at any time).
 - Manufacturers are required to pay the reconciled Total Incremental GUARD Model Rebate amount (if any) within 30 calendar days from date of receipt of the reconciliation report.
 - CMS notes that reconciliation reports may result in a refund being owed to a manufacturer. CMS would initiate the process to issue such refund 60 calendar days from the date of receipt of the reconciliation report.

Note that CMS has proposed only one method and schedule for providing rebate reports and invoices under GUARD, as opposed to GLOBE, in which it has proposed two options for comment.

Enforcement of Manufacturer Payment of Rebate. Consistent with the Part D Drug Inflation Rebate Program, CMS will impose Civil Monetary Penalties for manufacturer failure to timely pay the Total Incremental GUARD Model rebate amount outlined in each report. The CMP would be equal to 125 percent of the rebate amount owed for each GUARD Model drug for each performance year. The CMP would be calculated based on the outstanding Total Incremental GUARD Model rebate amount due at the payment deadline. CMS also states that, in certain cases of manufacturer noncompliance, it may refer the manufacturer to Department of Justice, the Treasury, and/or the Department of Health and Human Services' Office of Inspector General for further review and investigation.

CMS will also use existing appeal procedures for CMPs for manufacturers to appeal a CMP imposed under the GUARD Model. However, the scope of such appeals will be limited to 1) CMS determinations relating to whether payment of the Total Incremental GUARD Model rebate amount was made by the payment deadline and 2) the calculation of the CMP amount.

Quality and Monitoring Strategy. As part of the demonstration, CMS will monitor and evaluate the impact of the GUARD Model on quality of care, including by examining, at least annually or more frequently, multiple domains of quality, such as beneficiary OOP costs, enrollment trends, drug utilization, health care utilization, access to GUARD Model drugs, patient experience, and other quality measures.

Beneficiary Access Protections. As in GLOBE, in the GUARD Model CMS plans to monitor and protect beneficiary access to GUARD drugs, including a complaint reporting system for beneficiaries to submit complaints, including if a particular drug has become harder to source or obtain after implementation of the GUARD Model.

Impact on Other Programs. CMS acknowledges that the GUARD Model may affect the Part D plan sponsor market and seeks comments on any potential impact of the model, particularly for the standalone Part D plan market, which CMS notes has undergone increased pressure following the IRA's Part D Redesign.

Included Waivers. CMS will waive the Medicare Part D inflation rebate calculation provisions and the timing requirements for manufacturer rebate reports issued.

Model Savings Estimate. CMS estimates that the GUARD Model would result in overall savings of \$14.1 billion during the seven-year model.

CMS Assumptions Regarding Stakeholder Impact and Response. In reaching its overall model savings estimate, CMS made certain assumptions regarding manufacturer behavior and response to the GUARD Model. For example, in the regulatory impact analysis, CMS notes that it "anticipate[s] that there will be some collaboration between manufacturers and providers to incentivize the increased use of brown-bagging, where drug utilization would be shifted to the office or facility setting and would be reimbursed under the Part B benefit, allowing the

manufacturer to avoid owing a GUARD Model rebate amount for those units.” CMS lowered its estimated savings to account for this potential response.

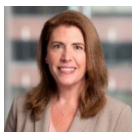
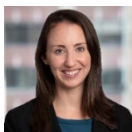
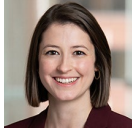
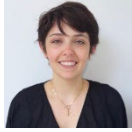
With respect to impact on beneficiaries, CMS initially states that the model will not directly impact Part D enrollees’ OOP costs for drugs subject to the model, but also states that the model may have downstream effects that will benefit Part D enrollees, including manufacturers reducing launch and list prices for drugs in the model, which could lead to lower OOP costs for enrollees.

However, in the portion of the proposed rule’s regulatory impact analysis evaluating impact of the Model on Part D enrollees, CMS makes certain assumptions with respect to manufacturer behavior in response to the GUARD Model, which lead CMS to estimate that the GUARD Model will *increase* Part D beneficiary costs (e.g., cost sharing and premiums). Specifically, CMS assumes that, in response to the GUARD Model, certain manufacturers will negotiate more aggressively for upcoming selected drugs under the IRA, which will result in a higher MFP for those drugs than would be the case absent the GUARD Model. According to CMS, because a higher MFP for those selected drugs would lead to higher point of sale prices, Part D beneficiaries will experience higher cost sharing as a result of the Model. Moreover, a higher MFP would also impact beneficiary premiums after the end of the IRA’s premium stabilization provisions. In all, CMS estimates that the GUARD Model will *increase* beneficiary costs for a total beneficiary impact of \$3.6 billion over the course of the performance period (2028-2033).

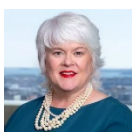
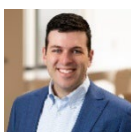
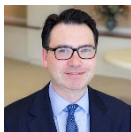
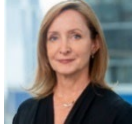
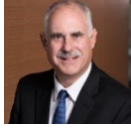
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Public comments on both proposed rules are due by February 23.

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