DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 513

[CMS–5545–P]

RIN 0938–AV66

Global Benchmark for Efficient Drug Pricing (GLOBE) Model

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule proposes to implement the Global Benchmark for Efficient Drug Pricing Model (''GLOBE Model''), a new Medicare payment model under section 1115A of the Social Security Act (the Act). The GLOBE Model would test whether a payment model that uses an alternative method for calculating Part B inflation rebate amounts for certain separately payable Part B drugs and biologicals products reduces costs for Medicare fee-for-service (FFS) beneficiaries and the Medicare program while preserving quality of care.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by February 23, 2026.

ADDRESSES: In commenting, please refer to file code CMS–5545–P.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–5545–P, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–5545–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Vinod Mitta, (667) 290–8712 or *GLOBEmodel@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments. We encourage commenters to include supporting facts, research, and evidence in their comments. When doing so, commenters are encouraged to provide citations to the published materials referenced, including active hyperlinks. Likewise, commenters who reference materials which have not been published are encouraged to upload relevant data collection instruments, data sets, and detailed findings as a part of their comment. Providing such citations and documentation will assist us in analyzing the comments.

Plain Language Summary: In accordance with 5 U.S.C. 553(b)(4), a plain language summary of this rule may be found at *https://www.regulations.gov/.*

I. Executive Summary and Background

A. Executive Summary

1. Purpose

The purpose of this proposed rule is to propose the implementation and testing of a new mandatory model under the authority of the Centers for Medicare & Medicaid Services (CMS) Center for Medicare and Medicaid Innovation (CMMI) (Innovation Center). Section 1115A of the Social Security Act (the Act) authorizes the Innovation Center to test innovative payment and service delivery models expected to reduce Medicare, Medicaid, and Children's Health Insurance Program (CHIP) expenditures while preserving or enhancing the quality of care furnished to the beneficiaries of such programs.

2. Summary of Major Provisions

a. Proposed GLOBE Model Drugs

The proposed Global Benchmark for Efficient Drug Pricing Model (''GLOBE Model'') would focus on a set of Part B rebatable drugs that are single source drugs and sole source biological products that are furnished to a cohort of beneficiaries in the traditional Medicare program. The set of included drugs, as proposed in section II.B. of this proposed rule, would include certain Part B rebatable drugs as identified in 42 CFR 427.101 for the purpose of the Medicare Part B Drug Inflation Rebate Program and that meet the proposed definition of GLOBE Model drugs in proposed 42 CFR 513.130. Drug selection (and removal, if applicable) for the model test would be determined by CMS based on the eligibility criteria and would not be subject to appeal.

b. Proposed Defined Population and Intervention

The proposed cohort of beneficiaries is described in section II.C. of this proposed rule. This cohort would be identified from approximately 25 percent of beneficiaries who are enrolled in traditional Medicare Part B and meet certain criteria (as determined by CMS as set forth in proposed 42 CFR 513.120). These beneficiaries must have traditional Medicare Part B as their primary payer, as defined by a beneficiary being enrolled in Medicare Part B fee-for-service (FFS), and must not be enrolled in a Medicare Advantage plan, section 1876 cost plan,[1] or section 1833 healthcare prepayment plan.[2] Beneficiaries must not have other group health coverage that is a primary payer (such as employer-sponsored health insurance). Finally, beneficiaries must be identified by CMS for inclusion in the model (based on the beneficiary's address of record at a certain point in time being within the GLOBE Model geographic areas) and must not be identified by CMS for inclusion in the comparison group or otherwise not eligible for inclusion. Medicare beneficiaries who are in the selected cohort, or ''GLOBE Model beneficiaries,'' would not be model participants[3] but would benefit from reduced coinsurance, as applicable, when they receive a GLOBE Model drug as described in section II.G.7. of this

[1] As established in section 1876 of the Act (42 U.S.C. 1395mm).

[2] As established in section 1833 of the Act (42 U.S.C. 1395l).

[3] As proposed in section II.E. of this proposed rule, manufacturers of GLOBE Model drugs would be model participants.

proposed rule. When a GLOBE Model beneficiary receives a GLOBE Model drug on a date of service where they are identified as a GLOBE Model beneficiary, separately payable claim lines for that service would be included in the calculation of GLOBE Model billing units as described in section II.G.4. of this proposed rule. Beneficiary selection for the model cohort and comparison group (and removal, if applicable) would be solely determined by CMS and would not be subject to appeal. Providers and suppliers who furnish GLOBE Model drugs to Medicare FFS beneficiaries who are in the model cohort would not be model participants and would continue to buy and bill for GLOBE Model drugs as usual and receive separate payment under Medicare Part B (if applicable). These providers and suppliers include, but may not be limited to, hospital outpatient departments, physician practices, ambulatory surgical centers, pharmacies enrolled as durable medical equipment (DME) suppliers. When the GLOBE Model reduced beneficiary coinsurance applies to units of GLOBE Model drugs furnished to Medicare Part B FFS beneficiaries who are included 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. For example, if the Medicare Part B allowed amount under the GLOBE Model is $100 and the GLOBE Model beneficiary coinsurance percentage is reduced to 10 percent (instead of the usual 20 percent), the Medicare Part B program payment to the provider or supplier would be adjusted upward and would be $90 (instead of the usual $80) and the beneficiary coinsurance financial responsibility would be $10.

c. Proposed Manufacturer Participation

The proposed GLOBE Model would require mandatory participation for all manufacturers (as defined in 42 CFR 427.20) of Part B rebatable drugs that are also GLOBE Model drugs (as identified in proposed 42 CFR 513.130 and discussed in section II.B. of this proposed rule). When Part B rebatable drugs subject to the GLOBE Model are furnished to Medicare FFS beneficiaries who are in the model cohort, manufacturers that are GLOBE Model participants would pay GLOBE Model rebates to the Medicare Part B account in the Federal Supplementary Medical Insurance Trust Fund if the amount specified in section 1847A(i)(3)(A)(ii)(I) of the Act for the GLOBE Model drug exceeds a benchmark amount that would be based on available international drug pricing information (as described in section II.G. of this proposed rule), which would not be less than any rebates owed under the Medicare Part B Drug Inflation Rebate Program. The total GLOBE Model rebate amount would only apply to certain units of the GLOBE Model drugs (as identified in proposed 42 CFR 513.520) and would be solely determined by CMS and would not be subject to appeal. Manufacturers would have the opportunity to submit a Suggestion of Error if the manufacturer believes that there is a mathematical error or errors to be corrected.

d. Model Purpose

The intent of the proposed GLOBE Model is to test an innovative payment model that modifies the Part B inflation rebate amount for GLOBE Model drugs using international drug pricing information to identify a benchmark that reflects prices paid in a set of economically comparable countries (as discussed in section II.G.1.e. of this proposed rule), which CMS expects would reduce program expenditures for Medicare Part B while preserving or enhancing beneficiaries' quality of care. As described in section II.G.2. of this proposed rule, CMS proposes that the model test would include two approaches for identifying a benchmark amount for the modified rebate calculation—using differently sourced international drug pricing information and different calculations—and the model evaluation would assess the impacts of testing these different approaches for identifying a benchmark amount for the modified rebate calculation. One approach, described in section II.G.2.a. of this proposed rule (Method I), would use existing international drug pricing information to identify a benchmark based on an estimation of the lowest international price among the set of economically comparable countries, which may be tied to pricing data that represent list, invoice, ex-manufacturer sales, other prices, or a combination of such prices as available in commercially-available data sources. The other approach, described in section II.G.2.b. of this proposed rule (Method II), would use voluntary manufacturer-submitted international drug net pricing data to estimate a benchmark based on an average international price among the set of economically comparable countries, which would reflect net prices realized by a manufacturer.

In this proposed rule, we propose to test the GLOBE Model in a manner that captures all applicable billing units for all separately payable Medicare Part B FFS claims for GLOBE Model drugs that are furnished to Medicare Part B FFS beneficiaries who are in the model cohort (on the date of service) and that are paid under the GLOBE Model for dates of service during a performance year and for which the GLOBE Model beneficiary coinsurance and adjusted payments to providers and suppliers could apply. For purposes of calculating the total GLOBE Model rebate amount, applicable billing units would be identified by CMS several months after the end of a calendar quarter (as described in section II.G. of this proposed rule) and additional time is necessary for calculations of rebate amounts and creating invoices. This means that GLOBE Model test processes for claims processing, data collection, invoicing, payment of GLOBE Model rebates, and reconciliation would occur concurrently with and continue after the end of a performance year and subsequent years after the last performance year.

e. Proposed Model Performance Period

The proposed GLOBE Model would have a 7-year test period that includes 5 performance years, beginning October 1, 2026, and ending September 30, 2031, during which the GLOBE Model beneficiary coinsurance and adjusted payments to providers and suppliers could apply and monitoring activities would occur, and 7 payment years, beginning October 1, 2026, and ending September 30, 2033, during which CMS would calculate, invoice, collect, and reconcile the GLOBE Model rebates for a performance year. The model evaluation would encompass the 7-year test period.

f. Proposed Model Waivers

We believe it would be necessary to waive certain requirements of title XVIII of the Act and related program requirements codified in regulations solely for purposes of carrying out the testing of the GLOBE Model under section 1115A(b) of the Act. Specifically, as further described in section II.O. of this proposed rule, we propose to waive provisions in section 1847A(i), 1833(a), and 1833(t) of the Act to the extent necessary to permit testing of an alternative rebate calculation for certain units of GLOBE Model drugs and collect GLOBE Model rebate amounts. We propose to issue waivers using the waiver authority under section 1115A(d)(1) of the Act. Each of the proposed waivers is discussed in detail in section II.O. of this proposed rule.

We propose to codify the requirements of the GLOBE Model at 42 CFR part 513. We propose at § 513.800 that should any provision of the proposed part 513 be held invalid or unenforceable by its terms, or as applied to any person or circumstance, such provisions would be severable from the remainder of part 513 and the invalidity or unenforceability would not affect the remainder of the provisions of part 513. For example, should the proposed alternate rebate calculation payment methodology in this proposed rule be deemed invalid or unenforceable, the underlying obligation under current statute will continue. We seek comment on our proposed severability policies.

3. Summary of Costs and Benefits

In section IV. of this proposed rule, we set forth a detailed analysis of the regulatory and Federalism impacts that the proposed GLOBE Model would have on affected entities and beneficiaries. As detailed in section II.A. of this proposed rule, this proposed rule would establish a 7-year GLOBE Model alternative payment test for certain separately payable Medicare Part B rebatable drugs furnished in the outpatient setting to Medicare FFS beneficiaries in the model cohort and that are paid under the GLOBE Model. Tables 13, 14, and 15 in section IV.D. of this proposed rule display the estimated overall impact of the proposed GLOBE Model on the Medicare and Medicaid programs.

We estimate that the GLOBE Model would result in overall savings of $11.9 billion in Medicare Part B net spending during the 7-year model, inclusive of $8.4 billion in Medicare Part B FFS, 7.5 billion in Medicare Advantage (MA) savings, and $4 billion in premium offset impacts. In this estimate, we assume manufacturer behavioral changes and beneficiary utilization changes, as described in section IV. of this proposed rule. We estimate savings for the MA program of $7.5 billion due to the way CMS calculates MA rates using Medicare FFS claims, which would include claims paid under the GLOBE Model beginning with rate setting for 2028, and savings for the Medicaid program of around $1.0 billion, of which roughly $0.7 billion would be federal savings and roughly $0.3 billion would be state savings.[4] When annualized over the 7-year period, we estimate that the GLOBE Model would result in overall cost savings in Medicare Part B FFS net spending of approximately $2.3 billion at both the 3 and 7 percent rates of discount.

B. Background

A 2024 report from the Office of the Assistant Secretary for Planning and Evaluation (ASPE) revealed that U.S. prices for U.S. originator drugs were 422 percent higher than other countries.[5] [6] A number of studies have also demonstrated observable differences in pricing dynamics of single source [7] versus multi-source,[8] where multi-source drugs and biological products typically have higher price concessions and manufacturer discounts than single source drugs and sole source [9] [10] [11] biologics.

Recent CMS analysis of claims data for 2024 shows that total Medicare spending is at $70.71 billion, with more than two-thirds ($46.38 billion) of this spend being attributed to Medicare Part B rebatable drugs. Research has shown Medicare Part B drug spending is also concentrated among a small number of drugs. In 2021, the top 20 drugs accounted for over half of total Medicare Part B FFS drug spending, with the top 10 representing 40 percent.[12] Notably, all 20 drugs were biological products.

To discourage drug manufacturers from increasing drug prices faster than the rate of inflation and to improve access to affordable treatments for Medicare beneficiaries, the Inflation Reduction Act of 2022 created the Medicare Part B Drug Inflation Rebate Program. If drug manufacturers raise prices for certain drugs faster than the rate of inflation for a calendar quarter beginning with the first quarter of 2023, manufacturers must pay a rebate to the Medicare Part B account in the Federal Supplementary Medical Insurance Trust Fund and Medicare lowers beneficiary coinsurance amounts for applicable drugs accordingly.

Medicare Part B FFS drug spending [13] has grown by 85.8 percent ($18.7 billion) [14] from 2014 to 2021 with the standard monthly Medicare Part B premium for beneficiaries increasing by 41.5 percent ($104.90 [15] to $148.50 [16]). Based on the increasing Medicare Part B FFS and beneficiary drug spending, we propose to test a model that reduces Medicare Part B FFS drug spending and beneficiary coinsurance amounts using international drug pricing information as a benchmark to test an alternative Part B inflation rebate amount calculation for certain single source drugs and sole source biological products that would reduce Medicare program expenditures while preserving or enhancing quality of care.

The pace of growth in drug prices varies across disease categories. A report by the Healthcare Distribution Alliance (HDA) Research Foundation, showed that drugs classified in immunology, oncology, rheumatology, endocrinology and ophthalmology are among the top 20 therapeutic classes based on spending or prescriptions volume in the United States and that most of these categories have shown notable growth

[4] *Note:* Totals do not add up due to rounding. See section IV. of this proposed rule for the Regulatory Impact Analysis.

[5] This study reports unadjusted ratios, meaning they have not been adjusted to account for GDP per capita. Available at: *https://aspe.hhs.gov/sites/default/files/documents/f96a072f8f82f3ba546abd52bfcaeb57/aspe-cover-idr-pricing-availability.pdf.*

[6] U.S. originator drugs are the original biological products and drugs developed and licensed or approved via section 351(a) of the Public Health Services Act or submitted under section 505(b) and approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). U.S. originator drugs are also sometimes called brand name drugs, reference listed drug, or reference products.

[7] Single source drugs and biological products in this sentence refers to drugs without generic competition (drugs approved under section 505(j) of the FD&C Act) and biological products without biosimilar competition (biological products licensed under 351(k) of the Public Health Service Act).

[8] Multi-source refers to drugs and biological product with generic (drug approved under section 505(j) of the FD&C Act) or biosimilar competition (biological products licensed under 351(k) of the Public Health Service Act).

[9] Jofre-Bonet, Mireia, et al. ''The Price Effects of Biosimilars in the United States.'' *Value in health: the journal of the International Society for Pharmacoeconomics and Outcomes Research* vol. 28,5 (2025): 742–750. doi: 10.1016/j.jval.2025.02.008.

[10] Changes in the List Prices of Prescription Drugs, 2017 to 2023, Office of the Assistant Secretary for Planning and Evaluation (October 6, 2023). Available at: *https://aspe.hhs.gov/sites/default/files/documents/e24f630a33f0a0585337c65745904487/aspe-drug-price-tracking-brief.pdf.*

[11] San-Juan-Rodriguez, A, et al. Trends in List Prices, Net Prices, and Discounts for Originator Biologics Facing Biosimilar Competition. *JAMA Netw Open*. 2019;2(12): e1917379. doi:10.1001/jamanetworkopen.2019.17379.

[12] Medicare Part B Drug Pricing, Office of the Assistant Secretary for Planning and Evaluation (June 9, 2023).

Available at: *https://aspe.hhs.gov/sites/default/files/documents/fb7f647e32d57ce4672320b61a0a1443/aspe-medicare-part-b-drug-pricing.pdf.*

[13] Measured by drug allowed charges.

[14] Medicare Part B Drug Pricing, Office of the Assistant Secretary for Planning and Evaluation (June 9, 2023).

Available at: *https://aspe.hhs.gov/sites/default/files/documents/fb7f647e32d57ce4672320b61a0a1443/aspe-medicare-part-b-drug-pricing.pdf.*

[15] CMS announces major savings for Medicare beneficiaries. Available at: *https://www.cms.gov/newsroom/press-releases/cms-announces-major-savings-medicare-beneficiaries.*

[16] 2021 Medicare Parts A & B Premiums and Deductibles. Available at: *https://www.cms.gov/newsroom/fact-sheets/2021-medicare-parts-b-premiums-and-deductibles.*

between 2023 and 2024.[17] This trend is also observed in Medicare Part B FFS drugs, where these five therapeutic classes represent at least $24 billion in Medicare Part B FFS allowed charges in 2024.[18] [19] [20]

Increasingly high drug costs limit access to care and treatment which in turn results in complications that can lead to worse health outcomes and premature death. This results in increased medical spending to treat patients' conditions and potentially avoidable expenditures for all payers, including CMS.[21] Results from recent surveys revealed that many Americans, including Medicare beneficiaries, face significant financial burden of care that results in skipping or rationing medication due to cost.[22] A survey conducted in June 2025 showed that one quarter of adults reported not filling their prescription in 2024 because of cost; among those who had taken a prescription, one in three stated they did not fill at least one prescription because of the cost.[23] Financial toxicity, or the negative impact that the monetary burden of medical care can have on patients' well-being, fiscal security, and overall health,[24] can be most pronounced among the elderly population and among patients where the cost of treatment is high and with low income. One in four adults taking prescriptions report difficulty affording their medication, including 40 percent of those with household income of less than $40,000 per year.[25] A separate survey conducted concluded that about 4 in 10 older adults with Medicare reported problems accessing healthcare because of its costs, and that 14 percent of Medicare beneficiaries stated they skipped taking or sometimes did not even fill their prescription because of the expense.[26] Studies show that Medicare patients with cancer and certain chronic conditions are more likely to report cost-related medication non-adherence (that is, not taking medications as prescribed or indicated by a physician due to cost).[27] [28] [29]

Studies have also shown that the impacts on access to care due to costs can be significant. A literature review concluded that annual costs of medication non-adherence are up to $290 billion, that 10 percent of hospitalizations in adults are attributed to medication non-adherence, with the typical non-adherent patient requiring three extra visits per year leading to $2,000 in increased treatment costs per year.[30] This paper also found that cancer patients experience more than double the cost variation compared to other disease groups. Further, a 2020 report estimated that up to 112,000 seniors could die prematurely because drug prices are so high that they cannot afford their medication, and that Medicare could be spending $17.7 billion annually on avoidable medical spending because of complications associated with cost-related medication non-adherence.[31]

1. Medicare Part B Drug Benefit

a. Medicare Payment for Separately Payable Under Medicare Part B Drugs

The majority of drugs covered under Medicare Part B generally fall into three categories: drugs furnished incident to a physicians' service which are not usually self-administered by the patient (section 1861(s)(2)(A) and (B) of the Act), drugs administered via a covered item of durable medical equipment (DME) (section 1861(s)(6) of the Act), and drugs specified by statute (for example, vaccines (section 1861(s)(10)(A) and (B) of the Act), oral cancer drugs (section 1861(s)(2)(Q) of the Act), oral antiemetics (section 1861(s)(2)(T) of the Act), and immunosuppressive therapy (section 1861(s)(2)(J) of the Act)).

Many drugs payable under Medicare Part B are administered via injection or infusion in a physician office, a Hospital Outpatient Department (HOPD), and certain other outpatient settings, such as ambulatory surgery centers (ASCs), and, when Medicare allows separate payment for these drugs, the payment limit is typically based on the methodology described in section 1847A of the Act. Payment for these drugs does not include payment for administration; payment for drug administration services is made in accordance with the applicable payment policy for the setting in which the drug was furnished, such as the Physician Fee Schedule (PFS), the Hospital Outpatient Prospective Payment System (OPPS), or the Ambulatory Surgical Center Payment System. Medicare Part B also allows separate payment for drugs in less common situations such as osteoporosis drugs furnished by a home health agency, and when a beneficiary does not have benefits available under the Medicare Part A program.

The payment methodology described in section 1847A of the Act is generally based on the volume-weighted average sales price (ASP) for all National Drug Codes (NDCs) that are assigned to a Healthcare Common Procedure Coding System (HCPCS) Level II code for the drug plus an add-on percentage. For most HCPCS Level II codes, the add-on percentage is 6 percent except during the initial sales period when ASP is not yet available, for certain qualifying

[17] HDA Research Foundation. HDA 96th Edition HDA Factbook. The Facts, Figures, and Trends in Healthcare (2025–2026). Available at: *https://www.hda.org/publications/.*

[18] CMS. Medicare Utilization for Medicare Part B FFS. Available at: *https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-fee-for-service-parts-a-b/medicare-utilization-part-b.*

[19] Dickson, S.R., and James, K.E. Treatments Associated with Manufacturer Payments to Ophthalmologists. *JAMA Health Forum,* 2023, 4 (9): e232951. doi:10.1001/jamahealthforum.2023.2951.

[20] Desai S., Sekimitsu, S., Rossin, E.J., Zebardast, N. Trends in Anti-Vascular Endothelial Growth Factor Original Medicare Part B Claims in the United States, 2014–2019. *Ophthalmic Epidemio,* 2024, 31(5): 468–477. doi: 10.1080/09286586.2024.2310854.

[21] Nekui F., Galbraith A.A., Briesacher B.A., Zhang F., Soumerai S.B., Ross-Degnan D., Gurwitz J.H., Madden J.M. *Cost-related Medication Nonadherence and Its Risk Factors Among Medicare Beneficiaries.* Medical Care. 2021;59(1):13–21. *https://doi.org/10.1097/MLR.0000000000001458.*

[22] Arnold Ventures, Commonwealth Fund, and PerryUndem. Drug Costs and Their Impact on Care. February 10, 2025. Available at: *https://www.arnoldventures.org/stories/drug-costs-and-their-impact-on-care.*

[23] Center for Opinion Research and I–MAK Survey. Understanding Americans' Top Concerns on Drug Pricing: Corporate Greed and Patent Reform. Available at: *https://www.i-mak.org/survey/.*

[24] Ehsan AN, Wu CA, Minasian A, et al. Financial Toxicity Among Patients With Breast Cancer Worldwide: A Systematic Review and Meta-analysis. JAMA Netw Open. 2023;6(2):e2255388. doi:10.1001/jamanetworkopen.2022.55388.

[25] Sparks, G., Kirzinger, A., Montero, A., et al. Public Opinion on Prescription Drugs and Their Prices. KFF Poll Finding, October 4, 2024. Available at: *https://www.kff.org/health-costs/public-opinion-on-prescription-drugs-and-their-prices/.*

[26] The Commonwealth Fund. Medicare's Affordability Problem: A Look at the Cost Burdens Faced by Older Enrollees. Issue Briefs, September 19, 2023. Available at: *https://www.commonwealthfund.org/publications/issue-briefs/2023/sep/medicare-affordability-problem-cost-burdens-biennial.*

[27] Zhang, J.X, and Meltzer, D.O. Prevalence and Persistence of Cost-related Medication Non-Adherence Before and During the COVID–19 Pandemic Among Medicare Patients at High Risk of Hospitalization. *PLoS One,* 2023, 18(8): e0289608. doi: 10.1371/journal.pone.0289608.

[28] Zhang, J.X., and Meltzer, D.O. Longitudinal Progression of Cost-related Medication Non-Adherence Among Medicare Patients with Diabetes at High Risk of Hospitalization: The Role of Dual Eligibility. *PLoS One, 2025,* 20(8): e0329031. doi: 10.1371/journal.pone.0329031.

[29] Cutler, R.L., Fernandez-Llimos, F., Frommer, M., Benrimoj, C, et al. Economic Impact of Medication Non-adherence by Disease Groups: A Systematic Review. *BMJ Open,* 2018, 8(1): e016982. DOI: 10.1136/bmjopen-2017–016982.

[30] Cutler, R.L., Fernandez-Llimos, F., Frommer, M., Benrimoj, C, et al. Economic Impact of Medication Non-adherence by Disease Groups: A Systematic Review. *BMJ Open,* 2018, 8(1): e016982. DOI: 10.1136/bmjopen-2017–016982.

[31] Xcenda. Modeling the Population Outcomes of Cost-Related Non-adherence: Model Report. September 21, 2020. Available at: *https://global-uploads.webflow.com/5e5972d438ab930a0612707f/5fa9bf4419f4da03a7daf190_WHPC-Xcenda_NonAdherence%20Population%20Model_Report_22Oct2020r.pdf.*

biosimilar biological products, and in certain circumstances specified within section 1847A(d)(3)(C) of the Act. When ASP is not yet available and the wholesale acquisition cost (WAC) is used, the add-on is 3 percent. Section 11403 of the Inflation Reduction Act of 2022 requires a temporary, 5-year increase for qualifying biosimilar biological products (as defined in section 1847A(b)(8)(iii) of the Act) that have an ASP less than the ASP of the reference biological product. In these cases, the add-on is 8 percent of the reference biological product's ASP. Following the applicable five-year period (as described in section 1847A(b)(8)(ii) of the Act) for these qualifying biosimilar biological products, the add-on percentage reverts back to 6 percent of the reference biological product's ASP.

The volume-weighted ASP for a HCPCS Level II code is calculated by CMS quarterly using manufacturer-submitted data on sales to all purchasers (with limited exceptions as articulated in section 1847A(c)(2) of the Act,[32] such as sales at nominal charge and sales exempt from Medicaid best price) [33] with manufacturer rebates, discounts, and price concessions included in the ASP calculation (that is, the sales price is net of these rebates, discounts, and price concessions). The ASP-based payment limit that Medicare pays for a separately payable Medicare Part B FFS drug claim does not vary based on the exact price an individual provider or supplier pays to acquire the drug. This payment methodology may create an incentive for the use of more expensive drugs. Although the statute does not specifically state what the add-on represents, as noted in the MedPAC report,[34] it may be needed to account for handling and overhead costs and additional mark-up in U.S. distribution channels that are not captured in the manufacturer-reported ASP.

Currently, under Medicare Part B, beneficiary cost-sharing [35] is generally 20 percent of the Medicare-allowed amount. The term ''Medicare-allowed amount'' means the maximum amount that a provider or supplier would be paid for a covered health care service or drug. However, for items and services paid under the OPPS, beneficiaries are only financially responsible for a copayment amount up to the amount of the inpatient hospital deductible.[36] Medicare pays for the remaining portion of the Medicare allowed amount.[37]

b. Medicare Part B Drug Inflation Rebate Program

Section 11101 of the Inflation Reduction Act of 2022 (IRA) (Pub. L. 117–169, enacted August 16, 2022) established requirements under which drug manufacturers must pay Part B inflation rebate amounts if they raise their prices for certain drugs payable under Medicare Part B faster than the rate of inflation. Specifically, section 11101 of the IRA amended section 1847A of the Act by adding new subsection (i) which establishes a requirement for drug manufacturers to pay rebates into the Medicare Part B account in the Federal Supplementary Medical Insurance Trust Fund for Part B rebatable drugs for each calendar quarter beginning on or after January 1, 2023, if the amount specified, as determined under section 1847A(i)(3)(A)(ii) of the Act exceeds the inflation-adjusted payment amount, which is calculated as set forth in section 1847A(i)(3)(C) of the Act. The IRA also provides for an adjustment to the beneficiary coinsurance amount in cases where the price of a Part B rebatable drug increases faster than the rate of inflation such that the beneficiary coinsurance is calculated based on the lower inflation-adjusted payment amount instead of the applicable payment amount, resulting in a coinsurance percentage that is equal to 20 percent of the inflation-adjusted payment amount as described in section 1847A(i)(3)(C) of the Act for a calendar quarter. Section 1847A(i)(2) of the Act defines a ''Part B rebatable drug,'' in part, as a single source drug or biological product (as defined in section 1847A(c)(6)(D) of the Act), including a biosimilar biological product (as defined in section 1847A(c)(6)(H) of the Act), for which payment is made under Medicare Part B. Certain product categories are excluded from the definition of a Part B rebatable drug pursuant to 42 CFR 427.101(b). Currently excluded product categories include: (1) qualifying biosimilar biological products; [38] (2) products with historically excepted grouped billing and payment codes; (3) products billed under a ''not otherwise classified'' (NOC) code; (4) radiopharmaceutical drugs and biological products; (5) skin substitutes; (6) drugs with average total allowed charges under the applicable threshold ; (7) certain vaccines and other products; [39] and (8) generic drugs.[40] The applicable threshold specified in section 1847A(i)(2) of the Act was equal to $100 for applicable calendar quarters in 2023. Thereafter, CMS calculates the applicable threshold as equal to the unrounded applicable threshold calculated for the prior calendar year increased by the percentage increase in the consumer price index for all urban customers (CPI–U) for the 12-month period ending with June of the previous year, rounded to the nearest multiple of $10.[41]

For each calendar quarter beginning on or after January 1, 2023, the manufacturer of a Part B rebatable drug is required, for such drug, not later than 30 days after date of receipt (as defined in 42 CFR 427.505) of the Rebate Report from CMS, to pay a rebate into the Medicare Part B account in the Federal Supplementary Medical Insurance Trust Fund if the amount specified in section 1847A(i)(3)(A)(ii) of the Act exceeds the inflation-adjusted payment amount (calculated as set forth in section 1847A(i)(3)(C) of the Act) for an applicable calendar quarter. With respect to invoicing manufacturers for the rebate amount owed, under section 1847A(i)(1) of the Act, CMS must report rebate amounts to each manufacturer of a Part B rebatable drug no later than 6 months after the end of each calendar quarter, except that for calendar quarters beginning in 2023 and 2024, CMS had until September 30, 2025, to invoice manufacturers for rebates. In the CY 2025 Physician Fee Schedule (PFS) final

[32] OMB Control Number 0938–0921, Centers for Medicare & Medicaid Services.

[33] Best price is defined in section 1927(c)(1)(C) of the Act.

[34] MedPAC, June 2017, ''Medicare Part B Drug Payment Policy Issues,'' accessed via *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun17_ch2.pdf.*

[35] Not including the annual deductible.

[36] Section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure performed in a year to the amount of the inpatient hospital deductible for that year. This limit is $1,676 in 2025.

[37] Centers for Medicare & Medicaid Services. Outpatient Services Payment for People with Medicare Part B, Revised May 2021. Available at: *https://www.medicare.gov/publications/02118-Part-B-Outpatient-Services-Payment.pdf.*

[38] Qualifying biosimilar biological products are defined under section 1847A(b)(8)(B)(iii) of the Act and, during the applicable 5-year period, must have an ASP that is not more than the ASP of the reference biological product for a calendar quarter to qualify for an add-on amount equal to 8 percent of the payment amount calculated under section 1847A(b)(4) of the Act for the reference biological product.

[39] This includes influenza, pneumococcal, hepatitis B, and COVID–19 vaccines, and monoclonal antibodies used for treatment or post-exposure prophylaxis of COVID–19.

[40] Part B drugs submitted in an Abbreviated New Drug Application (ANDA) and approved under section 505(j) of the FD&C Act.

[41] 42 CFR 427 Subpart B, Electronic Code of Federal Regulations. *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-427.* For applicable calendar quarters during 2023, the applicable threshold was $100.

rule (89 FR 98228 through 98313)[42] to implement section 11101 of the IRA, CMS codified these requirements and established other policies at 42 CFR part 427. In the CY 2026 PFS final rule (90 FR 49733 through 49739),[43] CMS adopted certain limited modifications to the policies for the Medicare Prescription Drug Inflation Rebate Program set forth in part 427 under title 42, chapter IV of the Code of Federal Regulations (CFR) for Part B. For example, at 42 CFR 427.302(c)(5) described how CMS identifies the payment amount benchmark quarter in certain instances and the calculation for the Part B rebate amount in such instances.

c. Medicare Drug Price Negotiation Program

Sections 11001 and 11002 of IRA establish the Medicare Drug Price Negotiation Program (hereinafter the ''Negotiation Program'') to negotiate maximum fair prices (MFPs)[44] for certain high expenditure, single source drugs and biological products. The requirements for this program are described in sections 1191 through 1198 of the Act, as added by sections 11001 and 11002 of the IRA. Additionally, on July 4, 2025, the Working Families Tax Cuts Act (Pub. L. 119–21) was signed into law. Section 71203 of the Working Families Tax Cuts Act expanded protections for certain orphan drugs in section 1192(e) of the Act. Drugs payable under Medicare Part B are eligible to be selected for negotiation for initial price applicability year 2028.

2. Medicare and Beneficiary Spending

a. Historical Trending

An Issue Brief from ASPE evaluated Medicare Part B total spending and fee-for-service (FFS) drug allowed charges from 2014 to 2021.[45] Medicare Part B total spending increased from $265.9 billion in 2014 to $405.5 billion in 2021, representing an increase of $139.6 billion. Medicare Part B FFS drug allowed charges increased from $21.8 billion in 2014 to $40.5 billion in 2021, an increase of $16.4 billion. While total spending and drug allowed charges have both increased significantly, Medicare Part B FFS drug allowed charges have seen higher spending growth. In 2014, Medicare Part B FFS drug allowed charges represented about 12.1 percent of Medicare Part B FFS spending but grew to approximately 20 percent in 2021.[46]

The same report also found that between 2014 and 2021, Medicare Part B FFS drug spending per enrollee grew on ''average at 9.2 percent annually'' more than three times the rate of Medicare Part D (2.6 percent) and nearly four times as high as the rate of per capita annual prescription drug spending (2.4 percent). Medicare Part B FFS drug spending was also concentrated among a few drugs where the top 20 drugs accounted for greater than 50 percent of drug spending in 2021 and the top 10 drugs accounted for 40 percent of drug spending in the same period. When comparing biological products to non-biologicals, biological products accounted for 89 percent of the Medicare Part B FFS drug spending growth between 2008 and 2021 and 79 percent of Medicare Part B FFS drug spending in 2021. When reviewing Medicare Part B FFS spending on multi-source drugs and biological products in 2021, generic drugs[47] accounted for only 2 percent of spending and only 3 of the top 20 drugs by spend[48] (all biological products) were multi-source. Therefore, the majority of Medicare Part B FFS drug expenditures in 2021 were attributable to single source drugs and sole source biological products.

An ASPE report evaluating Medicare Part B FFS spending from 2018 to 2023 estimated biosimilar biological product competition (multi-source biological products) reduced spending by $12.9 billion, a 31 percent decrease compared to projected spending if only the reference biological product existed.[49] Savings after biosimilar biological product competition entered the market were driven by a mix of beneficiary switches to a lower-priced biosimilar biological product and price reductions in the reference biological products.

It is also important to note that the number of enrollees for Medicare Part B FFS has decreased (8.8 percent) between 2016 to 2021 (34 million to 31 million),[50] while Medicare Part B FFS drug allowed charges has increased (47 percent) for the same time period.[51] Therefore, this increase in Medicare Part B FFS spending for drugs during this period is likely explained more by increases in the prices of drugs, introduction of new drugs,[52] changes in utilization of drugs, and changes in the mix of drugs for those beneficiaries who received them more so than the changes in Medicare Part B enrollment.[53]

b. Impact on Premiums, Beneficiaries, and Taxpayers

Medicare Part B is funded by premiums paid by beneficiaries and general federal revenues. Total Medicare Part B Premium amounts increased from $74 billion in 2016 to $113 billion in 2021, representing an increase of $39

[42] ''Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments,'' 89 FR 98228–98313 (December 9, 2024).

[43] ''Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program,'' 90 FR 49266–50481 (November 5, 2025).

[44] In accordance with section 1191(c)(3) of the Act, MFP means, with respect to a year during a price applicability period and with respect to a selected drug (as defined in section 1192(c) of the Act) with respect to such period, the price negotiated pursuant to section 1194 of the Act, and updated pursuant to section 1195(b) of the Act, as applicable, for such drug and year.

[45] Medicare Part B Drug Pricing, Office of the Assistant Secretary for Planning and Evaluation (June 9, 2023). Available at: *https://aspe.hhs.gov/sites/default/files/documents/fb7f647e32d57ce4672320b61a0a1443/aspe-medicare-part-b-drug-pricing.pdf.*

[46] Medicare Part B Drug Pricing, Office of the Assistant Secretary for Planning and Evaluation (June 9, 2023). Exhibit 3: Part B FFS drugs' share of Part B FFS spending, 2014 to 2021 from *https://aspe.hhs.gov/sites/default/files/documents/fb7f647e32d57ce4672320b61a0a1443/aspe-medicare-part-b-drug-pricing.pdf.*

[47] Generic drugs are submitted in an Abbreviated New Drug Application (ANDA) and approved under section 505(j) of the FD&C Act. For Medicare Part B FFS, generic drugs share the same HCPCS Level II code as the originator drug.

[48] The three multi-source biological products in the top 20 Part B drugs by total Medicare Payments were Rituxan (rituximab), Remicade (infliximab), and Neulasta (pegfilgrastim).

[49] Medicare Part B Enrollee Use and Spending on Biosimilars, 2018–2023, Office of the Assistant Secretary for Planning and Evaluation (January 2025). Available at: *https://aspe.hhs.gov/sites/default/files/documents/be065dbbd1f866c65cf627995bd2ea56/biosimilars-medicare-part-b.pdf.*

[50] Medicare Part B FFS enrollment derived from Table V.B3 of the 2023 Annual Report of the Board of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Trust Funds. *Available at: https://www.cms.gov/oact/tr/2023.*

[51] Medicare Part B Drug Pricing, Office of the Assistant Secretary for Planning and Evaluation (June 9, 2023). Exhibit 3: Part B FFS drugs' share of Part B FFS spending, 2014 to 2021. Available at: *https://aspe.hhs.gov/sites/default/files/documents/fb7f647e32d57ce4672320b61a0a1443/aspe-medicare-part-b-drug-pricing.pdf.*

[52] Hyland MF, Sachs RM, Robillard L., Hayford TB, Bai G. Spending on and Use of Clinician-Administered Drugs in Medicare. JAMA Health Forum. September 8, 2023. *Available at: https://jamanetwork.com/journals/jama-health-forum/fullarticle/2809283.*

[53] The average annual growth in number of Medicare Part B FFS beneficiaries was less than 2.5 percent from 2014 to 2021, so the change in Medicare Part B beneficiaries does not fully account for the average annual growth in Medicare Part B drug spending (9.2 percent annual growth). Instead, the increase during this period is more fully explained by increases in the prices of drugs, introduction of new drugs, changes in drug utilization, and changes in the mix of drugs than by increases in Medicare enrollment.

billion.[54] While this increase in total Medicare Part B premiums is partially attributable to the increase in beneficiaries from 52 million to 58 million,[55] there was also a rise in premium amount per enrollee from $1,423 in 2016 to $1,942 in 2021. A research study found the 2024 Medicare Part B premiums accounted for more than 10 percent of annual per capita income for 12 percent of Medicare Part B beneficiaries—approximately 7.4 million of the 61 million Medicare Part B beneficiaries.[56] The rise in premiums is partly due to projected costs for new drugs, price changes for health care services, new technologies, and assumed utilization increases.[57] [58] [59]

In addition to a monthly premium, Medicare Part B FFS beneficiaries typically need to cover 20 percent of the cost of a Medicare Part B drug once their Medicare Part B deductible is met. Medicare Part B FFS does not have an out-of-pocket maximum, whereas other forms of coverage such as MA plans and Medigap policies may have a maximum. While the IRA has reduced beneficiary coinsurance for certain Medicare Part B drugs whose prices have risen faster than inflation, beneficiaries may continue to experience significant cost sharing as overall Medicare Part B FFS spending has increased. As previously discussed, this increase is likely driven by high overall prices and the introduction of new drugs.[60] [61]

Further, as discussed earlier in this section, increasing high drug costs limit access to care and treatment which in turn results in complications that can lead to worse health outcomes and increased medical spending. For example, though not specific to Medicare Part B, the national healthcare expenditure (NHE) out-of-pocket (OOP) spending increased by 25.5 percent ($102.7 billion) between 2019 to 2023.[62] High OOP costs have been shown to reduce medication adherence. A study on specialty drugs found that 30 percent of new cancer drug prescriptions went unfilled among patients without low-income subsidies, while another showed that 7 percent of adults 65 and older skipped or did not take their medications as prescribed because of cost.[63] [64] Research has also found multiple indications of worse health status were associated with a higher likelihood of cost-related nonadherence to medications.[65]

The second source for Medicare Part B funding comes from general federal revenues, which taxpayers primarily finance. General revenues fund approximately 75 percent of Medicare Part B expenditures, with beneficiary premiums accounting for the remaining 25 percent of projected expenditures.[66] Historical trend analysis on Medicare Part B spending has shown an increase in annual federal revenue contribution from $235.6 billion in 2016 to $386.0 billion in 2024, illustrating the growth in general federal revenues in Medicare Part B financing.[67]

c. Relative High Price of Medicare Part B Drugs

Research from ASPE and RAND provides comparative data on U.S. prescription drug prices relative to 32 other Organisation for Economic Co-operation and Development (OECD) countries.[68] These studies examine pricing patterns of prescription drugs and present findings on how U.S. prescription drug costs compare to international benchmarks. OECD countries are generally developed, high-income nations, making them suitable comparators for evaluating drug prices.

ASPE funded research published in July 2022 indicated that U.S. prescription drugs prices exceeded those of non-U.S. OECD countries combined by 256 percent[69] using 2018 data.[70] In 2024, the study was updated with pricing information from 2022 and showed an even larger gap of 278 percent compared to non-U.S. OECD countries combined.[71] When comparing the U.S. against individual G7 countries,[72] the price differential ranged from 229 percent higher than Canada to 347 percent higher than Japan.

This analysis reveals even larger pricing differences when examining

[54] CMS Program Statistics—Medicare Premiums, Centers for Medicare & Medicaid Services. Medicare Part B Premiums are from Table, MDCR Premiums 4. *Available at: https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-premium-reports/cms-program-statistics-medicare-premiums.*

[55] These enrollment numbers include total Medicare Part B beneficiaries in Medicare Part B FFS, Medicare Advantage plans, section 1876 cost plans, and section 1833 healthcare prepayment plans. Medicare Part FFS enrollment for 2016 and 2021 were 34 million and 31 million, respectively.

[56] Cottrill A, Cubanski J, Neuman T, Smith K. Seven Million People with Medicare Spend More Than 10% of Income on Part B Premiums—The Reconciliation Bill Could Drive the Number Higher. Kaiser Family Foundation (June 23, 2025). *Available at: https://www.kff.org/medicare/issue-brief/seven-million-people-with-medicare-spend-more-than-10-of-income-on-part-b-premiums-the-reconciliation-bill-could-drive-the-number-higher/.*

[57] 2025 Medicare Parts A & B Premiums and Deductibles, Centers for Medicare & Medicaid Services (November 8, 2024). *Available at: https://www.cms.gov/newsroom/fact-sheets/2025-medicare-parts-b-premiums-and-deductibles.*

[58] Neuman T, Cubanski J, Freed M. Monthly Part B Premiums and Annual Percentage Increases. Kaiser Family Foundation (January 12, 2022). *Available at: https://www.kff.org/medicare/slide/monthly-part-b-premiums-and-annual-percentage-increases/.*

[59] Congressional Research Service. Medicare: Part B Premiums. CRS Report R40082. Washington, DC: Library of Congress, 2021. *Available at: https://www.congress.gov/crs_external_products/R/PDF/R40082/R40082.48.pdf.*

[60] Hyland MF, et al. Spending on and Use of Clinician-Administered Drugs in Medicare. JAMA Health Forum. 2023;4(9):e232941. doi:10.1001/jamahealthforum.2023.2941.

[61] Changes in the List Prices of Prescription Drugs, 2017 to 2023, Office of the Assistant Secretary for Planning and Evaluation (October 6, 2023). Available at: *https://aspe.hhs.gov/sites/default/files/documents/e24f630a33f0a0585337c65745904487/aspe-drug-price-tracking-brief.pdf.*

[62] The 25.5 percent and $102.7 billion was calculated using NHE Table 3: National Health Expenditures, by Source of Funds for out of pockets costs for years 2019 and 2023. *Available at: https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet.*

[63] Dusetzina SB, Huskamp HA, Rothman RL, Pinheiro LC, Roberts AW, Shah ND, Walunas TL, Wood WA, Zuckerman AD, Zullig LL, Keating NL. *Many Medicare Beneficiaries Do Not Fill High-Price Specialty Drug Prescriptions.* Health Affairs (December 2021). *https://doi.org/10.1377/hlthaff.2021.01742.*

[64] Anderer S. *High Drug Costs Influence Nonadherence to Medications Among Older Adults.* JAMA. Published online October 4, 2024; 332(16):1323. *https://doi.org/10.1001/jama.2024.19690.*

[65] Nekui F, Galbraith AA, Briesacher BA, Zhang F, Soumerai SB, Ross-Degnan D, Gurwitz JH, Madden JM. *Cost-related Medication Nonadherence and Its Risk Factors Among Medicare Beneficiaries.* Medical Care. 2021;59(1):13–21. *https://doi.org/10.1097/MLR.0000000000001458.*

[66] U.S. Government Accountability Office. Federal Trust Funds and Other Dedicated Funds: Fiscal Sustainability Is a Growing Concern for Some Key Funds. GAO–20–156. Washington, DC: GAO, January 2020. *Available at: https://www.gao.gov/assets/gao-20-156.pdf.*

[67] 2025 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds. Centers for Medicare & Medicaid Services, Office of the Actuary. June 2025. *Available at: https://www.cms.gov/oact/tr/2025.*

[68] The 32 countries compared to were Australia, Austria, Belgium, Canada, Chile, Czech Republic, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Japan, Latvia, Lithuania, Luxembourg, Mexico, Netherlands, New Zealand, Norway, Poland, Portugal, Slovakia, Slovenia, South Korea, Spain, Sweden, Switzerland, Turkey, and United Kingdom.

[69] Authors calculated price indexes using U.S. volume weights to account for differences in volume and mix of drugs across countries.

[70] Ratios from this study are not adjusted for differences in purchasing power-adjusted GDP per capita. See Andrew W. Mulcahy, Christopher M. Whaley, Mahlet Gizaw, Daniel Schwam, Nathaniel Edenfield, and Alejandro Uriel Becerra-Ornelas, *International Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons with Previous Studies,* RAND Corporation, RR–2956–ASPEC, 2021. *Available at: https://www.rand.org/pubs/research_reports/RR2956.html.*

[71] Ratios from this study are not adjusted for differences in purchasing power-adjusted GDP per capita. *Available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC11147645/.*

[72] The G7 countries are Canada, France, Germany, Italy, Japan the United Kingdom, and the U.S.

originator drugs separately. U.S. originator drug prices are 422 percent higher than non-U.S. OECD countries combined. Among individual G7 countries, the difference between U.S. and the international prices ranged from 324 percent higher than Canada to 464 percent higher than Japan. These data points indicate there are significant cost differences within the global pharmaceutical market for U.S. originator drugs and international originator drugs.[73]

In contrast, the unbranded generic drug market, not including biologics such as biosimilar biological products, shows different pricing dynamics. The same study showed U.S. unbranded generic pricing was 67 percent of the average price among non-U.S. OECD countries. The comparison of U.S. prices to individual G7 countries for unbranded generic drugs shows pricing that is 39 percent lower than Canada and 46 percent lower than Germany. This indicates that pricing patterns vary significantly between originator drugs and generic drugs in the U.S. market.

A separate ASPE analysis examined Medicare Part B drugs. The study evaluated drug prices for the top 50 Part B drugs against non-U.S. OECD countries using 2018 drug spending data.[74] Although this report included only 50 drugs, those drugs accounted for 80 percent of the total 2018 Medicare Part B drug spending. The analysis found that U.S. prices were 211 percent higher than other OECD countries on average.[75] In G7 country comparisons, the difference between the U.S. and individual countries for U.S. originators and international originators drugs ranged from 148 percent higher than Japan to 225 percent higher than France.[76]

The research findings indicate that U.S. prices used to calculate ASP rates for Medicare Part B FFS payment limits are different from prices in international comparator countries. This price differential has led to recurring policy discussions about potential approaches for reducing Medicare Part B drug and biological product spending by reviewing international prices. Research from the Brookings Institute indicates that many non-U.S. OECD countries use international reference pricing as a benchmark when negotiating with prescription drug manufacturers, demonstrating that this practice is established among manufacturers.[77]

The data shows that U.S. prescription drug prices, particularly for U.S. originator drugs,[78] exceed those found in other OECD countries. In addition, prior studies on generic drug pricing in the U.S. have shown that generic drug prices generally compare to or fall below international comparisons; suggesting that high overall drug costs are primarily driven by originator, single source drugs or sole source biological products. Based on the high spending by Medicare Part FFS and Medicare Part B beneficiaries on single source drugs and sole source biological products, in this proposed rule, we propose the GLOBE Model to test the impact of using international drug pricing information as a benchmark for an alternative Part B inflation rebate amount calculation for a subset of Medicare Part B rebatable drugs (certain single source drugs and sole source biological products) on Medicare program expenditures and quality of care.

II. Provisions of the Proposed Regulations

In this proposed rule, we propose our policies for the GLOBE Model, including the general framework for implementing and evaluating the GLOBE Model and model-specific parameters, requirements, and definitions. We note that section 1115A(b) of the Act gives the Secretary discretion in the design of models. In accordance with section 1115A(a)(3) of the Act, through this proposed rule, CMS seeks input from interested parties and welcomes comments on the proposed GLOBE Model.

The proposed model-specific parameters, requirements, and definitions are described in subsections of this section of this proposed rule and we propose to codify them at proposed 42 CFR 513. In addition, for purposes of this proposed rule and the proposed GLOBE Model, we propose that the following terms would have the same meaning as set forth for the Medicare Part B Drug Inflation Rebate Program in 42 CFR 427.20: allowed charges, applicable calendar quarter, average sales price, billing and payment code, billing unit, biosimilar biological product, final action claim, inflation-adjusted payment amount, manufacturer, National Drug Code (NDC), Not Otherwise Classified (NOC) code, Part B rebatable drug, single source drug, specified amount, and unit (with respect to a Part B rebatable drug). We propose that the following terms would have the same meaning as set forth in 42 CFR 427.400: currently in shortage, drug shortage or shortage, natural disaster, other unique or unexpected event, plasma-derived product, and severe supply chain disruption.

A. Proposed Model Test Period

In proposed 42 CFR 513.1(c), we propose that the GLOBE Model would have a 7-year test period consisting of 5 performance years, beginning October 1, 2026 and ending September 30, 2031, during which the GLOBE Model beneficiary coinsurance and adjusted payments to providers and suppliers would apply (as applicable) and monitoring activities would occur, and 7 payment years during which CMS would calculate, invoice, collect, and reconcile the GLOBE Model rebates for a performance year, unless sooner terminated in accordance with proposed 42 CFR 513.100(d)). It is necessary to include 2 payment years after the end of the final performance year to allow for

[73] An international originator is an original biological product or drug approved or licensed in a non-U.S. country under that non U.S. country's regulatory framework under a pathway similar to 351(k) of the PHS Act or approved under a pathway similar to section 505(c) of the FD&A Act in the U.S. Individual countries differ in the regulatory processes and standards governing approval of drugs and biologicals. Use of international drug pricing information in the proposed GLOBE Model should not be interpreted to connote FDA approval or to otherwise describe any scientific or regulatory relationship between U.S.-approved and non-U.S.-approved products.

[74] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation. (2020). *Medicare FFS Part B and International Drug Prices: A Comparison of the Top 50 Drugs.* Available at:

https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//197401/Part-B%20Drugs-International-Issue-Brief.pdf.

[75] These unadjusted price ratios of US to non-US OECD countries are taken from Table 4, Overall Ratios Spending for Matched Part B Drugs by Country, of this report: *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files/197401/Part-B%20Drugs-International-Issue-Brief.pdf.* The reported price ratio were converted to a percentage. The report also adjusts for purchasing power-adjusted GDP per capita. After adjusting for purchasing power-adjusted GDP per capita, the adjusted US to non-US OECD country price ratio decreases to 1.53 (153 percent). This price ratio is also volume weighted.

[76] These unadjusted price ratios of US to non-US OECD countries are taken from Table 4, Overall Ratios Spending for Matched Part B Drugs by Country, of this report: *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files/197401/Part-B%20Drugs-International-Issue-Brief.pdf.* The reported price ratios were converted to a percentage. The report also adjusts for purchasing power-adjusted GDP per capita. The adjusted price ratio changes to 1.06 (106 percent) for Japan and 1.66 (166 percent) for France. These price ratios are also volume weighted.

[77] Young, C.L., Frank, R.G., & Sachs, R. (2025). *International reference pricing for prescription drugs.* Brookings Institution. Available at: *https://www.brookings.edu/articles/international-reference-pricing-for-prescription-drugs/.*

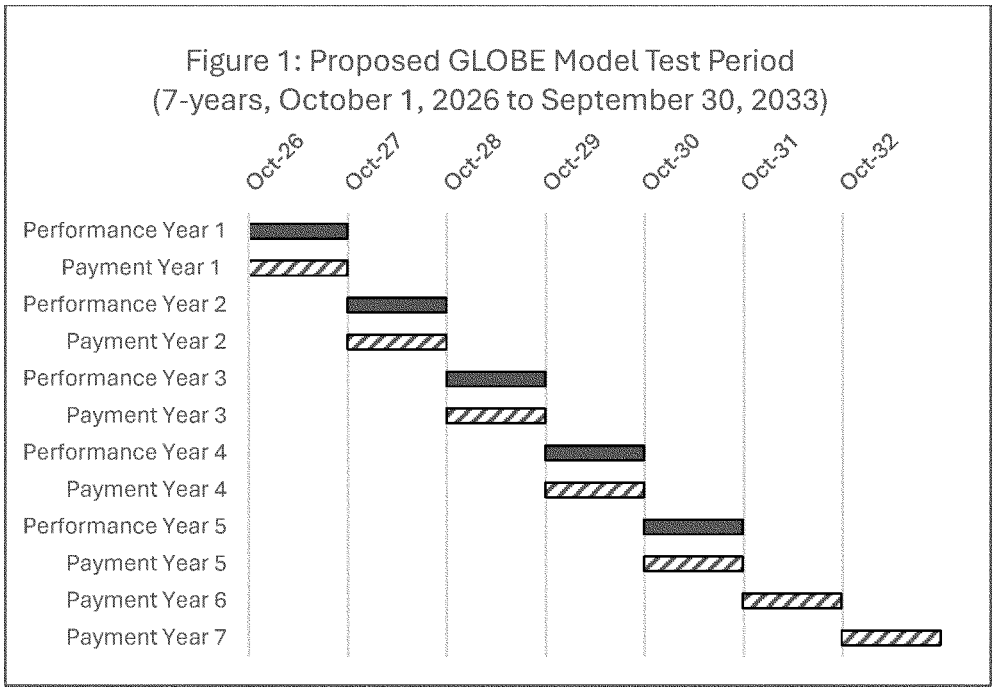
[78] U.S. originator drugs are the original biologics and drugs developed and licensed or approved via section 351(a) of the Public Health Services Act or submitted under section 505(b) and approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). U.S. originator drugs are also sometimes called brand name drugs, reference listed drug, or reference products.

rebate invoicing and reconciliation activities, as CMS delivers the information defined in 1847A(i)(1)of the Act no later than 6 months after the close of the calendar quarter, and, as codified in 42 CFR 427.501(d), CMS would perform reconciliation of the rebate amount in specified scenarios, including one regular reconciliation of the rebate amount within 12 months of the date of the receipt of the Rebate Report for each applicable calendar quarter. As such, CMS proposes a 7-year test period to include 7 payment years in order for rebate invoicing and reconciliation processes to take place for all of the applicable calendar quarters in the model performance period. The proposed model test period is illustrated in Figure 1.

In 42 CFR 513.20, we propose to define ''*performance year*'' (PY) as a 12-month period beginning on October 1 and ending on September 30 during the first 5 years of the GLOBE Model test period. As such, we propose to define ''*GLOBE Model performance period*'' as a 5-year period of time beginning on October 1, 2026, through September 30, 2031. We propose to define ''*payment year*'' as a 12-month period beginning on October 1 and ending on September 30 during the GLOBE Model test period. As such, we propose to define ''*GLOBE Model payment period*'' as the 7-year period of time beginning on October 1, 2026, through September 30, 2033.

We propose to test the GLOBE Model to capture all applicable billing units (as discussed in section II.G.4. of this proposed rule) for all Medicare Part B FFS claims for GLOBE Model drugs that are furnished to Medicare beneficiaries who are in the model cohort on the date of service during the model performance period and that are paid under the GLOBE Model. This means that, given the length of time during and after the end of an applicable calendar quarter that is necessary to conduct the proposed GLOBE Model processes for claims processing, data collection, rebate invoicing, manufacturer payment of GLOBE Model rebates, reconciliation, and model evaluation, model-related activities would continue into calendar year 2033, through September 30, 2033, as applicable, as codified in 42 CFR 513.1(c).

Figure 1: Illustration of the Proposed Globe Model Test Period [79]



B. Proposed GLOBE Model Drugs

The proposed GLOBE Model would include, as GLOBE Model drugs, a set of Part B rebatable drugs (single source drugs and sole source biological products) that are used to treat beneficiaries with conditions where access barriers like high costs likely contribute to deficits in care leading to poor clinical outcomes and high program expenditures which may be avoidable. Analysis of historical Medicare Part B FFS drug spending and non-U.S. OECD spending for similar drugs and biological products has highlighted U.S. originator drugs without generic [80] or biosimilar biological product [81] competition (called ''*single source drug*'' and ''*sole source biological*'' for purposes of this proposed rule and the GLOBE Model) as the main contributor to high drug spending within Medicare Part B FFS and globally.

[79] Payment Years 6 and 7 are for rebate invoicing and reconciliation for Performance Years 4 and 5.

[80] Part B drugs approved under an Abbreviated New Drug Application (ANDA) submitted under section 505(j) of the FD&C Act.

[81] Biosimilar biological product is defined in section 1847A(c)(6)(H) of the Act as ''biological product approved under an abbreviated application for a license of a biological product that relies in part on data or information in an application for another biological product licensed under section 351 of the Public Health Service Act.'' See *https://www.ssa.gov/OP_Home/ssact/title18/1847A.htm.*

The majority of Medicare Part B FFS drug spending is also concentrated in a select number of drugs and biological products. For example, and as illustrated in Table 2, spending for the top 50 Medicare Part B FFS drugs and biological products in 2024 was concentrated in the therapeutic areas of oncology (39 percent), immunology (19 percent), skin substitutes (13 percent), ophthalmology (12 percent), endocrinology (9 percent), and rheumatology (5 percent). Per 42 CFR 427.101(b), skin substitutes are an excluded product category for Part B rebatable drugs.

TABLE 1: ILUSTRATIVE PROPOSED KEY DATA TIMELINES FOR GLOBE PROVISIONS

	Reporting Window 1 Q3 2026	Reporting Window 2 Q4 2026	Reporting Window 3 Q1 2027	Reporting Window 4 Q2 2027
Applicable calendar quarter	Q4 2026	Q1 2027	Q2 2027	Q3 2027
Applicable ASP calendar quarter	Q2 2026	Q3 2026	Q4 2026	Q1 2027
Reduced coinsurance and rebate liability based on Method I or Method II benchmark effective	Q4 2026	Q1 2027	Q2 2027	Q3 2027
GLOBE Model rebate payments associated with applicable calendar quarter due	Q3 2027	Q4 2027	Q1 2028	Q2 2028

In addition, studies have shown notable spending growth in cancer, endocrinology, immunology, rheumatology, and ophthalmology. Increased drug costs limits access to care and treatment for beneficiaries with conditions in these categories increasing their risk for deficits of care and worse health outcomes. According to an ASPE report, between 2008 and 2021, the average annual payment for Medicare Part B drugs grew by 8.8 percent.[82] In contrast, Medicare Part B program payments in the therapeutic areas of oncology, immunology, endocrinology, and rheumatology grew by an average of 10.8 percent annually,[83] suggesting that these therapeutic areas experienced faster spending growth. The same ASPE report also found that ophthalmologists [84] had the highest average annual Medicare Part B payment increase at 15 percent, 1.7 times higher than the overall average annual payment growth for all Medicare Part B drugs. These therapeutic types and physician specialties use drugs and biological products to treat conditions related to cancer, endocrinology, immunology, rheumatology, and ophthalmology. CMS identified the categories for the top 50 Medicare Part B drugs using the standardized United States Pharmacopeia (USP) Drug Classification (DC) criteria paired with internal clinical knowledge and FDA label review. These therapeutic areas are associated with the following USP DC categories listed in Table 3.

TABLE 2. SUMMARY OF TOP 50 DRUGS AND BIOLOGICAL PRODUCTS BY SPENDING IN 2024 FOR MEDICARE PART B

Therapeutic Area	2024 Medicare Part B FFS Charges	Percent of Spend Among Top 50
Oncology	$ 17,713,141,933	39%
Immunology	$ 8,645,379,816	19%
Skin Substitutes	$ 5,819,236,768	13%
Ophthalmology	$ 5,475,187,474	12%
Endocrinology	$ 4,152,351,517	9%
Rheumatology	$ 2,295,127,222	5%
Skeletal Muscle Relaxants	$ 502,254,588	1%
Diagnostic Agents	$ 403,634,929	1%
Total	$ 45,006,314,247	-

While higher drug costs are not the only contributor to Medicare Part B spending growth, it may lead to increased financial burden for some beneficiaries. Previous studies have found that high costs can increase the

[82] Calculated from the ''All'' Category from Exhibit 5 of an ASPE 2023 Report (Nguyen, N., Olsen, A., Sheingold, S., and De Lew, N. Medicare Part B Drugs: Trends in Spending and Utilization, 2008–2021. Washington, DC: Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, June 2023. Available at: *https://www.ncbi.nlm.nih.gov/books/NBK605978/pdf/Bookshelf_NBK605978.pdf*).

[83] Calculated by combining therapeutic types of Cancer, Immunosuppressive, Intravenous Immunoglobulin (IVIG), Rheumatoid Arthritis, Oral Cancer, and Osteoporosis from Exhibit 5 of an ASPE 2023 Report (Nguyen, N., Olsen, A., Sheingold, S., and De Lew, N. Medicare Part B Drugs: Trends in Spending and Utilization, 2008–2021. Washington, DC: Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, June 2023. Available at: *https://www.ncbi.nlm.nih.gov/books/NBK605978/pdf/Bookshelf_NBK605978.pdf*).

[84] Ophthalmologists are more likely to have prescribed or used drugs in the ophthalmic agents category.

likelihood of nonadherence to medications leading to potentially worse health status.[85] [86] [87] Thus, CMS is proposing to scope the GLOBE Model to target potential deficits of care in specific USP DC categories as shown in Table 3 and defined in 42 CFR 513.130.

TABLE 3: USP DC CATEGORIES AND RELATED THERAPEUTIC AREAS

USP DC Category	Associated Therapeutic Area(s)*
Antigout Agents	**Rheumatology**
Antineoplastics	**Oncology**
Blood Products and Modifiers	**Immunology, Oncology**
Central Nervous System Agents	**Immunology**
Immunological Agents	**Immunology, Rheumatology, Oncology**
Metabolic Bone Disease Agents	**Endocrinology, Rheumatology**
Ophthalmic Agents	**Ophthalmology**

*Note: This is not an exhaustive list of therapeutic areas that correspond to the USP DC categories but illustrates how the named USP DC categories are associated with the 5 therapeutic areas of oncology, endocrinology, immunology, rheumatology, and ophthalmology.

Previous analyses have also shown that U.S. originator drugs are, on average, about 422 percent more expensive in the U.S. than in non-U.S. OECD countries. Other studies indicate that growth in Medicare Part B drug spending has largely been driven by single source drugs and sole source biologics. As such, we propose to scope this model to focus on testing drugs and biological products where program expenditures are most likely to arise.

To meet this GLOBE Model intent, we also propose to identify the single source drugs and sole source biological products in the selected drug categories in Table 3 that would be GLOBE Model drugs for an applicable calendar quarter by applying a set of criteria (as further described in section II.B.1. of this proposed rule) in advance of the applicable calendar quarter using information available to CMS (as determined by CMS). By applying the proposed criteria to identify GLOBE Model drugs for an applicable calendar quarter, CMS would use a consistent methodology to identify a set of Part B rebatable drugs that are used to treat beneficiaries with conditions where deficits in care and high program expenditures are potentially avoidable and a representative subset of Part B rebatable drugs that account for a substantial portion of annual Medicare Part B FFS spending for Part B rebatable drugs. By excluding Part B rebatable drugs that are not sole source biological products, the GLOBE Model would also avoid including drugs with biosimilar biological product approvals in the U.S. which may be subject to unique market dynamics that would confound the model test. We note by definition that Part B rebatable drugs includes single source drugs and have chosen to re-iterate the term ''*single source drugs*'' for clarity and completeness.

Using Part B rebatable drugs as the basis for identifying GLOBE Model drugs that are single source drugs and sole source biological products and meet the USP DC categories in Table 3 is necessary to allow CMS to test an alternative Part B inflation rebate amount calculation methodology. Limiting inclusion in the model test to a set of Part B rebatable drugs that meet the proposed inclusion criteria is necessary to focus the model test where model impacts related to expected high program expenditures may be observed within the study population over the course of the model evaluation (as described in section II.F. of this proposed rule). As further described in section II.B.1. of this proposed rule, CMS would identify GLOBE Model drugs and add them to the GLOBE Model Drug List that would be made available on the GLOBE Model web page at *https://www.cms.gov/priorities/innovation/innovation-models/globe.* The GLOBE Model Drug List would be maintained quarterly to add and remove drugs as appropriate in accordance with the inclusion criteria. We propose to identify a GLOBE Model drug using the same applicable billing and payment code (that is, Healthcare Common Procedure Coding System (HCPCS) Level II code) that is identified for the Part B rebatable drug pursuant to 42 CFR 427.101(a)(1)(ii) for the Medicare Part B Drug Inflation Rebate Program.

Further, for the purposes of the GLOBE Model test, we propose to treat biosimilar biological products and their reference biological products as ''multi-source'' products instead of sole source biological products when certain conditions are met due to the unique market dynamics of these products within the U.S and because qualifying biosimilar biological products are not Part B rebatable drugs.

We note that qualifying biosimilar biological products (as defined under section 1847A(b)(8)(iii) of the Act) are not included in the Part B rebatable drug definition at 42 CFR 427.20 and therefore, would not be a GLOBE Model drug regardless of whether the criteria for exclusion in proposed 42 CFR 513.130(c) were met. We also note that the Medicare Part B Drug Inflation Rebate Program includes non-qualifying biosimilar biological products and their reference biological products.

We believe there are observable differences in pricing dynamics of sole source and multi-source biological products that lead to unique market dynamics. For example, when there is no competing biological product licensed under section 351(k) of the Public Health Service (PHS) Act to a U.S. originator drug, manufacturers are less likely to provide price concessions and rebates. Compared with sole source biological products, when reference biological products and their biosimilar biological products that are licensed

[85] Nekui F, Galbraith AA, Briesacher BA, Zhang F, Soumerai SB, Ross-Degnan D, Gurwitz JH, Madden JM. *Cost-related Medication Nonadherence and Its Risk Factors Among Medicare Beneficiaries.* Medical Care. 2021;59(1):13–21. *https://doi.org/10.1097/MLR.0000000000001458.*

[86] Arnold Ventures, Commonwealth Fund, and PerryUndem. Drug Costs and Their Impact on Care. February 10, 2025. Available at: *https://www.arnoldventures.org/stories/drug-costs-and-their-impact-on-care.*

[87] Fusco, N., et al. (2023). ''Cost-sharing and adherence, clinical outcomes, health care utilization, and costs: A systematic literature review.'' *Journal of Managed Care & Specialty Pharmacy.*

under section 351(k) of the PHS Act are sold, manufacturers of multi-source biological products may provide higher price concessions and discounts to be competitive. These market differences result in varying manufacturer-to-provider incentives. In markets with competing biosimilar biological products, manufacturers may provide discounts to providers through price concessions and rebates that impact Medicare spending. Manufacturers may change these discount strategies depending on how many patients are within a GLOBE Model due to geographic location. As such, manufacturers may provide lower discounts to clinics with more patients in the GLOBE Model geographic region than to clinics with less patients. This difference in incentives may lead to providers switching between biosimilar biological products to their reference biological products, reference biological products to their biosimilar biological products, or from one biosimilar biological product to another.

We recognize that if the reference biological product for a biosimilar biological product that is licensed under 351(k) of the PHS Act were included in the GLOBE Model and the biosimilar biological product was not included, beneficiaries could face higher cost sharing amounts for biosimilar biological products than reference biological products. The discussion in section II.B.1. of this proposed rule further describes our proposed approach to exclude biosimilar biological products and their reference biological products.

1. Proposed GLOBE Model Drug Inclusion Criteria

We propose to apply the following criteria to identify GLOBE Model drugs for an applicable calendar quarter during the GLOBE Model performance period. In advance of each applicable calendar quarter, in 42 CFR 513.130, we propose that CMS would identify the GLOBE Model drugs for that applicable calendar quarter by applying these criteria to Part B rebatable drugs (as identified by CMS as set forth in 42 CFR 427.101): (1) are listed as antigout agents, antineoplastics, blood products and modifiers, central nervous system agents, immunological agents, metabolic bone disease agents, or ophthalmic agents as specified in the USP DC; (2) are single source drugs or sole source biological products as set forth in proposed 42 CFR 513.130; (3) have Medicare Part B FFS spending greater than $100 million over a 12-month period (as further specified in proposed 42 CFR 513.130(d)); and (4) are drug or biological products that are not excluded from the GLOBE Model under proposed 42 CFR 513.130(c). A Part B rebatable drug would have to meet all the four criteria to be included as a GLOBE Model drug.

To identify GLOBE Model drugs for the first criterion for the first applicable calendar quarter of the GLOBE Model performance period, we propose to use the USP Drug Classification 2025 (USP DC 2025) [88] to identify all Part B rebatable drugs that meet the categories listed in Table 3 using their scientific or nonproprietary name(s), brand name, and/or NDC. The publicly available USP DC system has four tiers, of which we propose to use the highest-level tier, USP DC category. CMS believes the drug category level is sufficient to identify therapeutic areas that may have deficits of care, while allowing for differences in mechanism of action and biological or molecular targets for products that treat the same therapeutic area. We recognize that a drug or biological product may be listed in more than one USP DC category. As such, as long as one of the categories listed in Table 3 applies to the drug or biological product, it would be considered to have met this criterion. We also recognize that drug and biological products may be added to the Part B rebatable drug list after the GLOBE Model's start and may not appear in USP DC 2025. As such, we propose that for Part B rebatable drugs that were not previously assigned a USP DC category, CMS would use the most recently published USP DC to identify the category for such Part B rebatable drug to determine whether it meets the first criterion. We also propose that once CMS has identified the USP DC category for a GLOBE Model drug or biological product, it would remain in that category for the entire model duration. Accordingly, drugs or biological products included in the initial GLOBE Model Drug List would retain their USP DC 2025 category, while newly added drugs and biological products to the GLOBE Model Drug List would retain the category assigned at the time of their identification, based on the most recently published USP DC available then. We also propose that, when posted on the GLOBE Model website, the GLOBE Model Drug List would include the USP DC category for each HCPCS Level II code. Table 4 shows the associated USP DC category for an illustrative list of HCPCS Level II codes. The USP DC 2025 has 50 categories of which Medicare Part B rebatable drugs during 2024 are listed in at least 34 of them. Our proposal to include 7 categories represents 21 percent of the 34 possible Medicare Part B rebatable drug categories. Analysis of 2024 Medicare Part B FFS spending data indicates that these 7 USP DC categories were responsible for most Medicare Part B spending (91 percent), with antineoplastics having the highest proportion of any single category at approximately 47 percent.

We are also proposing that if USP creates a new drug category that stems from the drug categories set forth in 42 CFR 513.130(b)(1), then such newly created drug categories would be incorporated into the GLOBE Model drug inclusion criterion. We propose that CMS would make this determination based on a review of USP revision bulletins, revision histories, and corresponding change log information published by USP.

For the second criterion, CMS would focus the GLOBE Model test on a subset of Part B rebatable drugs that are single source drugs or sole source biological products. We recognize by definition, only single source drugs are Part B rebatable drugs and are proposing to use the same definition of single source drug as defined in section 1847A(c)(6)(D) of the Act, which is not a multiple source drug and which is produced or distributed under a new drug application approved by the FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application. A *multiple source drug,* as defined in section 1847A(c)(6)(C) of the Act, means, for a calendar quarter, a drug for which there are 2 or more drug products which: (1) are rated as therapeutically equivalent (under the FDA's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations''); (2) except as provided in section 1847(A)(6)(E) of the Act, are pharmaceutically equivalent and bioequivalent, as determined under section 1847(A)(6)(F) of the Act and as determined by the FDA, and (3) are sold or marketed in the United States during the quarter.

We also propose to define ''sole source biological'' in 42 CFR 513.20 for the purposes of the GLOBE Model as a biological product licensed by the FDA in under a biologics license application (BLA) under section 351(a) of the PHS Act and that, at time of evaluating for inclusion into the GLOBE Model for each applicable ASP calendar quarter, is not the reference biological product, as defined in section 1847A(c)(6)(I) of the Act, for a biosimilar biological product

[88] The USP Drug Classification 2025 file can be found here: *https://www.usp.org/health-quality-safety/usp-drug-classification-system.*

licensed by the FDA in a BLA under section 351(k) of the PHS Act. The biosimilar biological product must be recognized in the FDA's Purple Book and be identified as sold or marketed in FDA's NDC Directory. We note that the proposed definition for sole source biological is different than the definition for *single source biological,* as defined in section 1847A(c)(6)(D) of the Act. As the proposed definition of a sole source biological is based on a 351(a) licensure and not being the reference biological product for a biosimilar biological product sold or marketed, any biological product that meets this definition—even if marketed by any cross-licensed producers or distributors operating under the BLA—qualifies as such sole source biological product. The counterpart to a sole source biological product is a multi-source biological product, and the difference is that they have a reference biological product and a biosimilar biological product that is recognized in the FDA's Purple Book and identified as sold or marketed.

We also propose to use the definition for ''*sold or marketed*'' established in 42 CFR 427.20 which would mean the marketing data as listed in either the ASP data reported to CMS by a manufacturer or an NDC directory list a start marketing date for the biosimilar biological product prior to the applicable calendar quarter and when one of the following criteria is met: (1) the NDC has units reported for the rebate quarter; (2) the end marketing date is during the rebate quarter; (3) the end marketing date is after the rebate quarter; or (4) the end marketing date is missing.

To apply this criterion, we propose, at the time of evaluating inclusion in the GLOBE Model for each applicable ASP calendar quarter, CMS would use the FDA's NDC Directory, including historical information from NDC Directory files such as discontinued, delisted, and expired listings, provided by the FDA or published on the FDA website to determine the marketing status of a biosimilar biological product. We propose that, if a biosimilar biological product is marketed, as determined by CMS for purposes of the GLOBE Model as of the beginning of an applicable calendar quarter, the biosimilar biological product, and reference biological product [89] for such biosimilar biological product would not be included as a GLOBE Model drug for the applicable calendar quarter. We propose that for an applicable calendar quarter CMS would conduct this analysis as of the beginning of the applicable calendar quarter to update the GLOBE Model Drug List.

We recognize for the GLOBE Model that authorized generics and unbranded biological products share the same new drug application approved by the FDA or 351(a) licensure as the original drug and biological product and therefore meet the proposed definition of single source drug and sole source biologicals. As such, authorized generics and unbranded biological products could potentially be GLOBE Model drugs. Authorized generics are drugs sold without their brand name by the original manufacturer or a third party under the NDA of the original drug. Unbranded biological products are biological products sold without their brand name by the original manufacturer or a third party licensed by the BLA 351(a) of the original biological product. Since both authorized generics and unbranded biological products, are directly or indirectly, sponsored by the original pharmaceutical drug manufacturer, we believe that if an authorized generic or unbranded biological product is included in the Medicare Part B Drug Inflation Rebate Program, then, subject to the exclusions described in the next section of this proposed rule, it would be included in the GLOBE Model. In other words, an authorized generic or unbranded biological product could meet the definition of a single source drug or sole source biological product if approved under section 505(c) of the FD&C Act or licensed under section 351(a) of the PHS Act.

For the third criterion, we propose to identify the Part B rebatable drugs with total Medicare Part B FFS allowed charges greater than $100 million over a 12-month period using separately payable final action claims (spend threshold). As specified in 42 CFR 513.130(d), we propose that CMS would identify Medicare Part B FFS final action claims with dates of service within the consecutive 12-month period ending 6 months prior to the start of the applicable calendar quarter that have separately payable allowed charges greater than $0 for any billing and payment code used to describe the GLOBE Model drug, and sum the allowed charges. For example, if the applicable calendar quarter is Q1 2027, all separately payable final action claims with Medicare Part B FFS allowed charges greater than $0 for any billing and payment code used to describe the Part B rebatable drug with a date of service from July 1, 2025 to June 30, 2026 would be summed together to determine if the spend threshold is met. By applying a minimum total annual Medicare Part B FFS spend as an inclusion criteria, CMS intends that the GLOBE Model would be focused on Part B rebatable drugs that account for a significant portion of annual Medicare Part B FFS drug spending and on drugs that would be expected to account for approximately a minimum of $8 million in allowed charges per month under the model. We also propose Part B rebatable drugs would need to meet the spend threshold at least one time during the duration of the GLOBE Model to meet this criterion for the applicable ASP calendar quarter and subsequent applicable ASP calendar quarters. For example, if Drug I meets the $100 million threshold for performance year 1 over a 12-month period for Q3 2026 but not for Q4 2026, Drug I is still considered to have met this criterion for Q4 2026 and the subsequent GLOBE Model ASP calendar quarters and would retain inclusion in the GLOBE Model.

Historical analysis of Medicare Part B FFS drug spending has shown that the majority of spending is focused on a select number of drugs. A threshold of $100 million in total annual Medicare Part B FFS spending applied to Part B rebatable drugs for the consecutive 12-month period ending on December 31, 2024 would encompass 90 percent of the total 2024 Medicare Part B FFS spending on Part B rebatable drugs and account for 21 percent of Part B rebatable drugs (by HCPCS Level II code). This analysis highlights that a small number of Part B rebatable drugs represent the majority of Medicare Part B FFS drug spending. A threshold of $100 million would therefore focus the GLOBE Model on a majority of Medicare Part B drug spending to enable detection of expected savings for the GLOBE Model test while reducing the burden of studying the impacts of the GLOBE Model on all Part B rebatable drugs.

2. Proposed Exclusion of Certain Part B Rebatable Drugs

To avoid interactions with other initiatives and programs that focus on manufacturers of drugs payable under Medicare Part B, in 42 CFR 513.130(c)(1)(ii), we propose to exclude from the GLOBE Model a Part B rebatable drug from the GLOBE Model for which a maximum fair price (MFP) (as defined in section 1191(c)(3) of the Act) under the Medicare Drug Price Negotiation Program is in effect. This proposal would mean that drugs that

[89] Reference product is defined in section 1847A(c)(6)(l) of the Act as ''biological product licensed under section 351 of the PHS Act that is referred to in application described in subparagraph (H) of the biosimilar biological product.'' See *https://www.ssa.gov/OP_Home/ssact/title18/1847A.htm.*

have been selected for Medicare Drug Price Negotiation (under section 1192 of the Act), for which a MFP has been agreed upon, and for which the manufacturer of such drug is required to provide access to the MFP, would be excluded from the GLOBE Model for appliable calendar quarters in which the MFP is in effect.[90] [91] For example, if a GLOBE Model drug is selected for negotiation in 2027 for initial price applicability year 2029, the manufacturer and CMS agree upon a MFP for the drug during 2027, and the MFP would go into effect on January 1, 2029, the GLOBE Model drug would exit the GLOBE Model on December 31, 2028. We note that the earliest date for which a MFP would apply for a drug payable under Medicare Part B is January 1, 2028, per section 1192(a)(3) of the Act. Because we are proposing to begin the GLOBE Model on October 1, 2026, we note that there would be no Part B rebatable drugs that could be a GLOBE Model drug for which the manufacturer is required to provide access to the MFP at model start. We propose that this exclusion from the GLOBE Model would end when the Medicare Part B payment limit for a Part B rebatable drug that would otherwise be eligible to be a GLOBE Model drug is no longer based on the MFP. We believe that excluding drugs when the Medicare Part B payment limit is based on a MFP is appropriate because these drugs are subject to different market dynamics within the U.S., and we believe that including them could confound the model test and impact our ability to evaluate the impacts of the model.

In addition, we propose, in 42 CFR 513.130(c)(1)(i), that a Part B rebatable drug would not be a GLOBE Model drug for applicable calendar quarters prior to the first applicable calendar quarter for which CMS identifies a specified amount pursuant to 42 CFR 427.302(b) for such drug. This proposal would ensure that the GLOBE Model and the Medicare Part B Drug Inflation Rebate Program would treat a subsequently approved drug (that is, a drug first approved or licensed by the FDA after December 1, 2020) in a similar manner. In other words, until a specified amount is established by CMS for a subsequently approved Part B rebatable drug, that drug would not be considered for the GLOBE Model. We note that, given the proposed GLOBE Model drug inclusion criteria in 42 CFR 513.130(b), this exclusion would only be applied to drugs that meet all the proposed inclusion criteria (that is, single source drugs or sole source biological products that are Part B rebatable drugs that are in the USP DC categories shown in Table 3 with total annual Medicare Part B FFS allowed charges greater than the $100 million during the consecutive 12-month period that ends 6 months before the applicable calendar quarter).

We note that during the duration of the GLOBE Model, certain drugs or biological products may no longer be Part B rebatable drugs. As such, in 42 CFR 513.130(c)(1)(iii) we propose that if a GLOBE Model drug is no longer a Part B rebatable drug for an applicable calendar quarter, it would be excluded from the GLOBE Model for that applicable calendar quarter and any other subsequent quarters in which it is no longer rebatable.

3. Summary of GLOBE Model Drug Inclusion and Exclusion

To summarize, GLOBE Model drugs as defined in 42 CFR 513.130 would be a subset of Part B rebatable drugs that: (1) have the listed USP DC categories in Table 3; (2) are single source drugs or sole source biological products; (3) have a HCPCS Level II code with Medicare Part B FFS spending greater than $100 million over a 12-month period; and (4) are not excluded from the GLOBE Model as proposed in 42 CFR 513.130(c).

In addition, once a drug or biological product has been identified as meeting the criterion for inclusion in the GLOBE Model, they would remain in the GLOBE Model unless the drug or biological product becomes multi-source (no longer a single source drug or sole source biological product) or meets the exclusions proposed in 42 CFR 513.130(c).

The drugs or biological products that meet the proposed definition of GLOBE Model drugs are frequently prescribed and administered by various providers in settings such as a physician's office or hospital outpatient department to Medicare beneficiaries with various medical conditions and would have had a minimum of $100 million in Medicare Part B FFS allowed charges over a 12-month period. Examples include drugs used to treat cancer and related conditions, rheumatoid arthritis and other immune mediated conditions, and macular degeneration and other serious eye conditions. Medicare Part B FFS beneficiaries who receive such drugs, often on a recurring basis, face substantial cost-sharing liability directly related to each drug administration in the form of monthly Medicare Part B premiums, the Medicare Part B annual deductible and coinsurance, and premiums and coinsurance through their supplemental insurance. The proposed approach for identifying GLOBE Model drugs could encompass approximately 55 percent [92] of annual Medicare Part B FFS drug spending for separately payable Medicare Part B drugs based on an analysis of all 2024 Medicare Part B FFS claims. This proposed approach also focuses the model test on single source drugs and sole source biological products with high Medicare Part B program expenditures that could have beneficiaries with deficits of care due to high costs.

Table 4, Illustrative GLOBE Model Drug HCPCS Level II Code List, in section II.B.6. of this proposed rule shows an illustrative list of how the GLOBE Model could apply to Part B drugs by HCPCS Level II code using available claims information from calendar year (CY) 2024 after applying the proposed drug inclusion and exclusions as discussed in this section of this proposed rule. This illustrative list may not fully capture all relevant HCPCS Level II codes for potential GLOBE Model drugs and may include HCPCS Level II codes for drugs that may not meet the inclusion criteria and exclusion criteria that would be specified in a final rule establishing the GLOBE Model.

4. Alternatives Considered

We considered including all Part B rebatable drugs in the GLOBE Model. However, Medicare Part B FFS drug spending is concentrated among high expenditure drugs, with 50 drugs (by HCPCS Level II code) accounting for 64 percent of 2024 Medicare Part B FFS

[90] CMS. Medicare Drug Price Negotiation Program: Final Guidance, Implementation of sections 1191 through 1198 of the Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028. September 30, 2025. Available at: *https://edit.cms.gov/files/document/ipay-2028-final-guidance.pdf.*

[91] In accordance with the IRA, CMS engages in good-faith negotiations with participating companies and uses statutory factors listed at section 1194(e) of the Act as the basis for negotiation an MFP. A Primary Manufacturer with a selected drug is required to ensure that the negotiated price, the MFP, is made available to MFP-eligible individuals and to pharmacies, mail order services, and other dispensing entities with respect to such MFP-eligible individuals who are dispensed such drug, and to hospitals, physicians, and other providers of services and suppliers with respect to such MFP-eligible individuals to whom they furnish or administer such drug. The MFP applies to a selected drug during its price applicability period.

[92] This statistic is based on an evaluation of all 2024 Medicare Part B FFS claims that would meet the GLOBE Model inclusion and exclusion criteria and does not account for any geography distinctions. Refer to section II.F. of this proposed rule for discussion on proposed GLOBE Model geographies.

drug spending. We also noted that many Medicare Part B rebatable drugs have average monthly total Medicare Part B FFS allowed charges of less than $10 million. For example, using separately payable claims, 302 Medicare Part B rebatable drugs had less than $100 million in total 2024 Medicare Part B FFS drug spending each, representing 7 percent of total 2024 Medicare Part B FFS drug spending. Similarly, 266 Medicare Part B rebatable drugs had less than $50 million in total 2024 Medicare Part B FFS drug spending each, accounting for 3 percent of total 2024 Medicare Part B FFS drug spending. These lower spend drugs could have approximately $8 million or less in allowed charges per month paid under the GLOBE Model, based on our proposed model design described in section II.B of this proposed rule. However, the approximately 80 Part B rebatable drugs with greater than $100 million in 2024 Medicare Part B FFS allowed charges accounted for 61 percent of 2024 Medicare Part B FFS drug spending. As such, it may be too burdensome for the operational and administrative efforts to include Part B rebatable drugs with less than $100 million in total Medicare Part B FFS allowed charges during a consecutive 12-month period in the model test at this time in order to detect potential changes in Medicare spending or beneficiaries' quality of care. We believe that the model test and evaluation could be efficiently focused on Medicare Part B rebatable drugs with over $100 million in total annual Medicare Part B FFS spending without sacrificing the potential for meaningful model findings and learning. Therefore, we are not proposing to include all Part B rebatable drugs in the GLOBE Model and instead are proposing to focus the model on a subset of drugs that would be anticipated to have a meaningful amount of Medicare spending under the model test and address deficits of care for beneficiaries.

In addition, we considered the alternative of including all Part B rebatable drugs in the GLOBE Model, which would introduce multi-source biological products (biosimilar biological products and their reference biological products) into the model. Most of the biosimilar biological products that are available now and are separately payable under Medicare Part B are qualifying biosimilar biological products, which are excluded from the definition of Part B rebatable drugs, and as such could be excluded from being a Part B rebatable drug for some portion of the model performance period. We recognize the list of qualifying biosimilar biological products may also change quarterly when the ASP of the biosimilar biological product exceeds the ASP of the reference biological product or when the applicable 5-year period for a temporary payment add-on has elapsed. Therefore, if biosimilar biological products that are not qualifying biosimilar biological products for an applicable calendar quarter were included as GLOBE Model drugs, there could be operational challenges related to monitoring, potential for beneficiary and healthcare provider confusion related to beneficiary coinsurance changes during the GLOBE Model performance years, and increased complexity and potential challenges in operating the model evaluation. As such and to meet our model intent, we propose to exclude biosimilar biological products licensed under 351(k) of the PHS Act and their reference biological products as proposed in 42 CFR 513.130(b).

We considered an alternate exclusion process for reference biological products by requiring the manufacturers of the reference biological product to submit an attestation of when a competing biosimilar biological product would be sold in the U.S. However, assessing whether market competition exists after a biosimilar biological product has been licensed by the FDA under section 351(k) of the PHS Act would likely require substantial investigation to verify a specific date of first sale. There would be insufficient time for CMS to review requests by a manufacturer of a reference biological product for GLOBE Model exclusion before the manufacturer submits ASP information for the applicable calendar quarter and prior to determination of the GLOBE Model beneficiary coinsurance for included drugs. Further, manufacturers of reference biological products may not have an accurate estimation of when sales of a biosimilar biological product would be first sold in the U.S. Therefore, our proposed approach to use the sold or marketed definition established in 42 CFR 427.20 and FDA's NDC Directory to identify biosimilar biological products that are marketed would likely be a faster and more efficient way than verifying reference biological product manufacturer attestations to identify when a biosimilar biological product and its reference biological product would be excluded from the GLOBE Model drug list of an applicable calendar quarter to support our goal of focusing the model test on single source drugs and sole source biological products.

We also considered including additional USP DC categories such as antimyasthenic agents, cardiovascular agents, dermatological agents; genetic, enzyme, or protein disorder: replacement, modifiers, treatment; and respiratory tract/pulmonary agents, which are also categories represented in Part B rebatable drugs with Medicare Part B FFS spending over $100 million in 2024. However, we believe starting the model with the high expenditure therapeutic areas and their USP DC categories shown in Table 3 would help focus the model test on patients with related conditions that are likely exposed to higher financial burden and greater deficits of care. We may explore a future expansion to other high spend USP DC categories outside of the therapeutic areas listed in Table 3 after we have made operational and administrative progress with respect to the model. We also considered reviewing the latest published USP DC at the beginning of each applicable calendar quarter to determine if a drug or biological product has changed categories. However, we believe using the 2025 USP DC for the GLOBE Model drug list, except in the case of drugs and biological products added after model start, would maintain data standardization. Similarly, we also believe keeping the same category for each drug and biological product once identified also maintains data standardization and allows CMS to test and evaluate an alternative Part B inflation rebate amount calculation. In addition, we considered categorizing the drugs or biological products by therapeutic areas such as endocrinology, immunology, rheumatology, oncology, or ophthalmology or for CMS to develop a classification method. However, we believe using a publicly available drug classification list such as the USP DC provides for a more transparent and straightforward method for identifying GLOBE Model drugs.

We considered other alternatives to the proposed subset of Part B rebatable drugs included as GLOBE Model Drugs such as including only a certain number of Part B rebatable drugs; only including drugs with high utilization among the Medicare population, for example, drugs furnished to more than 20,000 Medicare Part B FFS beneficiaries during a specified period; [93] and

[93] The minimum number of beneficiaries for a drug selected for the Medicare Drug Price Negotiation Program for the Initial Price Applicability Year 2026 is 20,000 (Imbruvica). Based on internal CMS analysis, if this was used as a threshold, then approximately 17 percent of all HCPCS Level II codes billed under Medicare Part B in 2024 would have met this criterion.

including drugs based on high annual per beneficiary coinsurance liability, for example, drugs with an average per beneficiary coinsurance amount greater than $200 during a consecutive 12-month period (assuming a coinsurance percentage of 20 percent, this alternative would focus on drugs with approximately $1,000 or more in average per beneficiary Medicare Part B allowed charges during a consecutive 12-month period). We also considered phasing in the inclusion of Part B rebatable drugs in the GLOBE Model over time, for example, starting the model with 50 drugs and adding drugs at the beginning of each performance year until all Part B rebatable drugs that would not be specifically excluded would be included in the model.

We are also considering if the spend threshold (total Medicare Part B FFS allowed charges greater than $100 million over a 12-month period) would be adjusted for each subsequent performance year by the percentage increase or decrease in the CPI–U for the previous performance year. This would mean that for each subsequent performance year, the GLOBE Model spend threshold would adjust to account for inflation. We welcome comments on whether CMS should update the spend threshold based on inflation.

We considered these alternative approaches and believe that focusing the model on higher spend drugs that impact beneficiaries who likely have a deficit of care allows a transparent, consistent, and clear approach that would provide sufficient opportunity to observe the impacts of the model test on a sufficient number of Medicare FFS beneficiaries who may receive a Part B rebatable drug. Our proposed approach would minimize complexity within the model implementation and evaluation and improve CMS' ability to understand the findings from model monitoring and evaluation activities by focusing on a subset of beneficiaries. We believe the benefits of including the higher spend drugs for specific USP DC categories of Part B rebatable drugs in the GLOBE Model with limited exclusions as discussed in this section of this proposed rule enable the model to encompass a large number of Part B rebatable drugs without increasing complexity and burden that may occur with a larger set of Part B rebatable drugs.

We welcome comments on our process for identifying the USP DC categories, our method for identifying and excluding certain drugs, and the alternatives we considered. We also welcome comments on CMS' proposed process for when a reference biological product would be excluded from the list of GLOBE Model drugs for an applicable calendar quarter. Specifically, we seek feedback on ways CMS could structure the exclusion process to minimize the potential for excluding a reference biological product for a biosimilar biological product that is marketed under a license under 351(k) of the PHS Act but not sold during an applicable calendar quarter.

5. Considerations Related to Cell and Gene Therapies and Plasma-Derived Products

We are also considering excluding cell and gene therapies (CGTs) from the GLOBE Model. CGTs include cellular immunotherapies, cancer vaccines and other products aimed to treat or prevent certain diseases including cancer, genetic diseases, and infectious diseases. We seek comments on the merits of excluding CGTs based on supply chain criteria, or if there are other factors that warrant their inclusion or exclusion. We similarly welcome comments on whether the GLOBE Model would exclude plasma-derived products, particularly because these products may be more likely to experience shortages and the rebate amount for these products may be reduced as discussed in section II.G. of this proposed rule.

6. Illustrative List of Proposed Performance Year 1 GLOBE Model Drugs and Model Participants

To create an illustrative GLOBE Model Drug HCPCS Level II Code List, we identified the 2024 Part B rebatable drugs by HCPCS Level II code, applied the proposed GLOBE Model drug inclusion criteria and exclusions as discussed in sections II.B.1. and II.B.2. of this proposed rule. Using this approach, an illustrative GLOBE Model Drug HCPCS Level II Code List is shown in Table 4 and includes drugs and biological products that met the proposed criteria for at least one applicable calendar quarter in 2024. Table 4 is an illustrative list of how the GLOBE Model might apply to Part B rebatable drugs and is not intended as a list of GLOBE Model drugs or Part B rebatable drugs that would be applicable for a quarter in a performance year. Further, this illustrative list is based on CMS' initial analyses and proposals discussed in this proposed rule and is provided for informational purposes only. Readers should note that the illustrative list may not reflect the final model design and does not indicate that these drugs or biological products would owe a GLOBE Model rebate.

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TABLE 4: ILLUSTRATIVE GLOBE MODEL DRUG HCPCS LEVEL II CODE LIST*

HCPCS Level II Code	Short Description	USP DC Category
J0129	Abatacept injection	Immunological Agents
J0178	Aflibercept injection	Ophthalmic Agents
J0485	Belatacept injection	Immunological Agents
J0490	Belimumab injection	Immunological Agents
J0717	Certolizumab pegol inj 1mg	Immunological Agents
J0881	Darbepoetin alfa, non-esrd	Blood Products and Modifiers
J0896	Inj luspatercept-aamt 0.25mg	Blood Products and Modifiers
J0897	Denosumab injection	Antineoplastics/Metabolic Bone Disease Agents
J1300	Eculizumab injection	Immunological Agents
J1303	Inj., ravulizumab-cwvz 10 mg	Immunological Agents
J1459	Inj ivig privigen 500 mg	Immunological Agents
J1555	Inj cuvitru, 100 mg	Immunological Agents
J1559	Hizentra injection	Immunological Agents
J1561	Gamunex-c/gammaked	Immunological Agents
J1568	Octagam injection	Immunological Agents
J1569	Gammagard liquid injection	Immunological Agents
J1602	Golimumab for iv use 1mg	Immunological Agents
J1930	Lanreotide injection	Antineoplastics
J2323	Natalizumab injection	Central Nervous System Agents
J2350	Injection, ocrelizumab, 1 mg	Central Nervous System Agents
J2353	Octreotide injection, depot	Antineoplastics
J2357	Omalizumab injection	Immunological Agents
J2507	Pegloticase injection	Antigout Agents
J2777	Inj, faricimab-svoa, 0.1mg	Ophthalmic Agents
J2781	Inj, pegcetacoplan, 1mg	Immunological Agents
J2796	Romiplostim injection	Blood Products and Modifiers
J3111	Inj. romosozumab-aqqg 1 mg	Metabolic Bone Disease Agents
J3241	Inj. teprotumumab-trbw 10 mg	Ophthalmic Agents
J3245	Inj., tildrakizumab, 1 mg	Immunological Agents
J3262	Tocilizumab injection	Immunological Agents
J3380	Inj vedolizumab iv 1 mg	Immunological Agents
J7170	Inj., emicizumab-kxwh 0.5 mg	Blood Products and Modifiers
J7503	Tacrol envarsus ex rel oral	Immunological Agents
J9022	Inj, atezolizumab,10 mg	Antineoplastics
J9023	Injection, avelumab, 10 mg	Antineoplastics
J9042	Brentuximab vedotin inj	Antineoplastics
J9043	Cabazitaxel injection	Antineoplastics
J9047	Injection, carfilzomib, 1 mg	Antineoplastics
J9055	Cetuximab injection	Antineoplastics
J9063	Inj, elahere, 1 mg	Antineoplastics
J9119	Inj., cemiplimab-rwlc, 1 mg	Antineoplastics
J9144	Daratumumab, hyaluronidase	Antineoplastics
J9145	Injection, daratumumab 10 mg	Antineoplastics
J9173	Inj., durvalumab, 10 mg	Antineoplastics
J9177	Inj enfort vedo-ejfv 0.25mg	Antineoplastics
J9223	Inj. lurbinectedin, 0.1 mg	Antineoplastics
J9228	Ipilimumab injection	Antineoplastics
J9271	Inj pembrolizumab	Antineoplastics
J9272	Inj, dostarlimab-gxly, 10 mg	Antineoplastics
J9298	Inj nivol relatlimab 3mg/1mg	Antineoplastics
J9299	Injection, nivolumab	Antineoplastics
J9301	Obinutuzumab inj	Antineoplastics

HCPCS Level II Code	Short Description	USP DC Category
J9303	Panitumumab injection	Antineoplastics
J9306	Injection, pertuzumab, 1 mg	Antineoplastics
J9308	Injection, ramucirumab	Antineoplastics
J9309	Inj, polatuzumab vedotin 1mg	Antineoplastics
J9316	Pertuzu, trastuzu, 10 mg	Antineoplastics
J9317	Sacituzumab govitecan-hziy	Antineoplastics
J9354	Inj, ado-trastuzumab emt 1mg	Antineoplastics
J9358	Inj fam-trastu deru-nxki 1mg	Antineoplastics
Q2043	Sipuleucel-t auto cd54+	Antineoplastics
Q2056	Ciltacabtagene car-pos t	Antineoplastics

*Note: The scientific or nonproprietary name was used to identify the 2025 USP DC category. A HCPCS Level II code may belong in more than one USP DC Category.

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C. Proposed Defined Population

For the GLOBE Model design, we considered ways to identify the Medicare beneficiaries who would be eligible for inclusion in either the intervention or comparison groups. After considering a number of factors, we propose to use a geographically randomized design such that the defined population for the GLOBE Model would be a set of CMS-selected Medicare Part B FFS beneficiaries who are identified as eligible for inclusion in the model cohort as set forth in 42 CFR 513.120 and receive a GLOBE Model drug (as set forth in 42 CFR 513.130) during the model performance period for which separate Medicare Part B payment is made under the GLOBE Model. The Medicare Part B FFS beneficiaries who are identified as eligible for inclusion in the model cohort would be included in the model cohort as a GLOBE Model beneficiary as of the date they are furnished a GLOBE Model drug for which separate Medicare Part B payment is made during the model performance period. GLOBE Model beneficiaries would be eligible for the GLOBE Model adjusted beneficiary coinsurance for GLOBE Model drugs, if applicable, and would remain in the model cohort unless they no longer meet the criteria for inclusion. A GLOBE Model beneficiary may receive one or more GLOBE Model drugs.

Specifically, we propose that, prior to the model start, CMS would randomly identify the model geographic areas (based on ZIP Code Tabulation Areas as discussed in section II.F.2. of this proposed rule). We also propose that, prior to model start and periodically thereafter, but no more frequently than weekly, CMS would identify eligible Medicare FFS beneficiaries (as set forth in 42 CFR 513.120) and update the *GLOBE Model Eligible Beneficiary List,* which would be effective when the Medicare claims processing system are updated with the *GLOBE Model Eligible Beneficiary List* information. We propose that the identification of eligible beneficiaries and the timing of such identification and updating of the *GLOBE Model Eligible Beneficiary List* and the Medicare claims processing systems, as well as the identification of Medicare FFS beneficiaries who are eligible for inclusion in the comparison group, would be performed by CMS and would not be subject to review. In 42 CFR 513.120, we propose how CMS would identify the Medicare beneficiaries who would be eligible for inclusion in the model cohort and comparison group. In 42 CFR 513.20, we propose to define the term ''GLOBE Model eligible beneficiary'' as a Medicare beneficiary who has been identified by CMS for potential inclusion in the model and added to the *GLOBE Model Eligible Beneficiary List* for some or a portion of the GLOBE Model performance period as set forth in 42 CFR 513.120. Specifically, in 42 CFR 513.120(b), we propose that, approximately 30 days prior to model start using available Medicare program administrative information as determined by CMS, CMS would identify Medicare beneficiaries who are enrolled in Medicare Part B, have Traditional Medicare Part B as their primary payer, and have an address of record within the GLOBE Model geographic areas selected for inclusion in the model at model start (as identified by CMS under 42 CFR 513.110(c)), as determined by CMS. These beneficiaries would encompass the Medicare FFS beneficiaries who would be eligible for inclusion in the GLOBE Model at model start. CMS would add such beneficiaries to the *GLOBE Model Eligible Beneficiary List* and update the Medicare claims processing systems with such list for the first applicable calendar quarter of performance year one.

Similarly, in 42 CFR 513.120(b)(2), we propose that, approximately 30 days prior to model start using available Medicare program administrative information as determined by CMS, we would identify Medicare beneficiaries who are enrolled in Medicare Part B, have Traditional Medicare Part B as their primary payer, and do not have an address of record within the GLOBE Model geographic areas selected for inclusion in the model at model start (as identified by CMS under 42 CFR 513.110(c)), as determined by CMS. These beneficiaries would be assigned as being eligible for inclusion in the comparison group. For a discussion on the evaluation, see section II.P. of this proposed rule.

To maintain a clear record of which beneficiaries are eligible for inclusion in the model cohort, in 42 CFR 513.120(c), we propose that, CMS would update the *GLOBE Model Eligible Beneficiary List* periodically, but not more frequently than weekly, using available Medicare program administrative information as determined by CMS, to: (1) identify the Medicare beneficiaries who are enrolled in Medicare Part B, have Traditional Medicare Part B as their primary payer, and have an address of record within the GLOBE Model geographic areas selected for inclusion (as identified by CMS under 42 CFR 513.110(c)), are not yet included on the *GLOBE Model Eligible Beneficiary List,* are not assigned as eligible for the comparison group, and adds such beneficiaries to the *GLOBE Model Eligible Beneficiary List* at the next update; and (2) identify beneficiaries on the *GLOBE Model Eligible Beneficiary List* that no longer meet the criteria for a GLOBE Model eligible beneficiary and removes such beneficiaries from the *GLOBE Model Eligible Beneficiary List* at the next update. CMS would not routinely reevaluate the eligibility of beneficiaries who were identified as eligible for the comparison group. That is, beneficiaries

who are identified as eligible for inclusion in the comparison group prior to model start would remain eligible for inclusion in the comparison group and model monitoring and analyses as determined by CMS.

In 42 CFR 513.120(d), we propose beneficiary exclusions for clarity regarding the beneficiaries who would not be eligible for assignment to the *GLOBE Model Eligible Beneficiary List* or comparison group, as applicable: beneficiaries who do not have Medicare Part B FFS as their primary payer, and beneficiaries who are enrolled in a Medicare Advantage plan, section 1876 of the Act cost plan, section 1833 of the Act healthcare prepayment plans, or who have other group health coverage that is a primary payer (such as employer-sponsored health insurance). In addition, 42 CFR 513.120(d)(3) clarifies that beneficiaries who are identified by CMS as eligible for inclusion in the comparison group prior to model start remain eligible for the comparison group as determined by CMS.

We propose that, for purposes of identifying a beneficiary's address and determining if the beneficiary's address is within the GLOBE Model geographic areas, we would use the beneficiary's address as recorded in CMS' Medicare Beneficiary Database (MBD), System No. 09–70–0536, at the time CMS identifies beneficiaries for inclusion in the model. We also propose to define in 42 CFR 513.20 the term ''GLOBE Model geographic areas'' as the set of ZIP Codes in the U.S., excluding U.S. territories identified as set forth in 42 CFR 513.110 (as discussed in section II.F. of this proposed rule).

Under our proposed approach for identifying the defined population, beneficiaries who are identified by CMS as a GLOBE Model eligible beneficiary, at the start of the model or subsequently, would be added to the *GLOBE Model Eligible Beneficiary List* and remain on the list until the model ends or the beneficiary is no longer enrolled in Medicare FFS or is otherwise ineligible for inclusion. For example, if a beneficiary is identified for inclusion on the *GLOBE Model Eligible Beneficiary List* based on the beneficiary's address as recorded in CMS' Medicare Beneficiary Database (MBD) being within the selected model geographic areas and then subsequently the beneficiary's address recorded in CMS' MBD changes such that the beneficiary no longer has an address within the GLOBE model geographic areas, the beneficiary would continue to be assigned as a GLOBE Model eligible beneficiary unless the beneficiary is no longer enrolled in Medicare FFS or is otherwise ineligible for inclusion. Beneficiaries who become newly enrolled in Medicare FFS due to becoming newly eligible for Medicare FFS after the model begins and are identified by CMS as a GLOBE Model eligible beneficiary (because all criteria are met) would be added to the *GLOBE Model Eligible Beneficiary List* from the time CMS next updates the list and remain on the list unless the beneficiary is no longer enrolled in Medicare FFS or is ineligible for inclusion. Beneficiaries for whom Medicare Part B FFS switches from being a secondary payer to being the primary payer and who are identified by CMS as a GLOBE Model eligible beneficiary (because all criteria are met) would be added to the *GLOBE Model Eligible Beneficiary List* when CMS next updates the list and remain on the list unless the beneficiary is no longer enrolled in Medicare FFS or is ineligible for inclusion. No other beneficiaries would be added to the *GLOBE Model Eligible Beneficiary List.* For example, the following changes would not enable beneficiary inclusion on the *GLOBE Model Eligible Beneficiary List* after the model starts: (1) beneficiaries who were enrolled in Medicare Part B at the time CMS creates the initial *GLOBE Model Eligible Beneficiary List* prior to the start of the model and had an address within CMS' MBD that was not selected as a GLOBE Model geographic area then had an address change to a GLOBE Model geographic area; and (2) newly enrolled Medicare Part B FFS beneficiaries with an address with a new ZIP Code that did not exist at the time that the GLOBE Model geographic areas were identified. In addition, beneficiaries who were identified by CMS as being eligible for the comparison group would not be eligible for the model cohort.

Testing the GLOBE Model in this population would allow the GLOBE Model alternative rebate test to apply to a broad set of conditions, clinical settings, localities, and manufacturers rather than having the model test focus on a limited set of conditions, drugs (for example, only including drugs approved under section 505 of the FD&C Act) or a single type of clinical setting (for example, only including GLOBE Model drugs that are furnished in a physician's office). Defining the population broadly and in a manner that fosters a stable and consistent model cohort and comparison group would allow CMS to observe the implications of an alternative approach to determining the net Medicare payment for GLOBE Model drugs across a broad set of providers and suppliers and beneficiaries, as well as a large set of manufacturers.

D. Proposed Scale for Inclusion of GLOBE Model Beneficiaries

Section 1115A(b) of the Act gives the Secretary discretion in the design of models, including the geographic reach of models. Section 1115A(a)(5) of the Act states that the Secretary may elect to limit testing of a model to certain geographic areas. Testing a model in randomly selected geographic areas facilitates identification of the intervention and comparison groups for model implementation. We have considered the variation in cost and use in the Medicare population of proposed GLOBE Model drugs along with other aspects of the proposed model design and determined that a sufficient allocation between intervention and comparison groups for achieving precise estimates in tests is approximately 25 percent of Medicare FFS beneficiaries. To determine the geographic areas that CMS would use to identify approximately 25 percent of Medicare FFS beneficiaries as GLOBE Model eligible beneficiaries, we propose that CMS would select geographic regions to represent 25 percent of Medicare FFS beneficiaries (as described in section II.F.2. of this proposed rule).

E. Proposed Model Participants

1. Proposed Mandatory Participation of Manufacturers of GLOBE Model Drugs

We propose that model participation would be mandatory for all manufacturers of GLOBE Model drugs (as described in section II.B. of this proposed rule) that are furnished to a GLOBE Model beneficiary during the GLOBE Model performance period. We propose that, for purposes of the GLOBE Model, ''manufacturer'' would have the same meaning as that term is defined and used in section 1847A(c)(6)(A) of the Act and 42 CFR 427.20. We note that this is consistent with how CMS defines ''manufacturer'' for purposes of the Medicare Part B Drug Inflation Rebate Program. We also note that the proposed GLOBE Model drugs, as single source drugs and sole source biological products, usually have one manufacturer. However, there could be GLOBE Model drugs for which multiple manufacturers report ASP data to CMS, for example, when there is a repackager or relabeler or when more than one manufacturer markets a single source drug or sole source biological product within the U.S. In such cases, we propose that all manufacturers of a GLOBE Model drug would each be

required to participate in the GLOBE Model.

We propose to define ''GLOBE Model participant'' as a manufacturer of a GLOBE Model drug that is required to participate in the GLOBE Model in accordance with proposed 42 CFR 513.100. We propose that there would be no specific enrollment activities for GLOBE Model participants; rather, their participation would be effectuated by the requirements under the Medicare Part B Drug Inflation Rebate Program, and where applicable, the application of the proposed GLOBE Model calculation for the GLOBE Model rebate amount. Mandatory participation can enhance the generalizability of model results, as mandatory model participants may be more broadly representative of all entity types that could be affected by a model. Requiring manufacturer participation in the GLOBE Model would allow us to observe the experiences of manufacturers of drugs with diverse characteristics. Further, we believe mandatory participation in the GLOBE Model would be essential to the model test because we believe that, despite the potential for the GLOBE Model to lower beneficiaries' financial liability for a manufacturer's Part B rebatable drug and reduce financial barriers to access such drugs which could increase utilization of such drugs, manufacturers of proposed GLOBE Model drugs would likely not volunteer to participate in this model.

In the proposed 42 CFR 513.100(a), we propose to codify that model participation would be mandatory for all manufacturers of GLOBE Model drugs.

We considered excluding manufacturers where the U.S. manufacturer may not be the same entity that is responsible for sales in other countries. Another option we considered was to except manufacturers that had existing sales or licensing agreements with other entities outside of the U.S. to sell GLOBE Model drugs prior to the publication of this NPRM. However, we were concerned about the possibility of manufacturers transferring responsibilities to other entities to avoid model participation. We also considered an application process through which a manufacturer could qualify for a model exemption given their lack of responsibility for sales of drugs outside of the U.S. However, given the complex nature of manufacturer relationships outside of the U.S., such an exclusion might potentially being too broad, diluting CMS' ability to rigorously evaluate the model's impact on costs and quality. Having considered these alternatives, CMS is not proposing such exclusions. We also seek comment on other factors, for example, manufacturer size, that CMS could consider exempting certain manufacturers while maintaining sufficient model participation and a robust model test.

We seek comments on our proposal for mandatory participation in the GLOBE Model by all manufacturers that may be subject to the model (that is, manufacturers of Part B rebatable drugs that could be designated as GLOBE Model drugs pursuant to the criteria in proposed 42 CFR 513.130). We also seek feedback on whether manufacturers of proposed GLOBE Model drugs would voluntarily participate in the proposed GLOBE Model absent a mandatory participation requirement and feedback on evidence that could support a voluntary participation approach which would ensure sufficient model participation for a robust model test and evaluation during performance year 1 and thereafter.

2. Proposed Model Participation Requirements

In 42 CFR 513.100, we propose to codify GLOBE Model participant requirements during the GLOBE Model test period. During the GLOBE Model test period described in proposed 42 CFR 513.100(b), we propose that GLOBE Model participants must—

- Adhere to the proposed GLOBE Model rebate payment instructions as proposed in 42 CFR 513.740 and established by CMS and its contractors responsible for providing rebate reports containing GLOBE Model rebate amounts and processing payments, including without limitation those described in proposed 42 CFR 513.500, to ensure appropriate and accurate GLOBE Model rebate payments; and
- Participate in GLOBE Model monitoring and evaluation activities in accordance with 42 CFR 403.1110(b), including collecting and reporting of information as the Secretary determines is necessary to monitor and evaluate the GLOBE Model.
- If electing to submit international drug net pricing data, adhere to the requirements set forth in proposed 42 CFR 513.610 and the GLOBE Model data agreement.

In addition, for GLOBE Model participants that elect to submit international drug net pricing data for the applicable ASP calendar quarter beginning April 1, 2025, we propose that such GLOBE Model participants would be required to adhere to the requirements set forth in proposed 42 CFR 513.620 and the GLOBE Model data agreement prior to the start of performance year 1.

We seek comments on our proposal for model participation requirements from potential GLOBE Model participants.

We refer readers to section II.G.6. of this proposed rule for a discussion of the option for eligible manufacturers of separately payable Part B single source drugs and sole source biological products determined to be GLOBE Model drugs to voluntarily submit manufacturer international net drug pricing information to CMS for purposes of identifying a per unit Method II GLOBE Model benchmark which could potentially lower the total GLOBE Model rebate amount that a GLOBE Model participant would be responsible for. If electing to submit international drug net pricing data, we propose that the manufacturer must adhere to the requirements set forth in proposed 42 CFR 513.610 and in the proposed GLOBE Model data agreement as described in proposed 42 CFR 513.620.

3. Standard Provisions

We propose that the Standard Provisions for Innovation Center Models, originally established in 42 CFR part 512, subpart A and applicable to certain Innovation Center models, would not apply to the GLOBE Model. Given the unique characteristics and operational framework of the GLOBE Model, we believe it differs substantially from most mandatory Innovation Center models. Therefore, rather than applying the Standard Provisions, we propose implementing GLOBE-specific requirements that would provide the necessary regulatory specificity and flexibility to effectively test and evaluate the GLOBE Model's innovative approach.

We propose specific audit, record access, and retention requirements for manufacturers participating in the GLOBE Model. These provisions are essential to ensure program integrity, enable proper oversight of the model's implementation, and protect the interests of Medicare beneficiaries and the Federal government. Given the unique structure and operational characteristics of the GLOBE Model, we believe it is necessary to establish clear audit rights, record access requirements, and retention standards that are specifically tailored to this model's framework.

We propose at § 513.100(d)(1) to establish explicit Federal audit rights to ensure that CMS, HHS, the Comptroller General, and their designees maintain comprehensive oversight authority over GLOBE Model implementation. This provision is necessary to verify compliance with model requirements,

assess program effectiveness, and identify potential areas for improvement or corrective action.

We propose at § 513.100(d)(2) record access requirements would ensure that manufacturers maintain and provide access to all documentation necessary for effective oversight. This includes, but is not limited to, records supporting the accuracy of voluntarily-submitted data and documentation related to CMS identified program integrity issues. Such access is critical for validating manufacturer-reported information and ensuring the model operates as intended.

We propose at § 513.100(d)(3) a six-year retention period for GLOBE Model-related records, with extensions under specific circumstances. This timeframe aligns with standard Federal audit and investigation cycles while providing flexibility for situations involving disputes, fraud allegations, or special retention needs identified by CMS. The proposed retention requirements balance the need for thorough oversight with reasonable administrative burden on participating manufacturers.

We propose at § 513.100(d)(4) that in the event we terminate the GLOBE Model, we would provide written notice to GLOBE Model participants specifying the grounds for termination and the effective date of such termination. As provided by section 1115A(d)(2) of the Act termination of the model under section 1115A(b)(3)(B) of the Act would not be subject to administrative or judicial review.

We seek comment on our proposed requirements for audit, record access, and record retention, and model termination parameters for GLOBE Model manufacturers.

F. Proposed GLOBE Model Test Design and Geographic Areas

1. Proposed Model Test Design

In 42 CFR 513.110, for the model test design, we propose a randomized design in which the GLOBE Model geographic reach would be determined by selection of geographic areas where approximately 25 percent of Medicare Part B FFS beneficiaries have an address of record within CMS' MBD (as determined by CMS as set forth in 42 CFR 513.120) and CMS would identify the selected geographic areas for the model start. Model test geographic areas would be randomly selected to balance the Medicare beneficiary population and Medicare expenditures nationwide. We also propose that after CMS finalizes a rule establishing the GLOBE Model, no later than 30 calendar days in advance of model start, CMS would provide a table on the GLOBE Model website that lists the GLOBE Model geographic areas by ZIP Code. CMS may include other information such as total Medicare beneficiary statistics and total Medicare Part A and Medicare Part B FFS expenditures. This table would identify the GLOBE Model geographic areas for model start. CMS would not change the list of GLOBE Model geographic areas by ZIP Code after the initial random selection of the model geographic areas. For example, during the model performance period, if a ZIP Code that is within the GLOBE Model geographic areas is split or redesignated, that ZIP Code would not get reassigned to a GLOBE Model geographic area.

2. Proposed Unit of Analysis

In developing the proposed GLOBE Model, CMS determined that conducting the proposed GLOBE Model test in the population of Medicare FFS beneficiaries who may receive Part B rebatable drugs that are included in the model (as discussed in section II.C. of this proposed rule) would provide the best means for testing an innovative payment model using the alternative rebate calculation. Defining the population in this manner would allow CMS to assess if the GLOBE Model payment test reduced Medicare costs while preserving or enhancing quality of care, in line with section 1115A(b)(2) of the Act across a broad set of providers and suppliers and beneficiaries, as well as a broad set of manufacturers. Learnings from the GLOBE Model would inform CMS and other interested parties about the effect of applying the proposed innovative rebate approach to a broad set of drugs on a diverse set of beneficiaries and to the Medicare program.

3. Proposed Method for Identification of GLOBE Model Geographic Areas

a. Proposed Geographic Unit of Randomization

We considered establishing the unit of geography CMS would use for randomization and for evaluation of model impacts based on existing well-defined geographic units that were sufficiently numerous to support statistical analysis. Based on CMS' review of existing defined geographic units that are suitable for statistical purposes, CMS, after consideration of alternatives, identified that ZIP Code Tabulation Areas (ZCTAs) would be an appropriate geographic unit for a limited scope model and for the proposed GLOBE Model specifically. ZIP Code Tabulation Areas (ZCTAs) are approximate area representations of USPS five-digit ZIP Code service routes that the Census Bureau creates using whole blocks to present statistical data from censuses and surveys. A change in site of service due to a difference in incentives between the intervention and comparison group could bias statistical analyses. Given that beneficiary address would be the basis for their geographic assignment as eligible for the model test or comparison group, the site of service for the administration of a GLOBE Model drug would not bias statistical analyses. As a result, the smallest practical geographic area is preferred to allow for a simpler randomized design, that would involve fewer strata or weights. A simple random selection of small geographic units would achieve the desired balance for both observable and unobservable characteristics between the model test and comparison groups. In particular, it would allow us to achieve our intended geographic scope in terms of approximate share of beneficiaries and Medicare spending.

Therefore, we are proposing to identify the GLOBE Model geographic areas through a simple random selection of 25 percent of all ZIP Code Tabulation Areas (ZCTAs) in the U.S., excluding the U.S. territories. Specifically, in 42 CFR 513.110(a), we propose that the GLOBE Model geographic areas would be identified by ZIP Codes that are aligned with ZCTAs that are randomly selected by CMS no later than 60 calendar days prior to the start of the model performance period. During the model performance period, if a ZIP Code that is within the GLOBE Model geographic areas is split or redesignated, that ZIP Code is not reassigned to a GLOBE Model geographic area.

b. Alternatives Considered

We also considered the suitability of the following as the geographic unit from which the GLOBE Model geographic areas would be identified: (1) ZIP Codes; (2) counties; (3) states; (4) Census-defined Core Based Statistical Areas (CBSAs) or Combined Statistical Areas (CSAs); and (5) Medicare Administrative Contractor (MAC) regions. ZIP Codes were considered because they are part of the beneficiary data that is maintained in Medicare beneficiary records and are the proposed basis for identifying GLOBE Model beneficiaries. However, ZIP Codes, unlike ZCTAs are not technically geographic areas, but represent U.S. postal delivery routes. ZIP Codes are useful identifiers to link a beneficiary record to a specific geographic area but are not geographic areas. Counties, states and CBSAs were determined to be too heterogeneous in their size and

population to achieve balance between selected and not selected regions for measured and unmeasured factors that may be linked to the outcomes for the proposed model design. The Medicare Administrative Contractor (MAC) regions were considered to reduce operational complexity but also were determined to be too large in size and heterogeneous.[94]

We also considered selecting the entire country as the model geographic area. However, we concluded that limiting geographies would facilitate the identification of a representative comparison group, which would improve CMS' ability to identify a suitable counterfactual for evaluating the impact of the GLOBE Model test.

We also considered starting the model with a greater number of geographic areas to include up to approximately 50 percent of Medicare Part B FFS beneficiaries in the model eligible beneficiary cohort instead of our proposal to test the model in geographic areas with approximately 25 percent of Medicare Part B FFS beneficiaries. We also considered an approach of initially testing the model in geographic areas with approximately 25 percent of Medicare Part B FFS beneficiaries and then, after initial monitoring observations were assessed, increasing the model beneficiary cohort to include up to approximately 50 percent of Medicare Part B FFS beneficiaries by including additional geographic areas. Under an approach where the number of included geographic areas would increase during the model performance period, we considered that CMS could update the table provided on the GLOBE Model website to include the complete list of GLOBE Model geographic areas by ZIP Code over time. We note that these alternatives would likely necessitate selection of the initial and potentially additional geographic areas at the same point, prior to model start and processes for including additional geographic areas. These approaches would have the benefit of enhancing the model evaluation as a random selection of approximately 50 percent of the Medicare FFS population would enable a 1:1 allocation of the treatment to comparison group.

We considered including the ZCTAs of U.S. territories among the geographic regions from which the randomly selected model geographic area would be selected.

We welcome comment on our proposal to use ZCTAs as the basis for the model geographic areas, exclude U.S. territories, and select the geographic area. We welcome comment on our proposal to test the model with geographic areas that would include approximately 25 percent of Medicare Part B FFS beneficiaries in the model beneficiary cohort and on whether CMS should test the model with an alternative approach that would include additional geographic areas and beneficiaries in the model as well as the processes that CMS should consider for such an approach.

G. Proposed Model Payment Test for GLOBE Model Drugs

In accordance with section 1847A(i) of the Act as codified in 42 CFR 427, CMS determines the rebate amount that manufacturers of Part B rebatable drugs owe to the Federal Supplementary Medical Insurance Trust Fund and computes adjusted beneficiary coinsurance and adjusted Medicare payment for Part B rebatable drugs as applicable. Under the GLOBE Model, we propose to test an alternative rebate calculation and an alternative calculation to adjust the beneficiary coinsurance and Medicare Part B payment for GLOBE Model drugs that are furnished to GLOBE Model beneficiaries. The alternative calculation would expand upon the current methodology by incorporating additional drug pricing information while ensuring that beneficiary coinsurance and net Medicare payment for a service would not exceed what they would be absent the model test.

We propose to base the alternative calculation on a per unit GLOBE Model benchmark that is described in section II.G.2. of this proposed rule. To test two methods for identifying a per unit GLOBE Model benchmark using different data sources, we propose that the per unit GLOBE Model benchmark for a GLOBE Model drug would be, subject to available information as determined by CMS (as described in section II.G.1. of this proposed rule), based on the greater of a per unit Method I GLOBE Model benchmark that reflects the lowest country-level price among a set of reference countries,[95] (as discussed in section II.G.2.a. of this proposed rule) or a per unit Method II GLOBE Model benchmark that reflects the volume-weighted average of the manufacturer's net pricing for sales within a set of reference countries based on data voluntarily reported by the manufacturer (as discussed in section II.G.2.b. of this proposed rule), after applying an economic adjustment under each method.[96] In section II.G.1.e. of this proposed rule, we propose the criteria that would be applied to identify the set of reference countries for purposes of identifying the information that would be used, as available, by CMS to determine the per unit Method I GLOBE Model benchmark and the per unit Method II GLOBE Model benchmark. To the benchmark that is greater, in section II.G.3.a. and II.G.3.b. of this proposed rule, we propose to apply an ''*applicable threshold percentage*'' and an amount, ''*add-on percentage amount*'', that would, in general, equal any add-on percentage included in the Medicare Part B payment limit under section 1847A(b) of the Act (which would, in general, be the same as the ''specified amount'' (as determined under 42 CFR 427.302(b))) to calculate a per unit GLOBE Model benchmark amount and then determine if a GLOBE Model rebate amount would apply. The alternative calculation would be structured such that the GLOBE Model rebate amount would not be less than the rebate amount (if any) determined under the Medicare Part B Drug Inflation Rebate Program as codified in 42 CFR part 427.

As discussed in section II.G.4.a. of this proposed rule, we propose that the per unit GLOBE Model rebate amount for an applicable calendar quarter would reflect the result of the alternative rebate calculation. That is, for a GLOBE Model drug, for an applicable calendar quarter, we propose that the per unit GLOBE model rebate amount would be the greater of: (1) the difference between the specified amount, as determined under 42 CFR 427.302(b), and the per unit GLOBE Model benchmark amount, as determined under 42 CFR 513.400(c); or (2) the difference between the specified amount determined under 42 CFR 427.302(b), and the inflation-adjusted payment amount determined under 42 CFR 427.302(g). In section II.G.4.b. of this proposed rule, we propose a methodology for identifying the included billing units of a GLOBE Model drug in the total GLOBE Model rebate amount calculation. In section

[94] Centers for Medicare & Medicaid Services. What's a MAC. Available at: *https://www.cms.gov/medicare/coding-billing/medicare-administrative-contractors-macs/whats-mac.*

[95] Individual countries differ in the regulatory processes and standards governing approval of drugs and biologicals. Use of international drug pricing information in the proposed GLOBE Model should not be interpreted to connote FDA approval or to otherwise describe any scientific or regulatory relationship between U.S.-approved and non-U.S.-approved products.

[96] The economic adjustment would be based on differences in gross domestic product and purchasing power between the U.S. and reference countries.

II.G.4.c. of this proposed rule, we propose that the total GLOBE Model rebate amount for a GLOBE Model drug during an applicable calendar quarter would be the product of the per unit GLOBE Model rebate amount of such drug, as determined under 42 CFR 513.510(a), and the total number of GLOBE Model billing units, as identified by CMS as set forth in 42 CFR 513.520 To facilitate the model test, we propose that the incremental GLOBE Model rebate amount for a GLOBE Model drug for an applicable calendar quarter would be the product of the incremental per unit GLOBE Model rebate amount of such drug, as determined under 42 CFR 513.510(b), and the total number of GLOBE Model billing units, as identified by CMS as set forth in 42 CFR 513.520. The incremental per unit GLOBE Model rebate amount would be the amount in excess of the per unit rebate amount calculated as set forth in 42 CFR 427.302. That is, as determined in 42 CFR 513.510(b) and discussed in section II.G.4.c. of this proposed rule, the incremental per unit GLOBE Model rebate amount would be an 'incremental amount' that taken together with the per unit rebate amount calculated as set forth in 42 CFR 427.302 would represent the per unit GLOBE Model rebate amount. To determine GLOBE Model billing units, in 42 CFR 513.520, CMS proposes to identify the number of billing units in accordance with 42 CFR 427.303(b) where, on the date of service, the beneficiary was identified by CMS as a GLOBE Model eligible beneficiary and for which Medicare Part B FFS made separate payment. We also propose, in section II.G.4.d. of this proposed rule, that the incremental GLOBE Model rebate amount may be reduced or adjusted in the same manner as described in 42 CFR 427 subparts E and F, if applicable, when a drug is currently in shortage or when there is a severe supply chain disruption, and/or through the reconciliation or suggestion of error process.

In section II.G.8. of this proposed rule, we present two alternative proposals, a combined approach and an incremental approach, for how CMS would provide rebate reports and reconciliation rebate reports to GLOBE Model participants, and a process for suggestion of error when GLOBE Model rebates are owed. Under the combined approach, CMS would delay Medicare Part B Drug Inflation Rebate Program invoicing for all manufacturers by up to two months and would provide a combined report (invoice) to all manufacturers of Part B rebatable drugs for both the Medicare Part B Drug Inflation Rebate Program and the GLOBE Model. Under the incremental approach, CMS would use a separate invoicing process that would run approximately a month after the Medicare Part B Drug Inflation Rebate Program reports and would invoice manufacturers of GLOBE Model drugs for the total GLOBE Model rebate amount using the *incremental GLOBE Model rebate amount* and reconciling the portion of the total GLOBE Model rebate amount invoiced through the Medicare Part B Drug Inflation Rebate Program processes. We seek comment on these alternative approaches for reporting, invoicing, and reconciliation and intend to adopt only one approach for the model. CMS' intent is to establish an efficient approach that closely aligns with processes currently used by the Medicare Part B Drug Inflation Rebate Program and would be familiar to manufacturers of Part B rebatable drugs. Under these alternative approaches, we propose that GLOBE Model participants would have access to reports, submit a Suggestion of Error to CMS, and pay GLOBE Model rebate amounts based on the GLOBE Model's alternative calculation in the same manner, or substantially similar manner, as set forth in 42 CFR 427.504 with respect to the Medicare Part B Drug Inflation Rebate Program. In addition, in 42 CFR 513.740, we propose that the provisions for the deadline and process for payment of the rebate amount in 42 CFR 427.505 would apply to GLOBE Model rebate amounts in the same manner as they do to Part B drug rebate amounts that are calculated under 42 CFR 427.301. However, to align GLOBE Model rebate processes closely with the Medicare Part B Drug Inflation Rebate Program, we have identified the need to adjust the timing for providing reports and are proposing to use the Innovation Center's waiver authority to do so as discussed in section II.G.8. of this proposed rule.

We also propose that, in addition to other applicable authorities, the provisions for enforcement of manufacturer payment of rebate amounts of the Medicare Part B Drug Inflation Rebate Program and the implementing regulations at 42 CFR 427.600, regarding civil money penalties would apply to manufacturers of GLOBE Model drugs with respect to GLOBE Model rebate amounts.

The proposed GLOBE Model would also test alternative calculations to adjust the beneficiary coinsurance and Medicare Part B payment for separately payable units of GLOBE Model drugs that are furnished to GLOBE Model beneficiaries (that is, beneficiaries who are on the GLOBE Model Eligible Beneficiary List as discussed in section II.C. of this proposed rule). As discussed in section II.G.7. of this proposed rule, we propose to use the alternative calculation for identifying the per unit GLOBE Model benchmark amount to identify the GLOBE Model beneficiary coinsurance that would be applied as a percent to the payment amount for a GLOBE Model drug for an applicable calendar quarter. To ensure that beneficiary financial liability for coinsurance amounts for GLOBE Model drugs under the GLOBE Model would not be more than it would be absent the model test, for a calendar quarter, we propose that CMS would compare a per unit GLOBE Model benchmark amount (that would be calculated in advance of the calendar quarter, with limited exceptions in cases of error, as determined by CMS, to the applicable inflation-adjusted payment amount as determined under 42 CFR 427.302(g) and the lesser of those amounts would be used in the computation of the GLOBE Model beneficiary coinsurance percentage and the GLOBE Model Medicare Part B FFS payment amount for separately payable units of the GLOBE Model drug furnished to GLOBE Model beneficiaries during the applicable calendar quarter. The GLOBE Model beneficiary coinsurance would only be applicable to separately payable units of GLOBE Model drugs that are furnished to the Medicare Part B FFS beneficiaries who are, for the date of service, on the GLOBE Model Eligible Beneficiary List in use by the Medicare claims processing systems on the date a claim was processed, as determined by CMS. When the GLOBE Model reduced beneficiary coinsurance applies to units of GLOBE Model drugs furnished to Medicare Part B FFS beneficiaries who are included 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.

For a discussion on the proposed approach for the GLOBE Model monitoring and evaluation, we refer readers to sections II.L. and II.P. of this proposed rule, respectively.

1. Proposed International Drug Pricing Information Data Sources

This section of this proposed rule discusses the proposed international drug pricing information data sources and the international drug pricing information that CMS proposes to use, if available, to identify the per unit

Method I GLOBE Model benchmark, based on available data from existing data sources (as described in section II.G.2.a. of this proposed rule). This section of this proposed rule also discusses the proposed data and information that eligible manufacturers would have the option to voluntarily submit to CMS, which would, if submitted and determined to meet completeness criteria, be used to identify the per unit Method II GLOBE Model benchmark (as described in section II.G.2.b. of this proposed rule). We propose that the availability of data and information, its completeness, and use for purposes of the GLOBE Model would be determined solely by CMS. In section II.G.2.e. we discuss the proposed criteria and process CMS would use to identify the non-U.S. countries that would be included in the set of reference countries for the GLOBE Model for purposes of identifying international drug pricing information available in existing data sources and calculating the per unit Method I GLOBE Model benchmark (as described in section II.G.2.a. of this proposed rule) and the per unit Method II GLOBE Model benchmark (as described in section II.G.2.b. of this proposed rule).

a. Existing Data Sources for International Drug Pricing Information

To identify the per unit Method I GLOBE Model benchmark (as described in section II.G.2.a. of this proposed rule), we propose to rely on existing data sources available to CMS that contain international drug pricing information, including pricing information, sales, and/or volume data (for example, package size, and number of items or packages sold), as available, in order to optimize operational efficiency and inform the identification of the per unit GLOBE Model benchmark amount including in the absence of voluntarily submitted manufacturer net pricing data and information (which we propose to use to inform the identification of the per unit Method II GLOBE Model benchmark as described in section II.G.2.b. of this proposed rule). Within available data sources, sales and list prices may be based on ex-manufacturer prices (sometimes referred to as ex-factory price), that represent actual or calculated prices paid to the manufacturer by wholesalers and other distributors, retail prices, prices for other distribution channels, or a combination thereof. Data sources have proprietary collection, and projection methodologies to harmonize data across countries. For example, data sources may use proprietary adjustment factors to facilitate comparison of different pricing level information or apply proprietary projection methodology to estimate data available for a sample of distribution channels to obtain a projected value for the entire country. Confidential manufacturer rebates would not likely be accounted for within these available data sources; therefore, existing sources for international drug sales data may overstate actual prices realized by manufacturers. On balance, we believe existing data sources are adequate for purposes of identifying country-level prices and a per unit Method I GLOBE Model benchmark (as described in section II.G.2.a. of this proposed rule), particularly because we are proposing that eligible manufacturers would have the option to voluntarily submit international drug net pricing data to CMS that could potentially be used instead to identify the per unit GLOBE Model benchmark.

We have assessed several existing data sources to determine the availability and sufficiency of international drug pricing information. These data sources include those made available by private companies, which may include data reported by manufacturers or data obtained through a review of publicly filed material by manufacturers in other countries or in the U.S. Specifically, we reviewed proprietary global pharmaceutical pricing data sources that include drug pricing data for a large diverse set of pharmaceutical products (that are the types of pharmaceutical products that could be covered under Medicare Part B) for more than 30 countries. These data sources vary with respect to the scope (such as products, manufacturer level, market level data, countries), and periodicity of updates (such as daily, monthly, quarterly). For example, IQVIA MIDAS® [97] is an IQVIA proprietary information service which integrates IQVIA's national audits into a globally consistent view of the pharmaceutical market, and provides estimated product volumes of registered medicines, trends and market share through retail and non-retail channels. IQVIA MIDAS [98] includes detailed drug product information, such as drug name, molecule, strength, dosage form, pack size, manufacturer, generic product classification (such as non-generic or generic), biologic classification (such as biosimilar or reference biological products), market information (such as country, distribution channel, the Anatomical Therapeutic Chemical (ATC) classification,[99] sales data, standard units, extended units, number of packs), pricing information (such as price per pack, price per unit, derived average list price), temporal information (such as month, quarter, year of sale), and other information.[100] IQVIA MIDAS is updated monthly and retains extensive historical data for 33 countries.

Another potential data source we assessed is GlobalData Pharmaceutical Prices (POLI) [101] which includes three price levels (ex-manufacturer, wholesalers, and retail) for at least 80 countries at the pack level (pharmaceutical name, generic name, dosage form, strength and number of units). POLI includes drug product information (such as drug descriptor, molecule type, dosage form, strength, classification as brand or generic), and market information (such as ATC classification, therapy area, and geography). POLI is updated monthly and provides historic data since 2016. Eversana NAVLIN's Price & Access database,[102] includes pricing data for more than 100 countries, as well as tools to compare international pricing information (specifically, pricing across

[97] The statements, findings, conclusions, views, and opinions contained and expressed in this proposed rule are based in part on data obtained under license from the following IQVIA information service(s): IQVIA MIDAS®. Copyright IQVIA. All Rights Reserved. The statements, findings, conclusions, views and opinions contained and expressed herein are not necessarily those of IQVIA or any of its affiliated or subsidiary entities.

[98] IQVIA MIDAS Overview. Available at: *https://www.iqvia.com/solutions/commercialization/data-and-information-management/midas.*

[99] For information about The World Health Organization's Anatomical Therapeutic Chemical classification see: *https://www.who.int/tools/atc-ddd-toolkit/atc-classification#:~:text=In%20the%20Anatomical%20Therapeutic%20Chemical,groups%20at%20five%20different%20levels.*

[100] IQVIA national audits and IQVIA MIDAS reflect local industry standard source of pack prices, which may be list price or average invoice price, depending upon the country and the available information; they do not take into account rebates or clawbacks, details of which are normally confidential, and therefore these estimated prices do not reflect net prices realized by the manufacturers. Sales values reflected in these IQVIA audits are calculated by applying such relevant pricing to the product volume data collected for, and reflected in, such audits. In addition, to allow the national audit sales values to be viewed at a common sales level, MIDAS applies a single average industry margin to the locally reported values. Prices derived from MIDAS data are therefore estimates, and IQVIA cautions against using prices in MIDAS data as metrics in their own right.

[101] GlobalData. Data Lake-Pharmaceutical Prices (POLI) Available at: *https://marketaccess.globaldata.com/product-solutions/data-lake-pharmaceutical-prices-poli/.*

[102] NAVLIN by Eversana. Available at: *https://www.navlin.com/products/navlin-price-access-data.*

countries), and is another potential data source.

These data sources, if available, would likely provide adequate information to inform CMS' identification of a Method I GLOBE Model benchmark for the vast majority of proposed GLOBE Model drugs (as discussed in section II.G.2.a. of this proposed rule).

Another data source option we considered would be for CMS to construct price comparisons from public sources of each country. However, we believe this would be cumbersome and we may not have all the information necessary for CMS to routinely identify a Method I GLOBE Model benchmark for a broad set of proposed GLOBE Model drugs.

In 42 CFR 513.310(c), we propose to use one or more existing data sources for international drug pricing available to CMS to identify the per unit Method I GLOBE Model benchmark for a GLOBE Model drug. Specifically, we propose to use one or more data sources available to CMS at least 60 business days prior to the start of the first applicable calendar quarter for which the drug is a GLOBE Model drug to identify if the per unit Method I GLOBE Model benchmark is available. As proposed in 42 CFR 513.310(c)(1)(ii), such data sources would utilize a standardized method for identifying drugs across countries within the data source, such as using an internationally recognized method for identifying scientific and nonproprietary product names and a standard method for identifying dosage form, route of administration such as using an internationally recognized nomenclature for pharmaceutical forms like the New Form Code classification (that, at a minimum, distinguishes among injectable, oral, and other forms of a drug), and strength. For example, the data source might use the International Nonproprietary Names (INN), as applicable.[103] We are proposing that the data source must use a standardized method for identifying drug names, dosage forms, and route of administration because the process that CMS proposes to use to identify the country-level prices to identify the per unit Method I GLOBE Model benchmark requires mapping between the data source's method for identifying drug names, dosage forms and route of administration to the HCPCS Level II codes that are associated with GLOBE Model drugs. We are proposing that the data source must use a standardized method for identifying strength because this could be used to identify the quantity of drug and the billing units. Further, we propose that the one or more data sources that we would use would contain international drug pricing information and the corresponding volume data (for example, number of items, packages, or units sold) or data sources with only pricing information, where applicable. We propose that the pricing information in the data sources would include sales data (which may be based on ex-manufacturer prices, sometimes referred to as ex-factory prices) that represent actual or calculated prices paid to the manufacturer by wholesalers and other distributors, or retail prices that represent actual or calculated sales for retail purchasers, or prices paid by other purchasers in the distribution channels (such pricing information must be expressed in U.S. currency. We also propose the data source would use a standard method based on regulatory approval pathways to identify U.S. originator drugs and international originator drugs (such as brand name products, reference listed drug, or reference products), and U.S. non-originator drugs and international non-originator drugs [104] (such as generics, biosimilars, biocomparable products, reference product equivalents, or off-patent products). In addition, we propose that the one or more data sources we would use must have mechanisms in place to maintain, update, and correct, if necessary, the data source on at least a quarterly basis. Further, we propose that the data sources we would use must be maintained by organizations that seek to limit the lag inherent in data to no more than 90 days from the end of the calendar quarter for which drug pricing information is compiled to the time that the organization makes such updates available to users of the data source. Based on CMS assessment of the available data sources, the current lag may be up to 90 days. We believe the limit of no more than 90 days provides sufficient time for organizations to collect data, perform data checks, and update their data sources, and for CMS to obtain and use the most current, timely available data for the purposes of the GLOBE Model.

Whenever possible, to identify the per unit Method I GLOBE Model benchmark for a GLOBE Model drug, we propose to use international drug pricing information from two calendar quarters prior to the first applicable calendar quarter to which the total GLOBE Model rebate amount would apply since the ASP payment limits that apply to that calendar quarter (and are generally the basis for the specified amount set forth in 42 CFR 427.302(b)) are based on manufacturers' U.S. sales from two calendar quarters prior. For GLOBE Model drugs to be included on the GLOBE Model drug list for the first calendar quarter of performance year 1 (that is, the calendar quarter beginning October 1, 2026), as proposed in 42 CFR 513.130, CMS would use international drug pricing information from the second calendar quarter of 2026 (that is, the ASP calendar quarter beginning on April 1, 2026). In addition, except for extracted data used by CMS to identify the most recent per unit Method GLOBE Model benchmark from January 1, 2024 to December 31, 2024, we propose to use international drug pricing information from no earlier than the second calendar quarter of 2025 (that is, the ASP calendar quarter beginning on April 1, 2025) to minimize the possibility of having no international drug pricing information to calculate the per unit Method I GLOBE Model benchmark while limiting the possibility that historical data would not reasonably approximate international drug pricing information for the applicable ASP calendar quarter and mitigating the potential effect of manufacturers' limiting the availability of international drug pricing information during the GLOBE Model performance period. If international drug pricing information from two calendar quarters prior to the first applicable calendar quarter to which the total GLOBE Model rebate amount would apply are not used, we propose that CMS would use international drug pricing information from the most recent ASP calendar quarter for which data are available.

b. Proposed Hierarchy for Using Existing Data Sources

To identify available data sources for purposes of identifying the per unit Method I GLOBE Model benchmark for each GLOBE Model drug, we propose that CMS would use the following hierarchy that we propose to codify in 42 CFR 513.310(c)(2):

- A data source with drug specific sales and volume data for the applicable

[103] World Health Organization. International Nonproprietary Names Programme and Classification of Medical Products. International Nonproprietary Names (INN). Available at: *https://www.who.int/teams/health-product-and-policy-standards/inn.*

[104] Individual countries differ in the regulatory processes and standards governing approval of drugs and biologicals. Use of international drug pricing information in the proposed GLOBE Model should not be interpreted to connote FDA approval or to otherwise describe any scientific or regulatory relationship between U.S.-approved and non-U.S.-approved products.

ASP calendar quarter from at least one country that is included in the set of reference countries identified by CMS in accordance with 42 CFR 513.310(b).

- Except for extracted data used by CMS to identify the most recent per unit Method GLOBE Model benchmark from January 1, 2024 to December 31, 2024, a data source with drug specific sales and volume data for any prior ASP calendar quarter beginning on or after April 1, 2025 from at least one country that is included in the set of reference countries identified by CMS in accordance with 42 CFR 513.310(b) when drug specific sales and volume data are not available for the applicable ASP calendar quarter from at least one country that is included in the set of reference countries identified by CMS in accordance with 42 CFR 513.310(b).
- The extracted data used by CMS to identify the most recent per unit Method I GLOBE Model benchmark available in a document posted on the GLOBE Model website. We note that could include a data source with drug specific sales and volume data from January 1, 2024, to December 31, 2024, from at least one country that is included in the set of reference countries identified by CMS in accordance with 42 CFR 513.310(b).
- A data source with drug specific ex-manufacturer price (sometimes referred to as ex-factory price) data for the applicable ASP calendar quarter from at least one country that is included in the set of reference countries identified by CMS in accordance with 42 CFR 513.310(b).
- A data source with drug specific list price data (for example, the price made available to wholesalers) for the applicable ASP calendar quarter from at least one country that is included in the set of reference countries identified by CMS in accordance with 42 CFR 513.310(b).

In cases when there is more than one data source meeting the requirements in 42 CFR 513.310(c)(2) for a GLOBE Model drug for a reference country, we propose to use the data source at the highest level of the hierarchy that contains information from the highest number of countries, and, if available, incorporates discounts, rebates, or other price concessions into its drug pricing information. Our proposed approach for using existing data sources would allow CMS to use different data sources for different GLOBE Model drugs over different quarters. We propose that CMS would select a data source and extract the data as available from that data source, and we would not make adjustments to account for differences between the data source selected and other available data sources. For example, for GLOBE Model drug X, suppose we identify Data Source 1 that meets the requirements of 42 CFR 510.310(c)(2) where Data Source 1 contains sales and volume data for GLOBE Model drug X for the applicable ASP calendar quarter from 7 out of a total of 19 reference countries, Data Source 2 contains sales and volume data for GLOBE Model drug X for the applicable ASP calendar quarter from 8 reference countries, Data Source 3 contains sales and volume data from one quarter prior to the applicable ASP calendar quarter for GLOBE Model drug X from 9 reference countries, and Data Source 4 contains list price information for the applicable ASP calendar quarter from all included countries. In this scenario, in accordance with our proposed approach, we would use information solely from Data Source 2, and we would not use Data Sources 1, 3, or 4 for that applicable calendar quarter.

We note that in that scenario, if CMS were unable to identify a data source for international drug pricing information for GLOBE Model drug X for a reference country, the lowest per unit country-level price would be identified using the information available. That is, a country-level price for each of the reference countries would not be required and CMS would solely use the available information for as many reference countries as possible. Further, we would not combine data from different data sources to identify international drug pricing information for GLOBE Model drug X across countries.

c. Alternatives Considered for Using Existing Data Sources

In cases when there is more than one data source meeting the requirements in proposed 42 CFR 513.310(c)(3) for a GLOBE Model drug, or in cases when there is more than one data source meeting the requirements in proposed 42 CFR 513.310(c)(3) for a GLOBE Model drug and for the same number of countries, we considered two alternatives. Under one alternative, we would first identify the data source at the highest level of the data source hierarchy that has the most pricing information available and use the lowest value of the pricing information available within that data source even if international drug pricing information is available from other reference countries within another data source. We also considered using all the available data sources for a drug and calculating the average of the pricing information available across all the data sources. Because these alternative approaches could result in cases where available international drug pricing information for a drug from a reference country would not be used or cases where different types of pricing information for a drug from a reference country would be combined, we are not proposing them at this time and may reconsider the potential value of these approaches based on feedback from interested parties and further information gathering. We also seek comments on these alternatives and how CMS could use the most comprehensive international pricing information available.

We are interested in better understanding the existing data sources for international drug pricing information that may be available to CMS and steps we could follow to best use such data sources for the GLOBE Model payment test. We welcome comments on the methods or processes CMS could consider when more than one existing data source is available at the highest level of the hierarchy to determine which data source is more comprehensive, as well as on how CMS might refine the hierarchy for potential use of more than one data source for a GLOBE Model drug or to incorporate new data sources that may become available during the GLOBE Model performance period.

d. Proposed Voluntary Submission of International Drug Net Pricing Data

Under the GLOBE Model, if a manufacturer elects to submit international drug net pricing data for a GLOBE Model drug, to be considered by CMS for identifying *the per unit Method II GLOBE benchmark,* we propose that the manufacturer would be required to execute a data agreement that must be effective prior to the manufacturer's first submission of voluntary international drug net pricing data. The data agreement would establish terms, conditions, and requirements, including data completeness and validity requirements, and compliance responsibilities. In 42 CFR 513.620(b), we propose that, once the data agreement is effective, it would remain applicable for the duration of the GLOBE Model unless either the manufacturer or CMS terminates the agreement. We considered having data agreements that were effective for a shorter duration such as one performance year or for one quarter of a performance year. However, we were concerned that allowing manufacturers to opt in and out of reporting for each quarter would potentially result in manufacturers choosing to report only if

the Method II benchmark would be higher than the Method I benchmark. Additionally, given the operational complexity associated with conducting reporting on a quarterly basis, CMS believes it would be less burdensome for CMS and manufacturers to enter one data agreement for the duration of the GLOBE model. Under the data agreement, manufacturers may make submissions for one or more GLOBE Model drugs for any applicable ASP calendar quarter. For each submission, we propose that the manufacturer must include ''*applicable international analog*'', defined in 42 CFR 513.600 as a non-US analog whose scientific or nonproprietary name, dosage form, and route of administration (if applicable) align with a GLOBE Model drug and that are sold in one or more reference countries identified in 42 CFR 513.310(b) during the applicable ASP calendar quarter, excluding those identified in their respective country as a generic or biosimilar biological product according to the country's own regulations.[105] We propose that manufacturers would use data that (1) represents the price of the international originator drugs; (2) have complete package size information; (3) have a strength; and (4) represents a dosage form that could be described by the GLOBE Model drug's HCPCS Level II code descriptor, including route of administration (if applicable). For example, if the HCPCS Level II code descriptor includes the word injection, manufacturers would provide applicable international analog net pricing data for products that are administered by injection (for example, data for liquid and dry powder for injection products would be submitted whereas data for tablets that are administered orally would not be submitted). Further information on the manufacturer voluntary submission is described in section II.G.6. of this proposed rule. We also propose that manufacturers who elect the option to submit international drug net pricing data for an applicable calendar quarter during the GLOBE Model performance period would submit data that corresponds to the applicable ASP calendar quarter for that applicable calendar quarter. The applicable ASP calendar quarter is the calendar quarter two quarters prior to the applicable calendar quarter. For example, for the proposed first applicable calendar quarter of model performance year 1 that would begin on October 1, 2026, the applicable ASP calendar quarter would be April 1, 2026, to June 30, 2026. We propose that submission of the data must occur no later than 30 days after the end of the applicable ASP calendar quarter. For example, for the proposed first applicable calendar quarter of performance year 1, manufacturers would have to submit data to CMS no later than July 30, 2026, for it to be considered submitted timely and, if determined to be acceptable by CMS, be considered by CMS for purposes of identifying the per unit Method II GLOBE Model benchmark. The manufacturer submitted data would include data for the entire applicable ASP calendar quarter (April 1, 2026 to June 30, 2026). This would mean manufacturers would have to establish an effective data agreement no later than July 30, 2026.

We propose that CMS would conduct a verification review for validity to determine whether the manufacturer's submission meets the submission requirements as proposed in 42 CFR 513.610, which is necessary for CMS to determine whether the submission represents an ''applicable submission'' to identify a per unit Method II GLOBE Model benchmark. To conduct the verification review, CMS would—(1) review the data for completeness to ensure all required data elements are present; (2) verify the validity of the data, including verifying that the submitted sales and volume data and calculated international net pricing values are greater than zero and adhere to data format requirements (for example, values are numeric and are rounded at the third decimal place); and (3) as part of verifying the validity of the data, CMS will assess the extent to which the submission reflects international drug net pricing in the reference countries using all available data sources and information, including data sources used to identify the per unit Method I GLOBE Model benchmark and previous submissions by the manufacturer for the same GLOBE Model drug (as determined by CMS). For example, existing data shows U.S. ex-manufacturer prices are, on average, 278 percent higher than prices in other OECD countries, with U.S. originator drugs exhibiting an even greater difference of 422 percent. Therefore, we expect, on average, that reported international net prices for applicable international analogs would be, in general, on average, less than the average sales price that is reported to CMS and below or similar to prices contained within existing international drug pricing information data sources. We also expect that manufacturer submitted international drug net pricing data for the applicable ASP calendar quarter would be within a reasonable margin of previous submissions by the manufacturer for the same set of applicable international analogs (if data exists), meaning we do not expect manufacturer submitted international drug net pricing data to increase beyond pricing in existing international data pricing information data sources. We welcome comments on other methods CMS could consider for verification. The proposed process for how manufacturers would submit international drug net pricing data to CMS is discussed in section II.G.6. of this proposed rule.

e. Proposed Criteria and Process for Identifying the Set of Reference Countries

In this section, we propose the criteria and process CMS would use to identify the non-U.S. countries that would be included in the set of reference countries for the GLOBE Model for purposes of identifying international drug pricing information available in existing data sources and calculating the per unit Method I GLOBE Model benchmark as described in section II.G.2.a. of this proposed rule and the per unit Method II GLOBE Model benchmark as described in section II.G.2.b. of this proposed rule.

Our proposed approach aims to select a large set of reference countries that are economically similar to the U.S., and have reasonably comparable purchasing power to the U.S. Specifically, we propose that CMS would identify a set of reference countries that are non-U.S. Organization for Economic Co-operation and Development members (that is, non-U.S. OECD-member countries) [106] as of October 1, 2025 with: (1) a real GDP per capita that is at least 60 percent of the U.S. real GDP per capita, as estimated and available in the Central Intelligence Agency (CIA) World Factbook; [107] and (2) an annual real GDP that is at least $400 billion (as measured in U.S. dollars) as estimated and available in

[105] Individual countries differ in the regulatory processes and standards governing approval of drugs and biologicals. Use of international drug pricing information in the proposed GLOBE Model should not be interpreted to connote FDA approval or to otherwise describe any scientific or regulatory relationship between U.S.-approved and non-U.S.-approved products.

[106] OECD. Members and Partners, available at: *https://www.oecd.org/en/about/members-partners.html.*

[107] The United States Central Intelligence Agency (CIA). The World Factbook, Country Comparisons-Real GDP per Capita. Available at: *https://www.cia.gov/the-world-factbook/field/real-gdp-per-capita/country-comparison/.*

the CIA World Factbook,[108] as determined by CMS. For each country, at 42 CFR 513.310(b) we propose to use the real GDP per capita and the annual real GDP based on purchasing power parity (PPP), as estimated and available in the CIA World Factbook for the year 2024 and available as of October 1, 2025. Further, while the CIA online World Factbook is updated daily, the underlying data such as GDP and PPP are reported no more frequently than annually, based on a July 1 mid-point. Therefore, our proposal to identify the set of reference countries using data available as of October 1, 2025, in the CIA World Factbook would mean that the set of reference countries would be identified using real GDP information from 2024. There are other existing sources for GDP per capita data besides the CIA World Factbook, including the World Bank,[109] and the International Monetary Fund.[110] Upon examining these sources, we noted that the GDP data across these sources are highly associated with one another. We propose using the CIA World Factbook as our source for real GDP per capita and real GDP data as it is issued by a U.S. government agency and includes data for countries that are economically comparable to the U.S. CMS seeks comments on the proposed data sources as well as other data sources considered.

Given that the identified set of countries are economically comparable to the U.S. based on real GDP per capita in 2024 and aggregate real GDP in 2024, we propose that the identified set of reference countries would remain the same throughout the 5-year GLOBE Model performance period, even if the CIA World Factbook shows that, based on more recent information, a country would no longer meet the criteria for the set of reference countries during any performance year of the model. We propose to codify the criteria that CMS would use once to identify the set of reference countries for purposes of the GLOBE Model in 42 CFR 513.310(b).

To illustrate the potential set of reference countries that would result if the proposed criteria for identifying the set of reference countries are adopted in a final rule establishing the GLOBE Model, we applied the proposed criteria (as set forth in 42 CFR 513.310(b)) using CIA World Factbook data that were available on October 1, 2025 and identified the following potential set of reference countries: Australia, Austria, Belgium, Canada, Czechia, Denmark, France, Germany, Ireland, Israel, Italy, Japan, Netherlands, Norway, South Korea, Spain, Sweden, Switzerland, and the United Kingdom (see Table 5). All 19 countries are economically comparable to the U.S. with real GDP per capita in 2024 (the most recent data available) falling between 63 and 170 percent of U.S. real GDP per capita in 2024 and aggregate real GDP in 2024 exceeding $400 billion and are non-U.S. OECD member countries.

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[108] The United States Central Intelligence Agency (CIA). The World Factbook, Country Comparisons—Real GDP (Purchasing Power Parity). Available at: *https://www.cia.gov/the-world-factbook/field/real-gdp-purchasing-power-parity/country-comparison/.*

[109] The World Bank Group. Data. GDP per capita (current US$). Available at: *https://data.worldbank.org/indicator/NY.GDP.PCAP.CD.*

[110] International Monetary Fund. Datasets. Available at: *https://www.imf.org/external/datamapper/datasets/WEO.*

TABLE 5: ILLUSTRATIVE LIST OF US AND REFERENCE COUNTRIES GDP PER CAPITA AND ECONOMY SIZE

Countries	Annual Real GDP ($billion)	Real GDP per Capita	Percent of U.S. Real GDP per Capita	GDP (PPP) Adjuster*
United States	$25,676	$75,500	100%	1.000
Canada	$2,341	$56,700	75%	1.332
France	$3,732	$54,500	72%	1.385
Germany	$5,247	$62,800	83%	1.202
Italy	$3,133	$53,100	70%	1.422
Japan	$5,715	$46,100	61%	1.638
United Kingdom	$3,636	$52,500	70%	1.438
Australia	$1,635	$60,100	80%	1.256
Korea, South	$2,607	$50,400	67%	1.498
Netherlands	$1,276	$70,900	94%	1.065
Spain	$2,361	$48,400	64%	1.560
Austria	$581	$63,300	84%	1.193
Belgium	$749	$63,100	84%	1.197
Czechia	$522	$48,000	64%	1.573
Ireland	$621	$115,300	153%	1.000*
Norway	$508	$91,100	121%	1.000*
Sweden	$669	$63,300	84%	1.193
Switzerland	$741	$82,000	109%	1.000*
Denmark	$441	$73,700	98%	1.024
Israel	$472	$47,300	63%	1.596

*Notes: Annual real GDP and real GDP per capita are based on PPP. The GDP (PPP) adjuster is calculated by dividing the U.S. real GDP per capita by the reference country's real GDP per capita for the same year; the GDP (PPP) adjuster is capped at 1 in cases where the ratio is below 1.0 (see section II.G.1.f. of this proposed rule for additional details). The GDP (PPP) adjuster is used to calculate the per unit Method I GLOBE Model benchmark and per unit Method II GLOBE Model benchmark (see section II.G.2. of this proposed rule).

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We believe that applying a minimum of 60 percent of the U.S. real GDP per capita and $400 billion aggregate real GDP strikes a balance between having too low a real GDP per capita threshold and including data from countries with economies that are substantially different from the U.S. while also not having such a high real GDP per capita threshold that the set of reference countries would be very small. For example, a real GDP per capita threshold of 80 percent of the U.S. real GDP per capita could result in the set of reference countries only including 9 countries (Austria, Belgium, Denmark, Germany, Ireland, Netherlands, Norway, Sweden, and Switzerland). By contrast, a real GDP per capita threshold of 40 percent of the U.S. real GDP per capita could result in a set of 23 reference countries including the 19 countries noted above as well as Chile, Poland, Portugal, and Turkey. We believe that our proposed approach would result in a set of reference countries that are economically similar, have reasonably comparable purchasing power to the U.S., and generally have existing international drug pricing information that is available.

We considered different criteria to identify economy size, including aggregate nominal and real GDP below $400 billion, between $400 billion and $1 trillion, between $1 and $2 trillion, and greater than $2 trillion. Lower aggregate real GDP thresholds would include more countries, while a threshold above real GDP $2 trillion would result in a small number of countries. For example, using the CIA World Factbook data for 2024 that were available on October 1, 2025, only eight non-U.S. OECD member countries—Canada, France, Germany, Italy, Japan, Spain, South Korea, and the United Kingdom—have economies larger than $2 trillion in real terms. We also considered criteria based on intergovernmental political and economic forums like the Group of Seven (G7) countries that include Canada, France, Germany, Italy, Japan, and the United Kingdom, or the Group of 20 (G20).[111]

[111] Non-US members of the G20 are Argentina, Australia, Brazil, Canada, China, France, Germany, India, Indonesia, Italy, Japan, Medico, Russia, Saudi Arabia, South Africa, South Korea, Turkey, and the United Kingdom.

We also considered alternative approaches to our proposed criteria for identifying the set of reference countries. Specifically, we considered including all non-U.S. OECD member countries or including countries based on factors such as the World Health Organization (WHO) recognition as a Stringent Regulatory Authority (to be replaced by the WHO-listed authority or WLA) and intellectual property protections.[112] [113] We also considered including only countries that may represent large markets for drug manufacturers such as all countries in the European Union, Canada, Japan, and United Kingdom. However, we do not believe that these approaches would be as objective and predictable for purposes of identifying the GLOBE Model benchmark amount.

We also considered alternatives that would phase-in countries or would adjust the set of reference countries over time based on a defined set of characteristics, such as real GDP per capita or average drug prices. However, at this time, we believe that phasing in countries over time or adjusting the set of reference countries periodically would create instability within the model test and could cause potential negative impacts on GLOBE Model participants (for example, creating confusion regarding voluntary data submission), GLOBE Model beneficiaries (for example, greater variation in coinsurance from calendar quarter to calendar quarter) and the Medicare Part B program (for example, additional administrative costs that would reduce potential model savings).

Despite our concerns about potential negative impacts that could occur if the set of reference countries is not held constant during the 5-year GLOBE Model performance period as stated in this section of this proposed rule, we welcome comment on the potential benefits and drawbacks of establishing a threshold for removing a country from the set of reference countries (that CMS would identify using CIA World Factbook data available as of October 1, 2025 for the year 2024) at certain points during the model performance period. Specifically, we seek comment on the proposed criteria to select the list of reference countries and whether or not to revise the list of reference countries. We also welcome comments on the processes and timing that would be necessary to operationalize a change to the set of reference countries that would minimize impacts on the model test.

f. Proposed Data and Methodology for Identifying the GDP (PPP) Adjuster

In this section we discuss the proposed data sources and calculation to identify the GDP (PPP) adjuster, which CMS proposes to codify at 42 CFR 513.430. Sections II.G.2. and II.G.6. of this proposed rule discuss the application of the GDP (PPP) adjuster in calculating the per unit GLOBE Model benchmark.

For each country in the set of reference countries identified as determined in 42 CFR 513.310(b) and discussed in section II.G.1.e. of this proposed rule, CMS proposes to use the most recent data on real GDP per capita based on purchasing power parity for a country available in the CIA World Factbook at the start of the applicable ASP calendar quarter (as defined in 42 CFR 513.20) as determined by CMS. CMS proposes to use the following calculation to determine the GDP (PPP) adjuster: divide the U.S. real GDP per capita by the country's real GDP per capita and round the result to the third decimal place. In calculating the GDP (PPP) adjuster CMS proposes to apply the following limitations: (1) the country's real GDP per capita and U.S. real GDP per capita data from the same year; and (2) the real GDP per capita used must be for the same year as the data used to calculate the per unit country-level price (as defined in 42 CFR 513.410), or the most recent earlier year available; and (3) in cases where the resulting ratio is less than 1.000, the GDP (PPP) adjuster is set to 1.000.

Table 5 presents an illustrative GDP (PPP) adjuster using 2024 data from the CIA World Factbook. As noted in section II.G.6. of this proposed rule, CMS intends to publish a supplemental document on the GLOBE Model website with details on which GDP (PPP) adjuster would be used for each applicable ASP calendar quarter. To establish the GDP (PPP) adjuster for each ASP calendar quarter, CMS would use the most recently available information from the CIA World Factbook for each reference country. CMS would publish this GDP (PPP)-adjuster at the beginning of each applicable calendar quarter.

2. Proposed Methodology To Identify the Per Unit GLOBE Model Benchmark

The proposed GLOBE Model would test alternative calculations to those used by CMS to determine the Part B inflation rebate amount that manufacturers of Part B rebatable drugs owe to the Medicare Supplementary Medical Insurance Trust Fund, adjusted beneficiary coinsurance, and the adjusted Medicare payment for Part B rebatable drugs, as applicable, pursuant to section 1847A(i) of the Act as codified in 42 CFR 427. Under the GLOBE Model, these alternative calculations would expand upon the current methodology by incorporating additional drug pricing information (as described in section II.G.1. of this proposed rule) while ensuring that beneficiary coinsurance and net Medicare Part B payment would not exceed what they would be absent the model test. In this section of this proposed rule, we propose to test two alternative calculation approaches using different data sources for international drug pricing information and methods to identify the per unit GLOBE Model benchmark. Specifically, we propose that, subject to available information as determined by CMS, the per unit GLOBE Model benchmark for a GLOBE Model drug for an applicable quarter during the model performance period would be based on the greater of—(1) a ''*per unit Method I GLOBE Model benchmark*'' that would reflect the GDP (PPP) adjusted [114] lowest country-level price among a set of reference countries at a baseline using existing data sources for international drug pricing information for the applicable ASP calendar quarter as available to and calculated by CMS (this benchmark would be identified by CMS for the first applicable calendar quarter for the GLOBE Model drug and remains in place for each applicable calendar quarter thereafter until the end of the model performance period, as proposed in section II.G.2.a. of this proposed rule; or (2) a ''*per unit Method II GLOBE Model benchmark*'' that would reflect the volume-weighted average of the GDP (PPP) adjusted manufacturer's international drug net pricing for sales among a set of reference countries for the applicable ASP calendar quarter based on data calculated and voluntarily reported by eligible manufacturers to CMS on a quarterly basis (this benchmark would only be available and identified by CMS if acceptable data was submitted by all manufacturers of the GLOBE Model drug, as determined by CMS), as proposed in section II.G.2.b. of this proposed rule.

As further described in section II.G.2.a. of this proposed rule, to identify the *per unit Method I GLOBE Model benchmark* and determine if such benchmark is available for purposes of identifying *the per unit GLOBE Model benchmark* for a GLOBE Model drug, we

[112] World Health Organization. WHO-Listed Authority (WLA). Available at: *https://www.who.int/initiatives/who-listed-authority-reg-authorities.*

[113] World Health Organization. Intellectual Property and Trade. WHO Response. Available at: *https://www.who.int/health-topics/intellectual-property#tab=tab_2.*

[114] GDP (PPP) means purchasing power parity (PPP)-adjusted per capita gross domestic product (GDP).

propose that, in general, CMS would follow these steps (subject to data availability): identify available international drug pricing information for the set of reference countries for the first applicable ASP calendar quarter (or prior calendar quarter, if necessary) for which the drug is a GLOBE Model drug; apply data checks; convert the available international drug pricing information to align with the HCPCS Level II code long descriptor associated with the GLOBE Model drug; identify per unit GDP (PPP) adjusted country-level prices using the applicable methodology for the available international drug pricing information for a country (for example, calculating a volume-weighted average per unit price when pricing and volume data are available or calculating an average per unit price when pricing data are available but volume data are not available in the selected data source); and identify the lowest per unit GDP (PPP) adjusted country-level price as the *per unit Method I GLOBE Model benchmark.* The results of the interim calculation steps would be rounded to the fifth decimal place and the last step would be rounded to the third decimal place.

As further described in section II.G.2.b. of this proposed rule, to identify the *per unit Method II GLOBE Model benchmark* and determine if such benchmark is available for purposes of identifying the *per unit GLOBE Model benchmark,* we propose that, in general, CMS would follow these steps for a GLOBE Model drug for each applicable calendar quarter (subject to data availability): identify voluntary manufacturer-submitted international drug net pricing data that was timely submitted and meets requirements for completeness and validity (as set forth in 42 CFR 513.610 and described in section II.G.6. of this proposed rule); identify the volume-weighted average per unit price as the *per unit Method II GLOBE Model benchmark.* As set forth in 42 CFR 513.420, the manufacturer across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit data element (further discussed in section II.G.6. of this proposed rule) would be calculated by the manufacturer and would be rounded to the third decimal place prior to being submitted to CMS.[115] As discussed in section II.G.6. of this proposed rule, CMS is proposing that manufacturers would have two data submission options—streamlined and limited—for the international drug net pricing data that would be voluntarily submitted. Refer to section II.G.6. of this proposed rule for additional details on the two manufacturer data submission options.

In 42 CFR 513.410, we propose that, prior to model start in accordance with proposed 42 CFR 513.410, CMS would identify the per unit Method I GLOBE Model benchmark for each GLOBE Model drug for the first applicable calendar quarter of performance year 1. These benchmarks would remain in place until the end of the model performance period. Similarly, subsequently, 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. Thus, quarterly for each GLOBE Model drug, after CMS would identify the *per unit Method I GLOBE Model benchmark* (as previously calculated at baseline, if available) and the *per unit Method II GLOBE Model benchmark* (as most recently calculated, if available), CMS would compare the *per unit Method I GLOBE Model benchmark* and the *per unit Method II GLOBE Model benchmark* to identify which is greater; the greater of the two would be identified as the *per unit GLOBE Model benchmark* for the GLOBE Model drug for the applicable calendar quarter. If only the *per unit Method I GLOBE Model benchmark* is available for the GLOBE Model drug (manufacturer has not submitted international drug net pricing data), then the *per unit Method I GLOBE Model benchmark* becomes the *per unit GLOBE Model benchmark* for the GLOBE Model drug for the applicable calendar quarter.

As discussed in section II.G.3. of this proposed rule, we propose how CMS would use the identified *per unit GLOBE Model benchmark* to calculate the *per unit GLOBE Model benchmark amount* for the GLOBE Model drug for that applicable calendar quarter which would be used to calculate the alternative rebate amounts, coinsurance adjustments, and adjusted Medicare payments to providers.

We believe that our proposed approach to identify the *per unit Method I GLOBE Model benchmark* for a GLOBE Model drug once, based on available international drug pricing information, is necessary to protect the integrity of the model test and minimize corresponding impacts if the international drug pricing information in available data sources become artificially inflated by shifts in manufacturers' pricing and rebate practices, such as a shift to higher prices along with greater rebates that do not change the net pricing realized by manufacturers. Given the potential ease with which available international drug pricing information could be potentially manipulated by manufacturers by changing their pricing and rebate strategies and/or by taking actions that would restrict data sources' ability to source or update international drug pricing information in a manner that represents actual prices and given that such behavioral change would impede CMS' ability to test the model, we believe it is essential to establish the *per unit Method I GLOBE Model benchmark* once at a baseline (at the time the drug enters the model) and use that benchmark for the duration of the GLOBE Model.

Therefore, under our proposal, prior to model start in accordance with proposed 42 CFR 513.410, CMS would identify the *per unit Method I GLOBE Model benchmark* for each GLOBE Model drug for the first applicable calendar quarter of performance year 1. These benchmarks would remain in place for the duration of the model. Similarly, subsequently, 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.

a. Proposed Methodology To Identify the Per Unit Method I GLOBE Model Benchmark Using Existing Data Sources

In this section of this proposed rule, we propose a methodology that CMS would use to identify the *per unit Method I GLOBE Model benchmark* for a GLOBE Model drug for the first applicable calendar quarter that the Part B rebatable drug is a GLOBE Model drug using existing data sources that are described in section II.G.1. of this proposed rule. As proposed in section II.G.1.b. of this proposed rule, CMS would use available international drug pricing information data sources in accordance with the proposed hierarchy to select the data source used to identify a per unit country-level price for each country that is included in the set of

[115] When there is more than one manufacturer submission for a GLOBE Model drug for an applicable calendar quarter, CMS proposes to calculate a volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit using data across all of the applicable submissions using the steps described in section II.G.2.b. of this proposed rule.

reference countries (as specified in 42 CFR 513.310(b)).

Specifically, we propose that CMS would first identify available data sources, available to CMS at least 60 business days prior to the start of the applicable calendar quarter, meeting the requirements in proposed 42 CFR 513.310(c), that have international drug pricing information for the scientific or nonproprietary name for the GLOBE Model drug for the applicable ASP calendar quarter for any country that is included in the set of reference countries identified in proposed 42 CFR 513.310(b). Then for each country that is included in the set of reference countries, CMS would select a data source at the highest level of the hierarchy as available, extract international drug pricing information for the scientific or nonproprietary name for the GLOBE Model drug, and using available data identify a per unit country-level price or determine that a per unit country-level price was unavailable for that reference country.

To select a data source at the highest level of the hierarchy as available and identify available international drug pricing data for the GLOBE Model drug, we propose that CMS would align the GLOBE Model drug's HCPCS Level II code long description (including dosage form and if applicable, route of administration) with the data sources' standardized method for identifying scientific names or nonproprietary names and dosage forms, as applicable. CMS would then extract available drug pricing information for that country from the selected international drug pricing information data source. We propose that CMS would extract and use data that, as determined by CMS, (1) represent the price of a U.S. originator drug or international originator drug (as applicable for data for a country); (2) have complete package size information; (3) represent scientific or nonproprietary name and dosage form that could be described by the GLOBE Model drug's HCPCS Level II code descriptor, including route of administration (if applicable); and (4) have strength data.[116] We propose to only extract and use data for dosage form that could be described by the GLOBE Model drug's HCPCS Level II code long descriptor (as determined by CMS) because a HCPCS Level II code may only describe drug products that are a certain type of formulation, such as short-acting intravenously administered drug products, and a data source's standardized method for drug names could apply more broadly such that a different formulation, such as a long-acting suspension for intramuscular injection, might be extracted if our proposed limitation was not adopted. For example, we would examine the data source's methods for describing dosage form and only extract data where the description is complete and clear, as determined by CMS. We would also examine the data source's methods for describing products in terms of being sold as a U.S. originator drug, international originator drug, or other indicator that would allow CMS to not extract and use pricing information for products that are identified as generic or biosimilar biological products.

To avoid unintentionally using extracted pricing information for drug products that do not align with the GLOBE Model drug's HCPCS Level II code descriptor, we would apply data checks to ensure that the extracted data aligns with the HCPCS Level II code descriptor for the GLOBE Model drug and information about formulations and package sizes sold. Based on our experience using existing international drug pricing information data sources, we propose to perform additional data checks to identify and discard extracted data when the sales or volume data are not greater than zero or the product information (for example, product strength or package size) is inconsistent or not verifiable with available product labeling or product approval information for the GLOBE Model drug. CMS proposes to exclude these records because these records could inappropriately contribute to the calculation of country-level prices.

In addition, we propose to make adjustments to align volume data with the HCPCS Level II code dosage descriptor, when necessary, as determined by CMS. For example, if we find that a data source from which we obtain international drug pricing information makes adjustments for overfill, we would make adjustments to the data that we extract from such source so that the extracted data would be used in a manner that is comparable to how CMS uses ASP data to calculate payment limits. In these cases, we propose to identify the quantity of drug without counting overfill based on the package labeling or other documentation related to product licensing within a country. There could be other cases where we may find it necessary to make adjustments to align the extracted data with a HCPCS Level II code descriptor for a GLOBE Model drug. For example, there may be cases where a selected data source shows package size information that is standardized (for example, ''per each'' which may not clearly distinguish the quantity of drug) or inconsistent with a manufacturer's publicly available information that describes their drug product or the amount of active drug in a presentation level. In such cases where we confirm a difference and an appropriate conversion method, we would make adjustments in how the pricing, sales and volume data are associated with the HCPCS Level II code descriptor, as necessary, before calculating the country-level price, such as limiting the number of HCPCS billing units assigned. HCPCS billing units, as defined in 42 CFR 513.20, are the standardized measurement quantities (such as milligrams, milliliters, or individual items) used to determine how medical services, procedures, supplies, and drugs are quantified and billed for reimbursement under the Healthcare Common Procedure Coding System, where the billing quantity is calculated by dividing the total amount administered or provided by the unit of measurement defined for that specific HCPCS Level II code. For the purposes of the GLOBE Model, this can be determined by dividing the quantity of drug in the package by the HCPCS dosage (quantity of drug represented in one HCPCS billing unit, which is the identifiable quantity of a drug or biological product associated with a billing and payment code (for example, a HCPCS Level II code), as established by CMS). Based on our experience, we believe that such cases would be uncommon, and, in most cases, the appropriate conversion would be straightforward. We note that there could be additional cases when adjustments would be necessary if international drug pricing data sources that are available show prices, sales or volume data that are inconsistent with other reliable data sources (for example, product information available on manufacturers' websites), include multiple ingredients for a single drug product and the data source presents information in a different manner from the HCPCS Level II code descriptor, or are in error (for example, the package size represents the maximum volume of a vial instead of the volume or quantity of drug in a package as indicated in product labeling).

In addition, to carefully align extracted data with the HCPCS Level II

[116] Individual countries differ in the regulatory processes and standards governing approval of drugs and biologicals. Use of international drug pricing information in the proposed GLOBE Model should not be interpreted to connote FDA approval or to otherwise describe any scientific or regulatory relationship between U.S.-approved and non-U.S.-approved products.

code for a GLOBE Model drug, CMS would assess whether there are differences in the international pricing information attributed to data source coding or country-specific considerations to determine whether the available international pricing information consistently and accurately aligns with the HCPCS Level II code long descriptor. An example of a data coding difference that CMS would consider equivalent is if some available international pricing information records describe the packaging as a disposable vial in some countries but in others, the packaging is described as a single-dose vial in other records. Because disposable vials are single-dose vials, in this case, CMS would determine that disposable vials and single-dose vials are equivalent packaging and would not consider such variations to be inconsistent with product information. An example of country-specific considerations that CMS would take into account is differences in drug naming standards across countries. For example, although not a GLOBE Model drug, in the U.S. and Japan, acetaminophen is the scientific or nonproprietary name while in most other countries, instead of being called acetaminophen, it is referred to as paracetamol. In this type of case, CMS would consider acetaminophen and paracetamol equivalent drugs when a data source's standardized method for identifying scientific names or nonproprietary names treats them as equivalent or alternative names.

To further avoid the potential that some international drug pricing information available in existing data sources may not represent actual prices and, if included in the calculation of country-level prices, could result in a per unit country-level price that would not be a reasonable benchmark, at 42 CFR 513.410(a)(4)(i)(A) we propose to remove pricing information at the dosage form and strength level for a country that falls below 5 percent of the average price in the U.S. Specifically, prior to calculating the per unit country-level price, CMS would calculate an average price for a reference country only using pricing information for the same scientific or nonproprietary name, dosage form, and strength using extracted international drug pricing information (that was not discarded due to data checks). If the resulting average price for a country for a dosage form and strength falls below 5 percent of the average U.S. price for the scientific or nonproprietary name (across all dosage forms and strength), CMS would remove the pricing information for that dosage form and strength and would not use such data to calculate the per unit country-level price.

For purposes of this step, which would compare and then remove certain pricing information from the calculation of per unit country-level prices for the Method I alternative calculation approach, CMS proposes to identify an ''average U.S. price'' using pricing information from the selected data source used for the reference country for the applicable ASP calendar quarter, if available, otherwise CMS would use the most recently published Medicare Part B payment limit (minus the add-on amount, that is, in general 100 percent ASP) for the HCPCS Level II code for the GLOBE Model drug for the calendar quarter *before* the applicable ASP calendar quarter. Because existing data sources for international drug pricing information have an unique approach for presenting drug pricing information and for making data within the data source useful for cross-country comparison, we believe that, if available, using drug pricing information for the applicable ASP calendar quarter that would be extracted from the same data source for both the reference country and the U.S. would be a more consistent and appropriate approach for this proposed purpose than using available ASP-based Medicare payment limit information, which, given time limitations, would be for a prior calendar quarter. Nevertheless, if the selected data source for the reference country did not contain available U.S. pricing information for the GLOBE Model drug, we believe that using available ASP data would be a reasonable alternative and would be suitable for purposes of removing pricing information that is low and may not reflect actual prices for a dosage form and strength.

We considered several alternatives, including not proposing to remove potentially inappropriately low pricing information, only using U.S. pricing information from external data sources, and applying a higher threshold (for example, removing pricing information that would fall below 10 percent of the average price in the U.S.). Using available international drug pricing information, we estimate that a 5 percent threshold, on average, could raise the benchmark about 1 percent overall. For a few potential GLOBE Model drugs, the impact would raise the benchmark to a more reasonable level and would still likely result in a country-level price for a reference country being available. At a 10 percent threshold level, we observed that reference country pricing information that appears consistent with U.S. pricing information would be removed which suggests that a lower threshold would be more appropriate. We also considered whether to compare reference country pricing information at the country level across all products regardless of dosage forms and strengths. This approach was more likely to result in a country-level price being unavailable, due to data for one dosage form and strength impacting the overall average price for all dosage forms and strengths when the data were combined.

For a GLOBE Model drug where CMS has selected a data source and extracted available international drug pricing information for an international drug for a country that is included in the set of reference countries, we propose that CMS would use the following steps to identify a per unit country-level price by country, apply the GDP (PPP) adjuster (as determined pursuant to 43 CFR 513.430) and identify the lowest per unit GDP (PPP) adjusted country-level price as the *per unit Method I GLOBE Model benchmark:*

Step 1: Apply data checks (as described above and in proposed 42 CFR 513.410(a)(2)) and discard or adjust data as applicable as determined by CMS.

Step 2: Convert the volume data to the unit of measurement delineated in the HCPCS Level II code descriptor (for example, mg, ml, mcg, etc.), as applicable, using volume and strength information as proposed in 42 CFR 513.410(a)(3). Note that volume data includes both information about the quantity of drug in the product packaging and, when available, the amount of sales.

Step 3: Adjust the volume data (as proposed in 42 CFR 513.410(a)(3)(i)), as applicable, before converting the volume data to the unit of measurement delineated in the GLOBE Model drug's HCPCS Level II code descriptor when the data source shows the package size for a presentation level that is inconsistent with the manufacturer's information about that product, as determined by CMS.

Step 4: Limit the number of HCPCS billing units (as proposed in 42 CFR 513.410(a)((3)(ii)) when—

- The available information (such as package labeling) indicates a limited quantity of drug to be used from the presentation level; and
- Depending on the HCPCS Level II code description, the HCPCS dosage is per therapeutic dose, per dose, or per treatment.

Step 5: By country, identify the per unit country-level price using the calculation that is applicable.

a. If an international drug pricing information data source with sales and volume data is used, the applicable calculation is as follows (as proposed in 42 CFR 513.410(a)(4)(i)):

(1) CMS removes pricing information at the dosage form and strength level for a country that falls below 5 percent of the average price in the U.S. as set forth in 42 CFR 513.410(d).

(2) Using remaining data, CMS sums the adjusted volume data for the presentation levels for the applicable international analog (as specified in 42 CFR 513.600).

(3) Using remaining data, CMS sums the total sales for the presentation levels for the applicable international analog (as specified in 42 CFR 513.600) (that remain after performing the data checks).

(4) CMS divides the sum determined in Step 5a.(3) by the sum determined in Step 5a.(2), resulting in an average country-level price per unit, where the unit is the same unit delineated in the HCPCS Level II code descriptor.

b. If an international drug pricing information data source with ex-manufacturer or list prices is used (that is, the data source does not contain available volume data and the pricing data is a positive value (note that data that have missing, negative, or zero values would be discarded by data checks)), the applicable calculation is as follows (as proposed in 42 CFR 513.410(a)(4)(ii)):

(1) For each extracted ex-manufacturer or list price, CMS calculates the number of HCPCS billing units in the presentation level by dividing the quantity of drug in the presentation level by the quantity of drug represented in the HCPCS dosage from the HCPCS Level II code descriptor.

(2) CMS divides the ex-manufacturer or list price, as applicable, by the number of HCPCS billing units in the presentation level, resulting in a price per unit where the unit is the same unit delineated in the HCPCS Level II code descriptor.

(3) CMS removes pricing information at the dosage form and strength level for a country that falls below 5 percent of the average price in the U.S. as set forth in 42 CFR 513.410(d)(2).

(4) CMS calculates the sum of the price per unit calculated in Step 5b.(2) for each ex-manufacturer or list price that was identified as available and not removed in step 5b.(3).

(5) CMS divides the sum calculated in Step 5b.(4) by the number of ex-manufacturer or list prices that were summed in Step 5b.(4), resulting in an average country-level price per unit where the unit is the is the same unit delineated in the HCPCS Level II code descriptor.

Step 6: Calculate the per unit GDP (PPP) adjusted country-level price by multiplying the average per unit country-level price calculated in Step 5 by the applicable GDP (PPP) adjuster for such country as set forth in 43 CFR 513.430 (and illustrated in Table 5) and round the result at the fifth decimal place.

Step 7: After identifying the available per unit GDP (PPP) adjusted country-level price by country, we propose that CMS would identify the lowest per unit GDP (PPP) adjusted country-level price, round that amount at the third decimal place, and identify the result as the per unit Method I GLOBE Model benchmark.

In developing our proposal to base the per unit Method I GLOBE Model benchmark on the identified lowest per unit GDP (PPP) adjusted country-level price we considered that a 2024 analysis comparing drug prices in the U.S. and other countries concluded that U.S. prices for brand drugs were at least 3.22 times as high as prices in OECD countries. This study did not account for economic differences across markets. We believe that testing this model by selecting the lowest per unit GDP (PPP) adjusted country-level price would more reasonably align the per unit Method I GLOBE Model benchmark with both the sum of beneficiary coinsurance amounts and net Medicare spending amounts for GLOBE Model drugs under the model and international prices for GLOBE Model drugs, which would represent an alternative Part B inflation rebate amount calculation that could reduce access barriers to GLOBE Model drugs and improve quality of care for beneficiaries with deficits in care and generate potential savings for the Medicare program and such beneficiaries. As such, we believe that the proposed GLOBE Model fits within the statutory authority under section 1115A of the Act which authorized the Secretary to test models to reduce program expenditures while preserving or enhancing the quality of care furnished to Medicare beneficiaries.

CMS believes that using the lowest GDP (PPP) adjusted country-level price after applying data checks that would remove pricing information at the dosage form and strength level for a country that falls below at least 5 percent of prices in the U.S. would more closely represent the actual net prices for the drug when available existing international drug pricing information data sources are used because these data sources may not include pricing information that reflects all price concessions. Further, the lowest country-level price, when volume data is available from existing international drug pricing information data sources, corresponds to how much of that country's sales volume is sold at that price. CMS considered using an across country average instead of the lowest country-level price. However, calculating an across country average of prices that does not represent actual prices paid for a GLOBE Model drug in the reference countries would not closely reflect the typical price in a country, particularly considering a result that would include data that was GDP (PPP) adjusted.

CMS also considered using the *n* lowest country-level price or the average of the *n* lowest GDP (PPP) adjusted country-level prices. As noted above, these methods do not closely represent the actual price of the drug and the corresponding volume. We also considered an alternative approach to identify the per unit Method I GLOBE Model benchmark that would involve applying a gross to net sales estimate in aggregate to available international drug pricing information. However, gross to net sales data is generally not publicly available at the drug level making this approach impractical for CMS to test and would not yield a transparent benchmark metric.

In our proposed methodology to determine the per unit Method I GLOBE Model benchmark amount, we opted to adjust the country-level prices to account for economic differences among countries, such as GDP per capita, prior to the comparison of the available country-level prices to identify the lowest country-level price for a GLOBE Model drug. We believe that adjusting a single country-level price using a GDP (PPP) adjuster is reasonable. Specifically, given that the reference countries are economically comparable to the U.S., we would expect that adjusting for country wealth differences based on PPP adjusted GDP would more likely result in appropriate international pricing information that align with other country-specific dynamics.

We seek comment on our proposed approach and steps to identify the per unit Method I GLOBE Model benchmark once in advance of the first applicable calendar quarter for the GLOBE Model drug and potential alternative approaches, including available data sources, methods for identifying an international pricing benchmark using existing international drug pricing

information, and ways to use such information to closely represent actual prices of a drug in reference countries. We also seek comment on whether we should consider data sources that report only in local currency, which could require CMS to perform a currency conversion in addition to a GDP (PPP) adjustment. We also seek comment on our proposal to apply a GDP (PPP) adjustment, including the extent to which it may be appropriate to make any adjustments based on other factors not considered in this proposed rule.

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

In this section of this proposed rule, we propose a methodology that CMS would use to identify the *per unit Method II GLOBE Model benchmark* for a GLOBE Model drug for an applicable calendar quarter using voluntarily manufacturer-submitted international drug net pricing data (as described in section II.G.2.b. of this proposed rule) when such data is available and meets acceptance criteria (as described in section II.G.6. of this proposed rule), as determined by CMS.

To identify available manufacturer-submitted international drug net pricing data for a GLOBE Model drug, we propose that CMS would use accepted manufacturer-submitted international drug net pricing data (that is, an ''*applicable submission*'' for a GLOBE Model drug as set forth in 42 CFR 513.610) for an applicable ASP calendar quarter that aligns with the applicable calendar quarter and the GLOBE Model drug's HCPCS Level II code long description (including scientific or nonproprietary name, dosage form, and route of administration (if applicable)).

We propose to only use data for dosage forms that can be described by the GLOBE Model drug's HCPCS Level II code long descriptor (as determined by CMS) because a HCPCS Level II code may only describe drug products that are a certain type of formulation, such as short-acting intravenously administered drug products, and manufacturer-submitted international drug net pricing data for an international drug could apply more broadly such that information for a different formulation, such as a long-acting suspension for intramuscular injection, might be available and used if our proposed limitation was not adopted. To avoid unintentionally using data for formulations that do not align with the GLOBE Model drug's HCPCS Level II code descriptor, we would apply data checks to ensure that the accepted manufacturer-submitted international drug net pricing data aligns with the HCPCS Level II code descriptor for the GLOBE Model drug.

Because manufacturers would submit net pricing data at the HCPCS Level II code billing unit level and would not include overfill in the net pricing data and because applicable submissions would meet a completeness and validity check, we do not foresee the need to make adjustments to the manufacturer-submitted international drug net pricing data for a GLOBE Model drug.

Because we are proposing that manufacturers have the option to submit international drug net pricing data for a GLOBE Model drug and we anticipate the potential situation where CMS would not identify available data, in such cases, we propose that, in the absence of available manufacturer-submitted net pricing information for a GLOBE Model drug for an applicable ASP calendar quarter, CMS would identify that the *per unit Method II GLOBE Model benchmark* was unavailable for an applicable calendar quarter.

Therefore, when there is one manufacturer submission of international drug net pricing data for a GLOBE Model drug for an applicable calendar quarter, we propose that the *across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit* data element (as defined in 42 CFR 513.20 and further discussed in section II.G.6. of this proposed rule), submitted by the manufacturer and accepted by CMS according to subpart G, would be identified as the *per unit Method II GLOBE Model benchmark.* Further, we propose that, when there is more than one manufacturer submission of international drug net pricing data for a GLOBE Model drug for an applicable calendar quarter, we propose to calculate a volume-weighted average using data across all of the applicable submissions. For example, when a manufacturer and a repackager submit international drug net pricing data and CMS accepts both manufacturer submissions, CMS would calculate a volume-weighted average using the *across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit* data elements and the volume data element (that is submitted in HCPCS billing units). Specifically, we propose that CMS would apply the following steps:

Step 1: Separately, for each applicable submission, CMS multiplies the *across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit* by the sum of the *volume in billing units.*

Step 2: CMS sums the amounts calculated in Step 1.

Step 3: CMS calculates the total volume by summing the billing units across all applicable submissions.

Step 4: CMS divides the sum calculated in Step 2 by the total volume calculated in Step 3. The resulting volume-weighted average would be rounded at the third decimal place and would be identified as the *per unit Method II GLOBE Model benchmark.*

However, we also propose that when a manufacturer submission for an applicable calendar quarter as set forth in 42 CFR 513.20 is either not accepted by CMS as set forth in 42 CFR 513.610 or was not submitted by all manufacturers of the GLOBE Model drug, CMS would identify that the *per unit Method II GLOBE Model benchmark* is unavailable for such applicable calendar quarter. That is, when there is more than one manufacturer of a GLOBE Model drug, all manufacturers of such GLOBE Model drug would have to voluntarily submit net pricing data for the applicable ASP calendar quarter and each of such data submissions would have to be acceptable (as per 42 CFR 513.400(b)(3)) in order for CMS to identify *a per unit Method II GLOBE Model benchmark.*

In cases where CMS does not identify a *per unit Method II GLOBE Model benchmark,* the *per unit GLOBE Model benchmark* would only be available if a *per unit Method I GLOBE Model benchmark* was available.

In our proposed methodology to determine the *per unit Method II GLOBE Model benchmark,* we opted to allow manufacturer-submitted international drug net pricing data to be adjusted using a GDP (PPP) adjuster, as specified by CMS. We believe, based on our proposed criteria for the set of reference countries, that all of the countries included in the set of reference countries would be economically comparable with the U.S. and each other reference country (that is, each reference country's GDP per capita would be no less than 60 percent of U.S. GDP per capita) and would have a comparable economy size (real GDP greater than $400 billion). Previous research comparing international prices of U.S. originator drugs and international originator drugs show that prices can vary widely across countries. For example, among the countries listed in Table 5, the U.S. originator prices are between 339 and 703 percent higher

than international originator drugs.[117] We expect that the *per unit Method II GLOBE Model benchmark* would tend to be higher than the per unit lowest country-level price identified under our proposed methodology for the *per unit Method I GLOBE Model benchmark*—before CMS would apply the proposed GDP (PPP) adjuster—because it reflects the price variations in reference countries and accounts for them through a volume-weighted price. As such, we believe this approach would be a strong incentive for manufacturers to conduct data gathering, analyses, and reporting activities related to voluntary manufacturer submission of international drug net pricing data as discussed in section II.G.6. of this proposed rule. Our goal is to encourage manufacturers to report international drug net pricing data (that is reflective of the actual transaction prices internationally) for GLOBE Model drugs to CMS for purposes of the GLOBE Model to enhance the model test and inform CMS' model monitoring and evaluation activities. We welcome comments or data on the extent to which the per unit Method II GLOBE Model benchmark would tend to be higher than the per unit Method I GLOBE Model benchmark, as well as comments on situations when the per unit Method II GLOBE Model benchmark may be lower than the per unit Method I GLOBE Model benchmark.

We welcome comment on our proposed methodology to identify the *per unit Method II GLOBE Model benchmark* for a GLOBE Model drug for an applicable calendar quarter.

c. Alternatives Considered

Instead of proposing that, for a GLOBE Model drug, CMS would identify *the per unit Method I GLOBE Model benchmark* once for the first applicable calendar quarter for such GLOBE Model drug and CMS would not reassess that benchmark, we considered an alternative that would allow CMS to revise the benchmark prospectively, no more frequently than quarterly, only if such benchmark would be lower than the currently applicable *per unit Method I GLOBE Model benchmark.* For example, prior to model start in accordance with proposed 42 CFR 513.410, CMS would identify the *per unit Method I GLOBE Model benchmark* for each GLOBE Model drug for the first applicable calendar quarter of performance year 1. These benchmarks would remain in place for the duration of the model performance period unless CMS identifies a lower GDP (PPP) adjusted country-level price for the GLOBE Model drug using available data sources that meet the requirements in proposed 42 CFR 513.310. Similarly, for drugs that become GLOBE Model drugs 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 performance period unless CMS identifies a lower GDP (PPP) adjusted country-level price for the GLOBE Model drug. Under this alternative, if a *per unit Method I GLOBE Model benchmark* was prospectively revised, the revised benchmark would remain in place for the remaining applicable calendar quarters until the end of the model performance period unless CMS identifies a lower GDP (PPP) country-level price for the GLOBE Model drug that would be used beginning with the next applicable calendar quarter. We note this approach would allow CMS to consider international drug pricing information that becomes available over time, for example, after a *per unit Method I GLOBE Model benchmark* is identified by CMS for a GLOBE Model drug, a new data source may become available, a data source may add data for additional countries to its offering, data for sales for certain countries in the set of reference countries might become available within an existing data source, or international sales pricing and volume data may reflect lower prices related to market changes in reference countries. A lower benchmark could result in a lower *per unit GLOBE Model benchmark amount* and greater total GLOBE Model rebate amount as well as lower GLOBE Model beneficiary coinsurance. Allowing for a potential lower per unit country-level price could potentially positively impact model beneficiaries' access to GLOBE Model drugs and lower beneficiary financial liability. However, doing so would increase operational complexity for the model and could impact manufacturers' decisions to voluntarily submit international drug net pricing data, which would interfere with the model test of implementing and testing an alternative rebate calculation using Method II and collecting such data. Therefore, to avoid unnecessary complexity in the model design and to reduce the potential for confounding events during the GLOBE Model test related to changes to the *per unit Method I GLOBE Model benchmark,* CMS has opted to not revise the *per unit Method I GLOBE Model benchmark* for a GLOBE Model drug once it has been identified by CMS.

Similarly, CMS considered identifying the lowest country-level GDP (PPP) adjusted net price per HCPCS billing unit reported by a manufacturer as the Method II benchmark. This also could result in a lower benchmark, lower *per unit GLOBE Model benchmark amount,* and likely greater total GLOBE Model rebate amount as well as lower GLOBE Model beneficiary coinsurance. However, CMS is concerned this could also impact manufacturers' decision to voluntarily submit international drug net pricing data, which could prevent CMS from being able to test the alternative rebate calculation using Method II.

We considered not adjusting the country-level prices for differences in economy size and purchasing power. That is, we considered not applying a GDP (PPP) adjustment within the calculations for the Method I and Method II benchmarks, which would result in lower benchmarks, and applying a GDP (PPP) adjustment to the Method II benchmark only, because there is some uncertainty in our belief that existing international drug pricing information closely reflects actual prices paid as those data may not include lagged price concessions and therefore may not closely represent actual prices. Using available 2024 international drug pricing information, we estimate that not applying a GDP (PPP) adjustment would result in lower benchmarks and greater anticipated model savings and beneficiary coinsurance reductions for GLOBE Model beneficiaries. Relatedly, manufacturers would also be more likely to owe total GLOBE Model rebates. Our analysis showed that including the GDP (PPP) adjustment, using illustrative 2024 data, could result in up to 28 percent less potential model performance year 1 savings, given that the reference countries are economically comparable to the U.S., we would expect that adjusting for country wealth differences based on PPP adjusted GDP would more likely result in appropriate international pricing information that align with other country-specific dynamics. We also considered that there are a range of alternative rebate calculations that could be appropriate for testing under the GLOBE Model and that it may be feasible to test other alternative approaches (or calculation steps) than the two methods we propose

[117] Andrew W. Mulcahy, Daniel Schwam, Susan L. Lovejoy. *International Prescription Drug Price Comparisons: Estimates Using 2022 Data,* RAND Corporation. *RR–2956–ASPEC, 2021b.* Available at: *https://aspe.hhs.gov/reports/comparing-prescription-drugs.*

to test. For example, a benchmark could be identified by using a formula that calculates an average ''lowest'' country-level price by calculating an average country-level price across the countries with the two lowest country-level prices. To test a limited model design, we have opted to propose a test for two alternative rebate calculations that each use unique calculations and different international drug pricing information data sources. Although there could be other appropriate alternative calculations for a model test, we opted to test alternatives that would have distinct features related to data sources and benchmark calculations to enhance the potential to understand the impact of each alternative and the overall model test.

In addition, we considered testing an alternative rebate calculation using the proposed Method I and Method II approaches in different subsets of the GLOBE Model beneficiary cohort, such as creating two separate model beneficiary groups using different model geographic areas (that is, after selecting the model geographic areas, about half would be aligned with testing each benchmark approach). We opted not to pursue this alternative because the proposed model test calculations are specific to a GLOBE Model drug and manufacturer submission of international net pricing information would be voluntary making separate test areas not necessary and potentially insufficient. For example, a separate population subset for testing each benchmark methodology could result in weaker incentives for manufacturers to voluntarily submit data necessary for CMS to test identifying a benchmark based on the proposed Method II approach. Further, we believe that, if the GLOBE Model were to test our proposed Method II approach, or any alternative rebate calculation, using a benchmark based on voluntary manufacturer reporting of international net pricing information in a distinct model beneficiary cohort, a default benchmark would still be necessary in cases when manufacturer net pricing information would not be available. As such, we believe our proposed approach of testing a Method I benchmark alongside a test of a Method II benchmark is essential for a feasible model design that would test an alternative rebate calculation that is based on manufacturer submitted net pricing information. Therefore, we opted to pursue the approach of a single model beneficiary cohort for testing both alternative rebate calculations.

We welcome comments on the alternative we considered and our proposed approach for identifying a *per unit GLOBE Model benchmark* using two alternative calculations.

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

In this section of this proposed rule, we propose the methodology CMS would use to determine the *per unit GLOBE Model benchmark amount* for a GLOBE Model drug for an applicable calendar quarter.

In 42 CFR 513.400, we propose that, quarterly for each GLOBE Model drug, after CMS identifies the *per unit Method I GLOBE Model benchmark* as set forth in 42 CFR 513.410, as available, and the *per unit Method II GLOBE Model benchmark* as set for the in 42 CFR 513.420, as available, CMS would compare the identified *per unit Method I GLOBE Model benchmark* (if available) and the identified *per unit Method II GLOBE Model benchmark* (if available) to identify which benchmark is greater and would be identified as the *per unit GLOBE Model benchmark* for the GLOBE Model drug for the applicable calendar quarter. In 42 CFR 513.400(b)(3), we propose that if CMS determines that neither of these benchmarks is available, CMS would determine that the *per unit GLOBE Model benchmark* for the GLOBE Model drug for the applicable calendar quarter is ''not available''.

In addition, we propose that CMS would apply an adjustment to the identified *per unit GLOBE Model benchmark* to calculate the *per unit GLOBE Model benchmark amount,* which would include: (1) a modest increase to account for potential differences between the U.S. market and markets in the reference countries that may remain after allowing for economic and purchasing power differences (called the ''*applicable threshold percentage*'' as set forth in 42 CFR 513.400 and discussed in section II.G.3.a. of this proposed rule); and (2) an amount that would equal the dollar value of the ''*add-on percentage*'' included in the Medicare Part B drug payment limit for the GLOBE Model drug for the applicable calendar quarter (as set forth in 42 CFR 513.400 and discussed in section II.G.3.b. of this proposed rule) which would be called the ''*add-on percentage amount*''. The *add-on percentage* would be the percentage above 100 percent that is specified under section 1847A(b)(1)(B) of the Act. In general, the Medicare Part B payment limit would be equal to the ''specified amount'' (as defined at 42 CFR 427.20). As noted previously, for most HCPCS Level II codes, the add-on percentage is 6 percent in most cases, but it may be 3 percent or 8 percent (when ASP is not yet available during the initial sales period, for certain qualifying biosimilar biological products, and in certain circumstances specified within section 1847A(d)(3)(C) of the Act).

The *per unit GLOBE Model benchmark amount* would be used in the calculation of *the per unit GLOBE Model rebate amount* for a GLOBE Model drug for an applicable calendar quarter as discussed in section II.G.4.a. of this proposed rule.

As discussed in section II.G.2. and proposed in 42 CFR 513.400(b)(3) of this proposed rule, for a GLOBE Model drug for an applicable period, if neither a *per unit Method I GLOBE Model benchmark* nor a *per unit Method II GLOBE Model benchmark* is available, CMS would identify that the *per unit GLOBE Model benchmark* for such GLOBE Model drug for such applicable calendar quarter as ''not available''. In such cases, we propose that CMS would determine that the *per unit GLOBE Model benchmark amount* was not available for purposes of calculating the *per unit GLOBE Model rebate amount* in proposed 42 CFR 513.400, as discussed in section II.G.4. of this proposed rule. We note that this scenario would be possible in cases where a GLOBE Model drug is sold in the U.S. and international drug pricing information for applicable international analog for that GLOBE Model drug is not available through at least one international drug pricing information data source, including voluntary manufacturer submission of international drug net pricing data, and in cases where such GLOBE Model drug is sold in the U.S. but is not sold in any of the reference countries. We also note that in such cases (as proposed in section II.G.4. of this proposed rule), the *per unit GLOBE Model rebate amount,* as proposed in 42 CFR 513.510, would be based on the difference between the *specified amount* (as determined under 42 CFR 427.302(b)) and the *inflation-adjusted payment amount* (as determined under 42 CFR 427.302(g)). This means that, in cases where CMS has not identified a *per unit GLOBE Model benchmark amount,* the *per unit GLOBE Model rebate amount* would equal the *per unit rebate amount* that CMS determines in accordance with the Medicare Part BDrug Inflation Rebate Program under 42 CFR 427.302, as applicable.

a. Proposed Applicable Threshold Percentage

In 42 CFR 513.400(c)(1), we propose to increase the *per unit GLOBE Model benchmark* by an *applicable threshold percentage* which would allow for a modest increase over the international benchmark to account for potential differences between the U.S. market and markets in the set of reference countries for which international drug pricing information was available for identifying the benchmark. Although the proposed calculation for the *per unit GLOBE Model benchmark* includes adjustments for economic and purchasing power parity differences, further adjustment for some potential remaining differences by applying a minimal threshold adjustment could be warranted.

Because the reference countries for which international drug pricing information would be available for identifying either the Method I or Method II benchmark (as described in sections II.G.2.a. and II.G.2.b. of this proposed rule, respectively) could vary by GLOBE Model drug, by applicable calendar quarter, and by the alternative calculation approach used (that is, Method I or Method II), we considered whether a consistent or variable approach for selecting the applicable threshold percentage would be appropriate for the model test. We considered that there could be many factors that could be included in the development of a threshold that would suit our aim of allowing for a modest margin over the identified *per unit GLOBE Model benchmark* that would be connected meaningfully to the different methods and data sources for an alternative rebate calculation that would be tested and would not be overly complex such that the calculation would be as transparent and easily implemented as practical. We also believe that applying a consistent threshold to the benchmarks that were identified using the same method and data sources is appropriate for the model test. That is, we believe that the threshold, if adopted for the model test, should be determined consistently for both methods, but that the magnitude of the threshold could be different for Method I and Method II to account for potential remaining differences for each method between the U.S. market and markets in the reference countries. We believe that this straightforward approach would avoid unnecessary variation in the model test and would increase the learning potential for the model.

Under our proposed approach for identifying the *per unit Method I GLOBE Model benchmark,* the benchmark would be based on available existing international drug pricing information data sources that contain prices that could represent list prices, ex-manufacturer prices (sometimes called ex-factory prices) that represent actual or calculated prices paid to the manufacturer by wholesalers and other distributors, retail prices that represent actual or calculated sales for retail purchasers, and/or prices paid by other purchasers in the distribution (as discussed in section II.G.1. of this proposed rule). Such pricing information may not include all applicable discounts such that net pricing would be lower than the identified benchmark particularly after the proposed GDP (PPP) adjustment, even though we propose to base the benchmark on the lowest country-level price. Further, existing data sources capture drug pricing information that is made available from various sources and, by its nature, does not likely reflect the full range of confidential discounts and net pricing. In addition, because drug pricing information that is made available to existing data sources becomes accessible to drug purchasers, the variation among such prices for a given drug would be expected to lessen over time. Thus, we believe a reasonable margin necessary for purposes of the model test above a benchmark that would be based on international drug pricing information from existing data sources would be minimal, perhaps a de minimis amount of up to 2 percent, to account for potential differences between the U.S. market and markets in the reference countries that would not be addressed by other proposed aspects of the alternative calculation that is based on the lowest-country-level price.

country-level price.

Under the proposed approach for identifying the *per unit Method II GLOBE Model benchmark,* the benchmark would be based on voluntary manufacturer-submitted international drug net pricing information which is intended to reflect the full range of discounts and net pricing. To account for the likelihood of larger price variations across countries that may occur in actual transaction prices abroad, CMS proposes to use a higher applicable threshold percentage of 5 percent. A lower applicable threshold is appropriate for the Method I benchmark since it relies on the lowest country level prices, which do not reflect the full range of discounts and net pricing. These variations in the applicable threshold percentage advance the testing of two alternative rebate calculations for the model, one that uses aggregate net pricing benchmarks while the other uses the lowest country level price that lacks net pricing information. In 42 CFR 513.400(d), we propose that, when the per unit GLOBE Model benchmark is based on the *per unit Method I GLOBE Model benchmark,* the applicable threshold percentage would be 102 percent. When the per unit GLOBE Model benchmark is based on the *per unit Method II GLOBE Model benchmark,* the applicable threshold percentage would be 105 percent.

In developing our proposal, we considered two options for structuring the threshold: (1) apply a fixed adjustment (such as a percentage amount) for all GLOBE Model drugs regardless of the benchmark method; or (2) apply a variable adjustment that reflects one or more characteristics of the GLOBE Model drug, the alternative rebate calculations, or reference countries. We also considered that no adjustment would be necessary. As noted above, we opted to prioritize a straightforward approach that would be connected to the alternative benchmark calculation methodologies.

In developing this proposal, we also considered that, although our proposal for how CMS would identify the *per unit GLOBE Model benchmark amount* would allow a modest threshold above the *per unit GLOBE Model benchmark* to account for potential remaining differences between the U.S. market and markets in the reference countries, the difference between the proposed adjustment, which is 102 percent of the per unit Method I GLOBE Model benchmark (that is, the lowest per unit GDP (PPP) adjusted country-level price) and the 105 percent of the per unit Method II GLOBE Model benchmark, might not provide sufficient incentive for manufacturers to voluntarily submit international drug pricing information for testing the Method II alternative rebate calculation. Without a sufficient incentive, the model test of the Method II benchmark could be limited or unsuccessfully implemented.

We welcome comments on our proposal for the applicable threshold percentage and alternatives that may help advance the aims of the model test.

b. Proposed Add-On Percentage Amount

In 42 CFR 513.400(c)(2), we propose to increase the *per unit GLOBE Model benchmark* by the *add-on percentage amount* (that is, the dollar value of the *add-on percentage*) that is included in the *specified amount* (as determined under 42 CFR 427.302(b)) when

calculating the *per unit GLOBE Model benchmark amount.* Specifically, CMS would identify the dollar amount of the statutory add-on amount, typically 6 percent of the Medicare Part B payment amount as calculated under section 1847A(b) of the Act (which is typically based on the volume-weighted average sales price). For example, if the per unit volume-weighted average sales price for a drug for an appliable calendar quarter is $100 and the 6 percent add-on applies, the statutory add-on amount per unit would be $6 and CMS would add $6 in the calculation of the *per unit GLOBE Model benchmark amount.* This proposed approach is intended to avoid including an amount equal to the add-on within the GLOBE Model rebate amounts that manufacturers would owe. We note that under the Medicare Part B Drug Inflation Rebate Program, when the specified amount (as determined under 42 CFR 427.302(b)) and the inflation-adjusted payment amount (as determined under 42 CFR 427.302(g)) are compared, each of these amounts could include an amount related to an add-on percentage. Our proposed approach would be consistent with the treatment of add-on amounts under the Medicare Part B Drug Inflation Rebate Program.

We considered an alternative of not increasing the *per unit GLOBE Model benchmark* to account for an add-on that would be included in the *specified amount* (as determined under 42 CFR 427.302(b)) but we decided to propose this increase because we believe that increasing the *per unit GLOBE Model benchmark* by the dollar value of the add-on included in the *specified amount* (as determined under 42 CFR 427.302(b)) would likely increase the rebate amounts manufacturers could owe simply due to one part of the rebate calculation including an add-on amount while the other part in the comparison would not.

We welcome comments on our proposed methodology for identifying the *per unit GLOBE Model benchmark amount* and our rationale for this approach. We also welcome comment on potential alternative approaches that would closely align the *per unit GLOBE Model benchmark amount* with the net pricing in various international markets. For the per unit Method I GLOBE Model benchmark, we also considered the possibility of adjusting annually for inflation. However, it is not clear how best to do that given differences across reference countries that exist and because each drug may have a different reference country that is used to identify the per unit Method I GLOBE Model benchmark. Therefore, we are soliciting comments on this potential policy to inflation adjust the default international benchmark and the best ways to implement this while maintaining the goals of the model test.

4. Proposed Methodology for Calculating the GLOBE Model Rebate Amount

In this section of the proposed rule, we propose how CMS would calculate the *per unit GLOBE Model rebate mount* and the *incremental per unit GLOBE Model rebate amount* due. We also propose a methodology to identify the *total number of GLOBE Model billing units* in order to calculate the *total GLOBE Model rebate amount* and the *incremental GLOBE Model rebate amount* due. Finally, we propose a methodology to reduce the *incremental GLOBE Model rebate amount* for GLOBE Model drugs in shortage and when there is a severe supply chain disruption.

a. Proposed Methodology for Calculation of the Per Unit GLOBE Model Rebate Amount and the Incremental Per Unit GLOBE Model Rebate Amount

In this section of this proposed rule, we propose how CMS would identify the *per unit GLOBE Model rebate amount* and the *incremental per unit GLOBE Model rebate amount* for a GLOBE Model drug for an applicable calendar quarter. The *per unit GLOBE Model rebate amount* would reflect the result of the alternative rebate calculation and the *incremental per unit GLOBE Model rebate amount* would be the amount in excess of the rebate amount calculated as set forth in 42 CFR 427.301. Thus, the *incremental per unit GLOBE Model rebate amount* would be an ''incremental amount'' in addition to the Medicare Part B drug inflation rebate amount to avoid complex operational overlap with the Medicare Part B Drug Inflation Rebate Program activities and potential confusion for GLOBE Model participants.

To test the program impact of the alternative rebate calculation, for a GLOBE Model drug for an applicable calendar quarter, we propose that the *per unit GLOBE Model rebate amount* would be the greater of: (1) the difference between the *specified amount* (as determined under 42 CFR 427.302(b)) and the *per unit GLOBE Model benchmark amount* (as described in section II.G.3. of this proposed rule), if available; or (2) the difference between the *specified amount* (as determined under 42 CFR 427.302(b)) and the *inflation-adjusted payment amount* (as determined under 42 CFR 427.302(g)). If the result is an amount less than $0, we propose that the *per unit GLOBE Model rebate amount* would be set at $0.

We intend to design the GLOBE Model in a manner that ensures Medicare FFS beneficiaries who are GLOBE Model eligible beneficiaries would not face greater financial liability when they receive a GLOBE Model drug for which Medicare Part B allows separate payment and the Medicare program would not also pay more in such cases. Therefore, we are proposing that the *per unit GLOBE Model rebate amount* would not be lower than the difference between the specified amount (as determined under 42 CFR 427.302(b)) and the inflation-adjusted payment amount (as determined under 42 CFR 427.302(g)). That is, our proposed approach would ensure that the *per unit GLOBE Model rebate amount* would not be less than the Part B inflation rebate amount, if any, for the applicable calendar quarter.

We are also proposing to calculate an *incremental per unit GLOBE Model rebate amount* for a GLOBE Model drug for an applicable calendar quarter which would represent the amount in excess of the per unit Part B rebate amount calculated as set forth in 42 CFR 427.302. We believe that calculating the *incremental per unit GLOBE Model rebate amount* for a GLOBE Model drug for an applicable calendar quarter is necessary for purposes of the GLOBE Model test to provide transparency to manufacturers with respect to how GLOBE Model rebate amounts would be invoiced, due, and paid—that is, the follow-on model operational activities that are inherent components of the model test but that, given the proposed limited geographic scope of the model, must coincide with Medicare Part B Drug Inflation Rebate Program operational activities for a Part B rebatable drug. We believe that calculating incremental distinct amounts for purposes of GLOBE Model follow-on activities would provide clarity, reduce potential confusion, and facilitate accurate invoices and rebate payment for both the GLOBE Model and the Medicare Part B Drug Inflation Rebate Program as further discussed in section II.G.8. of this proposed rule.

We propose to codify these calculations in 42 CFR 513.510, including that the results would be rounded to the second decimal place.

We note that in cases where CMS determines that the *per unit GLOBE Model benchmark amount* is not available, our proposal means that the *per unit GLOBE Model rebate amount* for an applicable calendar quarter would be the difference between the

specified amount (as determined under 42 CFR 427.302(b)) and the inflation-adjusted payment amount (as determined under 42 CFR 427.302(g)). We also note that, in these cases, the *incremental per unit GLOBE Model rebate amount* would be zero because there would be no amount in excess of the per unit Part B rebate amount calculated as set forth in 42 CFR 427.302.

We welcome comment on our proposed methodology for determining the *per unit GLOBE Model rebate amount* and calculating the *incremental per unit GLOBE Model rebate amount* for a GLOBE Model drug for an applicable calendar quarter.

b. Proposal for Identification of the Total Number of GLOBE Model Billing Units

In this section of this proposed rule, we discuss how the *total number of GLOBE Model billing units* for a GLOBE Model drug for an applicable calendar quarter would be identified for purpose of thereafter being used to calculate the *total GLOBE Model rebate amount* and the *incremental GLOBE Model rebate amount.*

For purposes of the Medicare Part B Drug Inflation Rebate Program, CMS identifies the total number of billing units as set forth in 42 CFR 427.303. We propose, in 42 CFR 513.520, that, to identify the *total number of GLOBE Model billing units,* CMS would identify the total number of billing units from the total number of billing units that CMS identified in accordance with 42 CFR 427.303(b) where, on the date of service, the Medicare beneficiary was identified by CMS as a GLOBE Model eligible beneficiary and for which Medicare Part B FFS made separate payment. We propose that the resulting sum of the identified billing units would be identified as the *total number of GLOBE Model billing units* that CMS would use to calculate the *total GLOBE Model rebate amount* and the *incremental GLOBE Model rebate amount* for a GLOBE Model drug for an applicable calendar quarter. This approach would ensure that units that are not included in the total number of billing units determined under 42 CFR 427.303, such as 340B units and units of discarded drugs, would also not be included in the *total number of GLOBE Model billing units.*

We note that, because the *total number of GLOBE Model billing units* would be determined from the total number of billing units that CMS identified in accordance with 42 CFR 427.303(b), the *total number of GLOBE Model billing units* would always be equal to or less than the total number of billing units identified for the Medicare Part B Drug Inflation Rebate Program and most likely substantially less given our proposal to limit the model scope to approximately 25 percent of Medicare Part B FFS beneficiaries. We also note that this method of identification of the *total number of GLOBE Model billing units* prevents any potential discrepancies related to the number of billing units used to calculate GLOBE Model rebate amounts because the total number of billing units as determined under 42 CFR 427.303 would be the starting point and the GLOBE Model Eligible Beneficiary List and Medicare claims would clearly facilitate CMS' identification of the subset of those billing units where, on the date of service, the Medicare beneficiary was identified by CMS as a GLOBE Model eligible beneficiary and for which Medicare Part B FFS made separate payment.

c. Proposal for the Calculation of the Total GLOBE Model Rebate Amount and Incremental GLOBE Model Rebate Amount Due for a GLOBE Model Drug for an Applicable Calendar Quarter

In this section of this proposed rule and in 42 CFR 513.500, we propose how the *total GLOBE Model rebate amount* and *the incremental GLOBE Model rebate amount* for a GLOBE Model drug for an applicable calendar quarter would be calculated. To clearly identify the alternative rebate under the GLOBE Model test, CMS would calculate the *total GLOBE Model rebate amount* that manufacturers would be accountable for. To avoid potential duplication across activities under the Medicare Part B Drug Inflation Rebate Program, a per unit incremental amount would be used to identify the *incremental GLOBE Model rebate amount* which manufacturers would owe to CMS in addition to any amount invoiced under the Medicare Part B Drug Inflation Rebate Program. Both of these amounts would be used for follow-on steps for GLOBE Model reporting, invoicing, and rebate payment as discussed in section II.G.8. of this proposed rule. The *incremental GLOBE Model rebate amount* would be adjusted prior to these follow-on steps, when applicable, for GLOBE Model Drugs in shortage and when there is a severe supply chain disruption as discussed in section II.G.4.d. of this proposed rule.

We propose that the *total GLOBE Model rebate amount* for a GLOBE Model Drug for an applicable calendar quarter owed by a manufacturer of the GLOBE Model drug to the Federal Supplementary Medical Insurance Trust Fund would be the amount calculated as the product of the *per unit GLOBE Model rebate amount* as calculated pursuant to 42 CFR 513.510(a) and the *total number of GLOBE Model billing units* (as identified as set forth in 42 CFR 513.520(c)). We note that when the *per unit GLOBE Model rebate amount* is zero, the *total GLOBE Model rebate amount* would also be zero. To simplify operations while clearly invoicing manufacturers for this amount, we propose to calculate an *incremental GLOBE Model rebate amount* that would represent the amount of the *total GLOBE Model rebate amount* that is in excess of the rebate amount for the Medicare Part B Drug Inflation Rebate Program that applies to the *total number of GLOBE Model billing units.*

In 42 CFR 513.500(b), we propose that the *incremental GLOBE Model rebate amount* would be the amount calculated as the product of the *incremental per unit GLOBE Model rebate amount* as set forth in 42 CFR 513.510(b) and the *total number of GLOBE Model billing units* (as identified as set forth in 42 CFR 513.520).

Table 6 presents illustrative incremental per unit GLOBE Model rebate amounts for an illustrative Part B rebatable drug that could potentially be a GLOBE Model drug for an illustrative quarter based on average estimates of a per unit Method I and Method II GLOBE Model benchmarks [118] using international drug pricing information that was available to CMS for purposes of this proposed rule. The illustrative specified amount, illustrative add-on percentage amount, estimated per unit inflation-adjusted payment amount, and estimated per unit Part B inflation rebate amount are based on CMS claims data for 2024 and represent averages for an illustrative GLOBE Model drug. The illustrative per unit GLOBE Model benchmark for Method I and Method II

[118] This estimate is not based on international net pricing information, but it is calculated based on the volume-weighted average across countries using a GDP (PPP) adjuster as described in this proposed rule, IQVIA national audits and IQVIA MIDAS® reflect local industry standard source of pack prices, which may be list price or average invoice price, depending upon the country and the available information; they do not take into account rebates or clawbacks, details of which are normally confidential, and therefore these estimated prices do not reflect net prices realized by the manufacturers. Sales values reflected in these IQVIA audits are calculated by applying such relevant pricing to the product volume data collected for, and reflected in, such audits. In addition, to allow the national audit sales values to be viewed at a common sales level, MIDAS applies a single average industry margin to the locally reported values. The drug price provided is an estimated price and its intended function is to convert volumes to sales—this estimated price is not intended to be used as a metric in its own right.

is based on international pricing information available to CMS following the process described in sections II.G.1. and II.G.3. of this proposed rule. The illustrative per unit Method I GLOBE Model benchmark represents the lowest per unit GDP (PPP) adjusted country-level price. To provide an illustrative per unit Method II GLOBE Model benchmark, CMS used international pricing data available as a proxy for an across country volume-weighted average GDP (PPP) adjusted net price. For example, for Method I the illustrative per unit benchmark amount ($16.16) is calculated by taking the sum of the product of the illustrative per unit Method I benchmark and a threshold percentage of 102 percent and the dollar value of the illustrative add-on percentage of the Medicare Part B payment limit ($13.378 * (1.02) + $2.514). The illustrative per unit GLOBE Model rebate amount for Method I is the greater of $28.26 or $0.59, where $28.26 is the difference between the illustrative specified amount and the illustrative per unit GLOBE Model benchmark amount ($44.416 − $16.16) and $0.59 is the difference between the illustrative specified amount and the estimated per unit Inflation-Adjusted rebate amount ($44.416 − $43.830). The illustrative incremental per unit GLOBE Model rebate amount is then calculated as the difference between the illustrative per unit GLOBE Model rebate amount and the estimated per unit Part B rebate amount ($28.26 − $0.59). We follow a similar process to calculate the illustrative Method II per unit GLOBE Model rebate amount using 105 percent as the threshold percentage. CMS welcomes comments on this proposal.

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TABLE 6: ILLUSTRATIVE INCREMENTAL PER UNIT GLOBE MODEL REBATE AMOUNT AND COINSURANCE REDUCTION FOR AN ILLUSTRATIVE HCPCS LEVEL II CODE UNIT: METHOD I AND METHOD II BENCHMARKS

Method	Illustrative Specified Amount[a]	Illustrative Add-on Percentage Amount of the Medicare Part B Payment Limit[a]	Estimated Per Unit Inflation-Adjusted Payment Amount[a]	Estimated Per Unit Part B Drug Rebate Amount[a]	Illustrative Per Unit GLOBE Model Benchmark[a]	Illustrative Per Unit GLOBE Model Benchmark Amount[a]	Illustrative Per Unit GLOBE Model Rebate Amount[a]	Illustrative Incremental Per Unit GLOBE Model Rebate Amount[a]	Illustrative Coinsurance Percentage[b]	Illustrative Adjusted Coinsurance Reduction Amount[b]
Method I	$44.416	$2.51	$43.83	$0.59	$13.38	$16.16	$28.26	$27.67	7.2%	$3.18
Method II	$44.416	$2.51	$43.83	$0.59	$20.97	$24.53	$19.89	$19.30	10.6%	$4.70

Notes: [a] This table provides highly simplified estimates for an illustrative HCPCS Level II code meeting the selection criteria for a GLOBE Model drug for an illustrative applicable quarter using data from 2024 for Method I and Method II. The illustrative per unit benchmarks are based on IQVIA MIDAS® annual sales and volume data for period January 2024 to December 2024. Copyright IQVIA. All rights reserved. [b] The illustrative coinsurance percentage is calculated as the product of 20 percent and the sum of the per unit GLOBE Model benchmark and the illustrative add-on percentage amount divided by the specified amount. For example for Method I, the illustrative coinsurance percentage of 7.16 percent is calculated as: 0.20*($16.16)/($44.42). The illustrative adjusted coinsurance reduction amount is the product of the illustrative coinsurance percentage and the specified amount. For example, the illustrative adjusted coinsurance reduction amount for Method I of $3.178 is the result of multiplying 0.0716 by $44.416.

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d. Proposal for Reducing the Incremental GLOBE Model Rebate Amount for GLOBE Model Drugs in Shortage and When There Is a Severe Supply Chain Disruption

(1) Reducing the Incremental GLOBE Model Rebate Amount for GLOBE Model Drugs in Shortage

In accordance with section 1847A(i)(3)(G)(i) of the Act as codified in 42 CFR 427.401, CMS reduces the total rebate amount determined under 42 CFR 427.301(a), if any is owed, for a Part B rebatable drug that is currently in shortage, as set forth in 42 CFR 427.400. For purposes of the Medicare Part B Drug Inflation Program, to calculate the reduction in the total rebate amount for a Part B rebatable drug that is currently in shortage, CMS calculates the number of days such drug is described as ''currently in shortage'' on an FDA shortage list in a calendar quarter, divides by the number of days in the calendar quarter, and then multiplies that amount by the applicable percentageas specified in 42 CFR 427.401(b)(2).

For purposes of the GLOBE Model, CMS proposes at 42 CFR 513.500(d) to reduce the *incremental GLOBE Model rebate amount* using in the methodology specified in 42 CFR 427.401(b)(1). Specifically, to closely align with the Medicare Part B Drug Inflation Rebate Program, for any GLOBE Model drug currently in shortage during an applicable calendar quarter during the model performance period, CMS proposes to use the applicable percent reduction and percentage of time the drug was currently in shortage during the applicable quarter as set forth in 42 CFR 427.401(b). In proposed 42 CFR 513.500(d), CMS would reduce the *incremental GLOBE Model rebate amount,* if any, for such GLOBE Model drug for such applicable calendar quarter. The ''applicable percent reduction'' in the formula would be determined as set forth in 42 CFR 427.401(b)(2) as applicable, including to account for whether the GLOBE Model drug is a plasma-derived product and the number of consecutive applicable calendar quarters such drug is currently in shortage. We note that this approach would maintain the meaning and use of the terms ''applicable percent reduction'' and ''time drug was currently in shortage'' as those terms are used in 42 CFR 427.401(b). Specifically, we are proposing that the equation would be—

Reduced incremental GLOBE Model rebate amount = the incremental GLOBE Model rebate amount multiplied by (1 *minus* ''applicable percent reduction'' determined under 42 CFR 427.401(b)(2) multiplied by (''percentage of time drug was currently in shortage during the applicable calendar quarter'' as determined in accordance with 42 CFR 427.401(b)(3)) added to the incremental GLOBE Model rebate amount multiplied by (1 *minus* ''percentage of time drug was currently in shortage during the applicable calendar quarter'' as determined in accordance with 42 CFR 427.401(b)(3)).

Further, CMS proposes to apply a reduction of the *incremental GLOBE Model rebate amount* as determined under 42 CFR 513.510(d)(2) to all the NDCs under the relevant billing and payment code as specified in 42 CFR 427.401(c). We codify our proposal in proposed 42 CFR 513.500(d). As discussed in section II.G.8. of this proposed rule, any applied reductions would be identified in the GLOBE Model Rebate Report.

As an alternative to our proposed approach, we considered whether, for purposes of the GLOBE Model, the applicable percent reduction should be greater than or less than the applicable percentage reduction specified in 42 CFR 427.401(b)(2). To maintain consistency with the Medicare Part B Drug Inflation Rebate Program and avoid creating different manufacturer incentives for addressing shortages and supply chain disruptions, we decided to propose to apply, for purposes of the GLOBE Model, the same applicable percentage reduction as used under the Medicare Part B Drug Inflation Rebate Program.

(2) Reducing the Incremental GLOBE Model Rebate Amount for a GLOBE Model Drug When There Is a Severe Supply Chain Disruption

Under section 1847A(i)(3)(G)(ii) of the Act as codified in 42 CFR 427.402, CMS reduces the total rebate amount determined under 42 CFR 427.301(a), if any is owed, for a Part B rebatable biosimilar biological product when CMS determines there is a severe supply chain disruption during the applicable calendar quarter such as that caused by a natural disaster or other unique or unexpected event. Additional instructions for submitting rebate reduction requests are provided in the collection of information that was approved on July 22, 2024, under OMB control number 0938–1474 and can be found on reginfo.gov. As discussed in section II.B.1. of this proposed rule, we are proposing to exclude biosimilar biological products from the definition of GLOBE Model drugs. But, if after notice and comment that proposal is not finalized, we are proposing that, for any GLOBE Model drug that is a biosimilar biological product as set forth in section 1847A(c)(6)(H) of the Act, CMS would reduce the incremental GLOBE Model rebate amount, if any, when there is a severe supply chain disruption during the applicable calendar quarter in the same manner as specified in 42 CFR 427.402, including the limitation on rebate reductions in 42 CFR 427.402(b)(4).

Specifically, to the extent that CMS finalizes a definition of GLOBE Model drugs that were to include biosimilar biological products, when CMS reduces the total rebate amount determined under 42 CFR 427.301(a), if any is owed, for a Part B rebatable biosimilar biological product that is a GLOBE Model drug for an applicable quarter, CMS would likewise reduce the *incremental GLOBE Model rebate amount* determined pursuant to 42 CFR 513.500(b), if any is owed, using the specifications for calculation of the reduced rebate amount set forth in 42 CFR 427.402(b), substituting ''the *incremental GLOBE Model rebate amount*'' for ''the total rebate amount'', subject to the eligibility requirements set forth in 42 CFR 427.402(c), and to apply that rebate reduction only if the eligibility criteria in 42 CFR 427.402(c) are met. Our intent is to maintain the meaning and use of other terms and provisions within 42 CFR 427.402. In other words, to the extent that biosimilar biological products are included in the GLOBE Model, CMS intends to reduce the incremental GLOBE Model rebate amount for such GLOBE Model drug, if any is owed, when there is a severe supply chain disruption using the same criteria and percentage reduction that CMS applied under 42 CFR 427.402 for such GLOBE Model drug for the applicable calendar quarter.

We note that, if our proposal to exclude biosimilar biological products from the definition of GLOBE Model drugs is finalized in a final rule establishing the GLOBE Model, our proposal for reduction of the incremental GLOBE Model rebate amount for GLOBE Model drugs that are biosimilar biologicals when there is a severe supply chain disruption would not be necessary and we would not include such provision in such final rule.

(3) Other Considerations for Reducing the Incremental GLOBE Model Rebate Amount for GLOBE Model Drugs in Shortage and When There Is a Severe Supply Chain Disruption

Previous ASPE analysis showed that a small number (3 percent) of Part B drugs and biological products were listed in the FDA list of current shortages in January 2023.[119] The same study showed that most of the products in shortage were injectables and products that have been approved longer than 11 years. Using the FDA's lists of drugs in shortage,[120] [121] we identified three Part B drugs associated with a shortage in 2024, but none of these drugs was a proposed GLOBE Model drug. Prior work that examined the extent to which changes in U.S. volume and price of drugs in shortage affect volume and prices of the same drugs in other OECD countries concluded there is little evidence that U.S. shortages are associated with volume and price changes in the sample of OECD countries examined.[122] Although the potential number of GLOBE Model drugs associated with a shortage or supply chain disruption may be small, the impacts of a single shortage may be large in terms of costs to patients and health care providers when managing a shortage as well as negative impacts on patient health due to delayed or unavailable treatments; [123] [124] [125] for this reason and for consistency with section 1847A(i)(3)(G)(i) and (ii) of the Act, we are proposing to reduce the incremental GLOBE Model rebate amount for GLOBE Model drugs in shortage and, to the extent biosimilar biological products are included in the model, when there is a severe supply chain disruption as discussed in section II.G.4.d.(2). of this proposed rule. We also considered not reducing the incremental GLOBE Model rebate amount or applying a smaller or larger reduction than determined under 42 CFR 427 subpart E.

We seek comments on our proposal for reduction of the incremental GLOBE Model rebate amount for GLOBE Model drugs in shortage and for GLOBE Model drugs that are biosimilar biologicals when there is a severe supply chain disruption.

5. Proposed Payment Responsibilities

As discussed in section II.E. of this proposed rule, we propose that model participants would be manufacturers of GLOBE Model drugs. Consistent with the Medicare Part B Drug Inflation Rebate Program, under the GLOBE Model, we propose that a ''*manufacturer*'' would be identified using the same approach used for reporting ASP and the Medicaid Drug Rebate Program data. The manufacturer of a GLOBE Model drug would be responsible for all GLOBE Model rebate payments for each applicable GLOBE Model drug. We propose that manufacturers of GLOBE Model drugs with a total GLOBE Model rebate amount due of $0 or greater would be provided a rebate report which would serve as an invoice for the *total GLOBE Model rebate amount due,* using an *incremental GLOBE Model rebate amount,* as described in section II.G.4.c. of this proposed rule. As discussed in section II.G.8. of this proposed rule, CMS is proposing to include the *total GLOBE Model rebate amount* and *incremental GLOBE Model rebate amount* in either the Preliminary Rebate Report and Rebate Report provided to the manufacturer pursuant to 42 CFR 513 subpart H (which would be the same rebate reports used for the Medicare Part B Drug Inflation Rebate Program) or in separate Preliminary GLOBE Model Rebate Report and GLOBE Model Rebate Report that CMS would provide to the manufacturer.

When multiple manufacturers are linked to a single HCPCS Level II code that represents a GLOBE Model drug (for example, GLOBE Model drugs that have NDCs involving multiple labeler codes), we propose to apportion the *incremental GLOBE Model rebate amount* as set forth in paragraph (b) or (c) of 42 CFR 427.301 as applicable. That is, a manufacturer's liability for the *incremental GLOBE Model rebate amount* would be calculated by CMS and would be proportionate to the manufacturer's total billing units sold during the applicable calendar quarter. This approach adopts CMS' current operational approach for the Medicare Part B Drug Inflation Rebate Program and is necessary for testing the model in an efficient and consistent manner.

We seek comment on this proposed approach for calculating the manufacturer payment responsibility for total GLOBE Model rebate amounts due, if any, for a GLOBE Model drug for an applicable calendar quarter.

6. Proposed Reporting Requirements and Process for Voluntary Manufacturer-Provided Data

In order for CMS to identify a per unit Method II benchmark in the alternative inflation rebate amount calculation for a given GLOBE Model drug, a manufacturer must voluntarily report international pricing data. A manufacturer must submit this data in accordance with reporting requirements and process set forth for voluntary manufacturer-provided data. For CMS to determine that the submission is an ''applicable submission'', we propose in 42 CFR 513.610(a)(3)(i) that the data must include all the basic data elements (as set forth in 42 CFR 513.610(b) and described in section II.G.6. of this proposed rule) required for each ''applicable international analog'' as defined in 42 CFR 513.600 that corresponds to a GLOBE Model drug. An applicable international analog means a non-U.S. analog whose scientific or nonproprietary name, dosage form, and route of administration (if applicable) align with a GLOBE Model drug and that are sold in one or more reference countries during the applicable ASP calendar quarter, excluding those identified in their respective country as a generic or biosimilar biological product according to the country's own regulations.

In addition, the submission must contain all the net pricing data elements (as set forth 42 CFR 513.610(c)) required under one of the two options

[119] Beleche, T., Parasrampuria, S., and Adetunji, O. Characteristics of Part B Drugs in Shortage. Washington, DC: Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. December 2024. Available at: *https://aspe.hhs.gov/sites/default/files/documents/d38b00602b2f24f02b85ca4731457616/part-b-drug-shortages-ib.pdf.*

[120] Food and Drug Administration. Current and Resolved Drug Shortages and Discontinuations reported to FDA. Available at: *https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.*

[121] Food and Drug Administration. CBER-Regulated products: Current Shortages. Available at: *https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/cber-regulated-products-current-shortages.*

[122] Mulcahy, A.W., Rao, P., Kareddy, V., andAgniel D. Assessing Relationships Between Drug Shortages in the United States and Other Countries. RAND Research, October 27, 2021. Available at: *https://www.rand.org/pubs/research_reports/RRA1070-1.html.*

[123] Office of the Assistant Secretary for Planning and Evaluation and NORC at the University of Chicago. Impact of Drug Shortages on Patients in the United States: A Case Study of Three Drugs. Washington, DC: Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services. April 2024. Available at: *https://aspe.hhs.gov/reports/shortages-three-drugs.*

[124] Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services. Impact of Drug Shortages on Consumer Costs. May 2023. *https://aspe.hhs.gov/https://aspe.hhs.gov/sites/default/files/documents/87781bc7f9a7fc3e6633199dc4507d3e/aspe-rtc-costs-drug-shortages.pdf.*

[125] Beleche, T., and Kolbe, A. Medical Product Shortages in the United States: Demographic and Geographic Factors and Impacts. Washington, DC: Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. July 2024. Available at: *https://aspe.hhs.gov/sites/default/files/documents/1c348191e0660572cfe642e2fbca572c/ASPE_IssueBrief_shortages-2024-07-05_edited_ASPE_508c.pdf.*

manufacturers can select to submit net pricing data (as described in section II.G.6.b. of this proposed rule). We also propose in 42 CFR 513.610 that the submission must be complete, meaning the submission—(1) has a proper and full execution of the manufacturer data agreement; (2) has a proper and full attestation by the manufacturer's authorized representative; (3) was submitted using the proper portal and all security requirements within; (4) was executed in the manner and form required by CMS; and (5) includes supporting documentation that explains how each of the elements of the submission were compiled or calculated and any reasonable assumptions that were applied. Incomplete submissions, as determined by CMS, would not be assessed for validity and would not be used by CMS for purposes of identifying a per unit Method II GLOBE Model benchmark.

In addition, we propose that complete data submissions would be assessed by CMS for validity. As discussed previously in section II.G.1. of this proposed rule, to do so, CMS would utilize all available existing data sources and information to assess the extent to which the submission reflects international drug net pricing for the applicable international analogs that were sold in the reference countries during the applicable ASP calendar quarter. To inform the review, as determined by CMS, CMS may use available data sources. We propose that CMS may choose to request additional supporting information and/or data from the manufacturer who submitted the data to inform CMS' assessment of the validity of the submission. Because the amount of time that CMS would have to complete the review would be minimal (for example, approximately 2 weeks), CMS would limit the amount of time that a manufacturer would have for submission of additional supporting information to no more than 5 business days from the agency's request for additional supporting information or data or both.

a. Basic Data Requirements

Under the data agreement, manufacturers may make submissions for one or more GLOBE Model drugs for any applicable ASP calendar quarter. If a manufacturer chooses to make a submission for a GLOBE Model drug to enable identification of a per unit Method II GLOBE Model Benchmark, the manufacturer would include all applicable international analogs as defined by 42 CFR 513.600. We also propose that the basic data element requirements would consist of data elements, including but not limited to presentation level information, that manufacturers must submit in order for CMS to corroborate that an applicable international analog (as defined in 42 CFR 513.600) which is included in the manufacturer submitted data corresponds to a GLOBE Model drug and to verify the results of the manufacturer's conversion to HCPCS billing units. To verify a manufacturer's conversion to HCPCS billing units, CMS proposes to calculate the number of HCPCS billing units (as defined in 42 CFR 513.20) in the applicable international analog, by dividing the quantity of drug in the package by the HCPCS dosage (quantity of drug represented in one HCPCS billing unit).

In 42 CFR 513.610, we propose that the required basic data elements that would be used by CMS to identify the international net pricing data that corresponds to a GLOBE Model drug, would include the GLOBE Model drug brand name, nonproprietary name, and HCPCS Level II code. We also propose that the basic data elements provided by the manufacturer contain a list of every applicable international analog as defined in 42 CFR 513.600 that was sold in that reference country for the applicable ASP calendar quarter. The list is the required basic data elements including presentation level information. We propose that a complete submission must have these data elements for all of the applicable international analogs as defined in 42 CFR 513.610 by reference country:

- Scientific or nonproprietary name.
- Brand name, all international drug names.
- HCPCS Level II code.
- Names of manufacturers, marketers, or licensees.
- Non-U.S. country regulatory approval status [126] (international originator drug or international non-originator drug).
- Dosage form and route of administration (if applicable).
- Strength.
- Volume per item (for example, 10 ml in one vial).
- Package type (for example, syringe, vial, ampule, etc.).
- Number of items per package (for example, 10 vials in a package).
- HCPCS dosage (published by CMS each for HCPCS Level II code).
- Number of HCPCS billing units.

We propose that these data elements would be required to be submitted for all applicable international analogs sold in the reference country during the applicable ASP calendar quarter that corresponds to a GLOBE Model drug. If there are missing data elements, the submission would be considered incomplete and would be deemed unacceptable for identifying a per unit Method II benchmark until the manufacturer provides all the necessary data elements to CMS no later than 30 calendar days after the end of the applicable ASP calendar quarter. This means that if, for a GLOBE Model drug, there are six applicable international analogs in a reference country, the manufacturer submitted data must include the basic data elements for every applicable international analog in that reference country. If an applicable international analog was sold in multiple reference countries, then the manufacturer submitted data must also include the basic data elements for all applicable international analogs in each of the reference countries. That is, the basic data element requirements necessitate submitting the data elements separately for each applicable international analog for each reference country. This information would be necessary to allow CMS to identify each applicable international analog within each reference country where the drug is sold.

Figure 2. Illustrative Example of Basic Data Elements

[126] As defined at proposed 42 CFR 513.600 ''*non-U.S. country regulatory approval status*'' means information relevant for CMS to determine whether each applicable international drug's regulatory approval status (according to the applicable reference country's regulatory framework), is an international generic (international non-originator drug), international biosimilar biological product (international non-originator drug), international originator drug, or other. Individual countries differ in the regulatory processes and standards governing approval of drugs and biologicals. Use of international drug pricing information in the proposed GLOBE Model should not be interpreted to connote FDA approval or to otherwise describe any scientific or regulatory relationship between U.S.-approved and non-U.S.-approved products.

Basic Data Elements are:

1. GLOBE Model drug elements for identification: brand name, non-proprietary name, and HCPCS Level II code; and
2. For every reference country where at least one applicable international analog was sold during the applicable ASP calendar quarter:

Country A

i.e. all applicable international analogs in the reference country

e.g. brand name

Applicable International Analog	Scientific or Non-proprietary name (s)	Drug Name (s)	Manufacturer(s), marketer (s), licensee(s)	Regulatory Approval Status	Dosage Form and Route of Administration	Strength	HCPCS Dosage	HCPCS Billing Units	Volume per item	Package Type	Number of items per package
Analog 1											
Analog 2											
Analog …											
Analog n											

Country B

Country …

Country n

Note: This is an illustrative example for structure of the basic data elements for each reference country and the applicable international analogs. The specific format for how manufacturers would submit the data is further discussed in section II.G.6.d. of this proposed rule.

We propose that if, for any of the basic data elements, third-party individuals and organizations were used to gather, analyze, or submit the data, the manufacturer must specify their use of third party data with respect to each of the type of activity (gather, analyze, or submit the data) engaged in by the third party, and the third-party individual or organization identified in the basic data element submission.

We recognize the complexities inherent in international pharmaceutical markets, including variations in strengths, formulations, and routes of administration; packaging differences; and diverse relationships between U.S. and international entities responsible for product marketing and distribution. CMS seeks comments on whether the proposed voluntary framework, which includes basic required data elements to ensure applicable international analogs correspond with GLOBE Model drugs, adequately addresses these market complexities. We also seek comments on whether additional basic data elements should be required or if any of the proposed elements presents significant data collection, analysis, or submission challenges.

b. Options for Submission of Net Pricing Data Elements

When manufacturers choose to submit voluntary international drug net pricing, we propose a two-step process: (1) submission of basic data elements as previously described; and (2) submission of international drug net pricing data from one of the two options proposed in this section. For submission of international drug net pricing data, we propose manufacturers can choose between these 2 options to submit: *streamlined* or *limited*. In both options, we propose manufacturers would provide the required volume-weighted average GDP (PPP)-adjusted net pricing per HCPCS billing unit for the applicable international analogs for all reference countries the applicable international analogs were sold in for the applicable ASP calendar quarter (across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit). The difference between the two options is the level of aggregation allowed for the submission of gross sales, net sales, and sales volume that was used by the manufacturer to calculate the across country volume-weighted average GDP (PPP)-adjusted net pricing per HCPCS billing unit. In the streamlined option, we propose reporting prices for each applicable international analog in each reference country. In the limited option, we propose reporting prices aggregated at the reference country level.

We also propose in 42 CFR 513.610 that manufacturers who elect to submit international drug net pricing data must submit all of the net pricing data elements required for one of the two options described later in section, in addition to the basic data elements that are discussed in section II.6.a. of this proposed rule. The required net pricing data elements are further described in the next sections and in 42 CFR 513.610(c)(i) for the streamlined option and 42 CFR 513.610(c)(ii) for the limited option. Manufacturers would select which option to follow but must select one option. For each GLOBE Model drug, manufacturers must report net pricing data elements for *all* the applicable international analogs that are sold in the set of reference countries, as described in 42 CFR 513.600, using one of the two available options.

(1) Streamlined Option

Under the streamlined option, CMS proposes that manufacturers would be required to report a set of net pricing data elements for the applicable international analogs that correspond to the GLOBE Model drug. For the purposes of the streamlined option, we propose to define in 42 CFR 513.600 that ''gross sales'' refers to each sale the manufacturer made in that reference country to a purchaser, the amount of money owed to a manufacturer by the purchasers, before subtracting any discounts, rebates, or other price concessions. We propose to define ''purchaser'' in 42 CFR 513.600 as the entities or organizations acquiring the drug product for subsequent sale within

the pharmaceutical supply chain or for administration or dispensing to a human. It may include, among others, wholesalers, distributors, hospitals, pharmacies, and other healthcare providers and practitioners. For ''price concessions'', we propose the following definition in 42 CFR 513.600 to mean the sum of the value of the following types of transactions and items whether at the time of sale or afterwards:

- Volume discounts: ''Volume discounts'' are also known as quantity discounts or bulk discounts where the price per unit is reduced when purchased in larger quantities.
- Prompt pay discounts: The term ''prompt pay discounts'', also known as early payment discounts, means any reduction in the total value of units purchased routinely offered to a purchaser when a payment is made within a specified timeframe and consistent with customary business practices for payment.
- Cash discounts: The term ''cash discounts'' refers to reductions on the price per unit when payment is made in cash. This may be facilitated through discount cards, coupons, or other agreements.
- Free goods includes samples or other benefits provided to purchasers or patients that are contingent on any purchase requirement.
- Chargebacks: This term refers to retrospective payments made from manufacturers to purchasers.
- Rebates: This term refers to reimbursements made by a manufacturer to a wholesaler or other purchaser, for the difference between the price the wholesaler or other purchaser initially paid for the product and the lower price at which the wholesaler or other purchaser sold the product.
- Other price concessions that lower the amount realized by the manufacturer.

We also propose to define in 42 CFR 513.600 that ''net sales amount'' means for each sale the manufacturer made in that reference country to a purchaser, the amount of money owed by the purchaser exclusive of any price concessions. Each net sales amount would have a corresponding sales volume, expressed in HCPCS billing units. The net sales amount is not a list price (for example., the equivalent of WAC in the United States); rather, it is based on the net price of the applicable international analog sold in each reference country. We propose ''net price level,'' defined at 42 CFR 513.600, to mean with respect to sales of applicable international analogs, means all sales of the applicable international analogs in a reference country at the same price net of price concessions during the applicable ASP calendar quarter. We also propose the submission include the net sales amount in the reference country currency, what the local currency is (for example, euro, yen, etc.), and its equivalent U.S. dollar amount, at the net price level. This means the data submitted would report each sales transaction's net sales amount, at an aggregated net price level, along with the corresponding volume sold expressed in HCPCS billing units. In addition, we propose the gross sales amount and net sales amount to be rounded to 5 decimal places.

We recognize that manufacturers may not have access to every sale in a reference country if they are not the ones who are making the sale. Under our proposal, we would expect the manufacturer to obtain data for every transaction that is made directly to health care entities, distributors, wholesalers, or other international purchasers and aggregate those that share a price and concession amount resulting in sales by the net price level.

In Table 7 an example of a voluntary submission of net pricing data by the manufacturer of GLOBE Model drug I is shown. This fictitious GLOBE Model drug I has more than one applicable international analog in 3 reference countries, A, B and C. In reference country A it has 2 applicable international analogs, in reference country B it has 4, and in reference country C it has 3. For reference country A, the applicable international analog 1 has 5 net price levels, thus an applicable submission would include gross and net sales amounts and volume sold expressed in HCPCS billing units for each of the 5 levels. In the same reference country A, applicable international analog 2 has 3 net price levels, thus the acceptable submission includes 3 gross and net sales amounts with the corresponding volumes. This logic is repeated in Table 7 for the other reference countries with applicable international analogs to GLOBE Model drug I. Because the net price level represents all sales transactions that occurred at the same net price during the applicable ASP calendar quarter, there may be multiple individual sales of each applicable international analog. However, all such sales were aggregated into a single net price level when they share the same net price after applying any applicable price concessions.

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TABLE 7. TABLE SHOWING NET PRICE DATA ELEMENTS REQUIRED UNDER THE STREAMLINED OPTIONS FOR ILLUSTRATIVE GLOBE MODEL DRUG "I"

Reference Country	Applicable International Analog	Net Price Levels	Gross Sales Amount (Local Currency)	Net Sales Amount (Local Currency)	Volume (in HCPCS Billing units)	Average Net-to-Gross Ratio	Exchange Rate (Local Currency to USD)	Volume-weighted Net Price per HCPCS billing units (U.S. Dollars)	GDP (PPP)-Adjuster	Across Country Volume-weighted Average GDP (PPP)-Adjusted Net Price per HCPCS billing unit (U.S. Dollars)
Streamlined Option										
A	1	1	100.00000	65.00000	5	0.54947	0.800	187.00231	1.000	182.761
		2	460.00000	350.00000	20					
		3	367.00000	270.00000	15					
		4	80.00000	30.00000	10					
		5	204.00000	48.00000	15					
	2	1	321.00000	132.00000	14					
		2	245.00000	89.00000	6					
		3	123.00000	60.00000	23					
B	1	1	540.00000	340.00000	89	0.61368	10.000	38.10080	1.300	
		2	345.00000	140.00000	90					
		3	76.00000	70.00000	35					
		4	345.00000	260.00000	72					
		5	222.00000	90.00000	34					
	2	1	678.00000	540.00000	90					
		2	856.00000	345.00000	104					
		3	1,020.00000	589.00000	302					
		4	345.00000	140.00000	120					
	3	1	567.00000	300.00000	270					
		2	908.00000	650.00000	309					
	4	1	345.00000	301.00000	190					
		2	284.00000	187.00000	102					
		3	401.00000	302.00000	201					
C	1	1	207.00000	130.00000	40	0.58011	0.860	533.03 078	1.500	
		2	196.00000	89.00000	36					
	2	1	467.00000	123.00000	60					
	3	1	178.00000	90.00000	40					
		2	376.00000	201.00000	32					
		3	999.00000	777.00000	222					
		4	111.00000	60.00000	3					

Notes: Net price level means the sum of individual sales or volume sold for an applicable international analog in a reference country at the same price and price concession amounts; this means there can be more than one sale in each net price level. Gross and net sales amounts are in local currency for the reference country in this table and must include what the local currency is. Volume in this table is expressed in HCPCS billing units that aligns with those of the GLOBE Model drug I. The exchange rate is for currency conversion (local currency to USD); in this case the sales amount is divided by the exchange rate to convert from local currency to U.S. dollars. The volume-weighted net price is obtained by adding for a reference country the products of the net sales amounts in U.S. dollars multiplied by the corresponding volume and then dividing by the total volume (this includes all net price levels for all applicable international analogs in a reference country). The across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit is obtained by adding for all reference countries the products of the net sales amounts in U.S. dollars multiplied by the corresponding reference country's GDP (PPP)-adjuster and multiplied by the corresponding volume and then dividing by the total volume (this includes all net price levels for all applicable international analogs in all reference countries).

In addition, under the streamlined option, we propose that manufacturers provide one ''average net-to-gross ratio'' for each GLOBE Model drug per reference country. For the purposes of the streamlined option, we propose to define the ''average net-to-gross ratio'' to be the total net sales of the applicable international analogs in the reference country divided by the total gross sales of the applicable international analogs in the reference country. We also propose the average net-to-gross ratio to be rounded to 5 decimal places. An example of how the average net-to-gross ratio would be reported is shown in Table 7. In Reference Country A, the sum of all net sales amount for all applicable international analogs is 1044.00000 and the sum of all gross sale amount for the same set of drugs is 1900.00000. Thus, the average net-to-gross ratio would be all net sales amount divided by the sum of all gross sales amounts resulting in 0.54947. A more detailed calculation is shown later in this section.

In addition, we propose manufacturers would be required to report for each country, the volume-weighted net price across all applicable international analogs, in U.S. dollars. We also propose to define ''volume-weighted net price'' to mean exclusive of any price concessions, the volume-weighted reference country average net price in U.S. dollars where the weights are volumes in HCPCS billing units. In addition, we propose volume of the applicable international analog in HCPCS billing units must be expressed using the same number of decimals places as the submitted GLOBE Model Drug's HCPCS billing units. The volume-weighted net price per reference country must also be rounded to 5 decimal places.

Using again the example of reference country A shown in Table 7, each of the net price sales amounts for both applicable international analogs contribute to the volume-weighted net price according to how much volume was sold. The net sales amounts are converted from local currency to U.S. dollars using an exchange rate that is described by 3 decimal places and expressed as number of local currency units to U.S. dollars. In other words, net sales amounts are converted to U.S. dollars by dividing the net sales by the exchange rate. Our proposal for exchange rate considerations is discussed in section II.G.6.c. of this proposed rule. For this example, each net sale is divided by 0.800. This results in an average price for one HCPCS billing unit of GLOBE Model Drug I in reference country A being $187.00231. A more detailed calculation is shown later in this section.

We also propose that manufacturers would be required to submit, across all the reference countries, the *across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit,* which is the volume-weighted average GDP (PPP)-adjusted net price of all the applicable international analogs corresponding to a GLOBE Model drug in U.S. dollars along with the GDP (PPP) adjuster that was used for the adjustment. We propose to define at 42 CFR 513.20, the across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit to mean a volume-weighted average for all reference countries of GDP (PPP)-adjusted net prices, where the weights are the volume in HCPCS billing units for each reference country, in U.S dollars from international drug net pricing data from an applicable submission. In addition, we propose the across volume-weighted average GDP (PPP)-adjusted net price per HCPCS billing unit to be reported and rounded to 3 decimal places.

We propose that the GDP-adjustment would be based on PPP and that manufacturers must use the GDP (PPP)-adjuster from CMS that aligns with the applicable ASP calendar quarter as specified by CMS. CMS would publish a supplemental document on the GLOBE Model website with details on which GDP (PPP) adjuster would be used for each applicable ASP calendar quarter. To establish the GDP (PPP) adjuster for each ASP calendar quarter, we propose to use the most recent data of GDP per capita based on purchasing power parity for a country (GDP (PPP)) available in the CIA World Factbook at the start of the applicable ASP calendar quarter (as defined in 42 CFR 513.20) as determined by CMS. CMS would publish this GDP (PPP) adjuster at the beginning of each applicable calendar quarter.

An example of the across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit for all reference countries can also be observed in Table 7. In this example for GLOBE Model Drug I, there is only one across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit for all three reference countries. Each net sales amount for all applicable international analogs in the three reference countries contribute to this average according to the volume sold. Each of the 29 net sales amounts are converted to U.S. dollars using the appropriate exchange rate (0.800 for the 8 net sales amounts for reference country A, 10.000 for the 14 net sales amounts for reference country B, and 0.860 for the 7 net sales amounts for reference country C) and adjusted by the reference country's GDP (PPP) adjuster (1.000 for reference country A, 1.300 for reference country B, and 1.500 for reference country C). In this illustrative example for GLOBE Model drug I, the across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit in all reference countries where it is sold is $182.761, having accounted for how much quantity is sold, the country's currency, and its PPP.

As a summary, after manufacturers have identified applicable international analogs as defined in 42 CFR 513.600, for an applicable ASP calendar quarter, we propose manufacturers use the following steps to identify average net-to-gross ratio, volume-weighted net price per reference country, and across country volume-weighted average net GDP (PPP) adjusted net price per HCPCS billing unit for all reference countries for each GLOBE Model drug:

Step 1: By reference country, apply the following data checks. Identify and discard data as follows:

a. Exclude sales for international biosimilar biological products and international generic products. In other words, sales data must be based on international originator drugs.

b. Exclude international drug pricing data without both sales and volume data that are greater than zero.

Step 2: By reference country, convert the volume data to unit of measurement delineated in the GLOBE Model drug's HCPCS Level II code descriptor (for example, mg, ml, mcg, etc.), as applicable, for each applicable international analog and net price level. Volume must be expressed using the same rounding convention as the corresponding GLOBE Model Drug. We propose to calculate the number of HCPCS billing units in the applicable international analog as defined in 42 CFR 513.610 by dividing the quantity of drug in the package by the HCPCS dosage (quantity of drug represented in one HCPCS billing unit, which is the identifiable quantity of a drug or biological product associated with a billing and payment code (for example, a HCPCS Level II code), as established by CMS).

Step 3: By reference country, aggregate gross sales amount, in local currency, for each applicable international analog that has the same net price level for each reference country. Gross sales amount must be rounded to 5 decimal places. Report what the local currency is.

Step 4: By reference country, aggregate net sales amount, in local currency, for each applicable international analog for the corresponding GLOBE Model drug that have the same net price level for each reference country. Net sales amount must be rounded to 5 decimal places. Report what the local currency is.

Step 5: By reference country, calculate the average net-to-gross ratio, in local currency, for each reference country. Report what the local currency is.

a. Sum the gross sales amount for all net price levels of all applicable international analogs.

b. Sum the net sales amount for all net price levels for all applicable international analogs.

c. Divide the sum determined in Step 5b. by the sum determined in Step 5a., resulting in the average net-to-gross-ratio per reference country. The average net-to-gross-ratio must be rounded to 5 decimal places.

Step 6: By reference country, convert the net sales amount, in local currency, to U.S. dollars. Divide the net sales, in local currency, by, the exchange rate to convert to U.S. dollars and round to 5 decimal places.

Step 7: By reference country, calculate the per unit volume-weighted net price—

a. Multiply the net sales, in U.S. dollars, by the volume in HCPCS billing unit for each applicable international analog and net price level.

b. Add together the sums determined in Step 7a.

c. Sum together the volume sold in HCPCS billing units for all applicable international analogs and all net price levels.

d. Divide the sum determined in Step 7b by the sum determined in Step 7c, resulting in the average volume-weighted net price per HCPCS billing unit per reference country. Round the average volume-weighted net price per reference country to 5 decimal places.

Step 8: Calculate the across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit for all applicable international analogs to a GLOBE Model drug for all reference countries.

a. Per reference country, multiply the average volume-weighted net price calculated in Step 7d by the applicable GDP (PPP) adjuster per applicable ASP calendar quarter (to be published by CMS in a supplemental document).

b. Per reference country, multiply the sum in Step 8a by the sum in Step 7c. (total volume sold in HCPCS billing unit for all applicable international analogs and all net price levels).

c. Sum together the amounts in Step 8b and divide by the total billing units for all applicable international analogs in all reference countries, resulting in the across country average volume-weighted GDP (PPP) adjusted net price per HCPCS billing unit for all applicable international analogs to a GLOBE Model drug across all reference countries. Round the across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit to 3 decimal places.

We propose that manufacturers submit information on how the data elements were compiled and computed and consistent with ASP reporting, any reasonable assumptions that were made during this process. We also propose manufacturers provide any other pertinent information that CMS should consider in its verification process for the data. Examples of information to submit include if a third party was used to gather, analyze, or submit the net pricing data element, or if the manufacturer made any reasonable assumptions to determine the average gross-to-net ratio (for example, expected clawbacks and other price concessions based on past historical data that may have delayed reporting to the manufacturer and would not be available to the manufacturer in time to be included in the manufacturer's data submission to CMS no later than 30 days after the end of the applicable ASP calendar quarter). We seek comments on reasonable assumptions manufacturers may make during their reporting of average gross-to-net ratio and net sales such as how they account for clawbacks and other price concessions that may have delayed reporting to the manufacturer.

We also recognize that manufacturers may need to allocate gross and net sales amounts to the applicable international analogs in order to provide the data elements required. We propose in 42 CFR 513.610 that any allocation and calculations be done in a manner consistent with the generally acceptable accounting principles (GAAP), international financial reporting standards (IFRS), or other internationally recognized accounting approaches.[127] We solicit feedback on whether there are other accounting approaches that CMS should consider.

(2) Limited Option

Under the limited option, we propose that manufacturers would be required to submit a set of data elements that are aggregated at higher levels than CMS is proposing under the streamlined option. For all the applicable international analogs to a corresponding GLOBE Model drug, as defined in 42 CFR 513.600, and for each reference country, we propose that manufacturers submit the *total* gross sales amount in local currency and its equivalent U.S. dollar amount, which would be computed as the sum of all gross sales amounts for the applicable international analogs in the reference country's currency, the *total* net sales amount in local currency and its equivalent U.S. dollar amount, which would be computed as the sum of all net sales amounts for the applicable international analogs in the reference country's currency, and the corresponding *total* sales volume in HCPCS billing units. In other words, the total gross sales, total net sales, and total sales volume by reference country is an aggregate of all the applicable international analogs and net price levels. For the purposes of the limited option, we propose to use the same definition as the streamlined option for ''gross sales amount'' and ''net sales amount'' as defined in 42 CFR 513.600. Manufacturers must also report what the local currency is (for example, euro, yen, etc.) We also propose the total gross sales and total net sales to be rounded to 5 decimal places and that the total sales volume must be expressed using the same number of decimals places as the corresponding GLOBE Model Drug's HCPCS billing units.

We recognize that manufacturers may not have access to every sale in a reference country if they are not the ones who are making the sale. Under our proposal, we would expect the manufacturer to obtain every transaction that is made directly to health care entities, distributors, wholesalers, or other international purchasers. In addition, we propose to require manufacturers to submit the average net-to-gross ratio for each of the reference countries where the applicable international analogs were sold for a GLOBE Model drug. We propose to define the ''average net-to-gross ratio'' for the limited option to be the same as the streamlined option which is the total net sales of the applicable international analogs in the reference country divided by the total gross sales of the applicable international analogs in the reference country. We propose manufacturers round the average net-to-gross ratio to 5 decimal places.

We also propose manufacturers to report, for each country, the volume-weighted net price across all applicable international analogs corresponding to a

[127] Sean Ross, *GAAP vs. IFRS: What's the Difference?, Investopedia* (Apr. 18, 2025), Available at *https://www.investopedia.com/ask/answers/011315/what-difference-between-gaap-and-ifrs.asp* (Last accessed Nov. 4, 2025).

GLOBE Model drug, as defined in 42 CFR 513.600, in U.S. dollars. To convert from local currency to U.S. Dollars, the net sales amount, in local currency, is divided by an exchange rate with 3 decimal places expressed as number of local currency units to U.S. dollars. Our proposal for exchange rate considerations is discussed in section II.G.6.c. of this proposed rule. For the limited option, we also propose to define the ''volume-weighted net price'' the same as the streamlined option, which is the volume-weighted reference country average net price in U.S. dollars where the weights are volume in HCPCS billing units exclusive of any price concessions as defined in 42 CFR 513.600. The volume-weighted net price per reference country must be rounded to 5 decimal places.

In addition, we propose that manufacturers would be required to submit, across all the reference countries, the across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit of all the applicable international analogs to a corresponding GLOBE Model drug, as defined in 42 CFR 513.600, in U.S. dollars along with the GDP (PPP) adjuster that was used for the adjustment. The limited option would use the same definition as the streamlined option for the across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit as defined in 42 CFR 513.610. This across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit for all reference countries must be rounded to 3 decimal places.

We propose that the GDP adjustment would be based on PPP and that manufacturers must use the GDP (PPP) adjuster from CMS that aligns with the applicable ASP calendar quarter. CMS would publish a supplemental document on the GLOBE Model website with details on which GDP (PPP) adjuster to use for each applicable ASP calendar quarter. To establish the GDP (PPP) adjuster for each ASP calendar quarter, we propose to use the most recent data of GDP per capita based on purchasing power parity for a country (GDP (PPP)) available in the CIA World Factbook at the start of the applicable ASP calendar quarter (as defined in 42 CFR 513.20) as determined by CMS. We would publish this GDP (PPP) adjuster at the beginning of each applicable calendar quarter.

The across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit would represent the average net price per HCPCS billing unit of the applicable international analogs corresponding to a GLOBE Model drug, as defined in 42 CFR 513.600, across all reference countries where the applicable international analogs are sold and would include an adjustment using GDP (PPP). To calculate the across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit in all reference countries where applicable international analogs are sold, the volume-weighted net price per reference country (in U.S. dollars) is multiplied by the GDP (PPP) adjuster per reference country and then the weighted mean for all reference countries is calculated using the sum of volume in HCPCS billing units for each reference country as the weights.

Table 8 shows the net pricing data elements that would be required for GLOBE Model Drug I for the limited option. In this option, while there may be multiple applicable international analogs to GLOBE Model Drug I and multiple net pricing levels, only total gross sales, total net sales, total volume, average net-to-gross-ratio, volume-weighted net price in U.S. dollars per reference country, and across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit in U.S. dollars is reported.

TABLE 8 TABLE SHOWING NET PRICE DATA ELEMENTS REQUIRED UNDER THE STREAMLINED OPTIONS FOR ILLUSTRATIVE GLOBE MODEL DRUG "I"

Reference Country	Gross Sales Amount (Local currency)	Net Sales Amount (Local currency)	Volume	Reference Country	Gross Sales Amount (Local currency)	Net Sales Amount (Local currency)	Volume	Reference Country
Limited Option								
A	1,900.00000	1,044.00000	108	0.54947	0.800	187.00231	1.000	
B	6,932.00000	4,254.00000	2,008	0.61368	10.000	38.10080	1.300	182.761
C	2,534.00000	1,470.00000	433	0.58011	0.860	533.03078	1.500	

Notes: Gross and net sales amounts are in local currency for the reference country in this table. Manufacturers would also report the type of local currency. Volume in this table is expressed in HCPCS billing units that aligns with those of the GLOBE Model drug I. The exchange rate is for currency conversion (local currency to USD). In this case the sales amount is divided by the exchange rate to convert from local currency to U.S. dollars. The volume-weighted net price is obtained by adding for a reference country the products of the net sales amounts in U.S. dollars multiplied by the corresponding volume and then dividing by the total volume. The across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit is obtained by adding for all reference countries the products of the net sales amounts in U.S. dollars multiplied by the corresponding reference country's GDP (PPP) adjuster and multiplied by the corresponding volume and then dividing by the total volume.

As a summary, after manufacturers have identified applicable international analogs sold that correspond to a GLOBE Model drug for an applicable ASP calendar quarter, we propose manufacturers use the following steps to identify average net-to-gross ratio, volume-weighted net price per reference country, and across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit for all reference countries for each GLOBE Model drug:

Step 1: By reference country, apply the following data checks. Identify and discard data as follows:

a. Exclude sales for international biosimilar biological products and international generic products. In other words, sales data must be based on international originator drugs.

b. Exclude international drug pricing data without both sales and volume data that are greater than zero.

Step 2: By reference country, convert the total volume data to the unit of measurement delineated in the GLOBE

Model drug's HCPCS Level II code descriptor, as applicable, for all applicable international analogs. Total volume must be expressed using the same rounding convention as the corresponding GLOBE Model Drug. We propose to calculate the number of HCPCS billing units in the applicable international analog as defined in 42 CFR 513.610 by dividing the quantity of drug in the package by the HCPCS dosage (quantity of drug represented in one HCPCS billing unit, which is the identifiable quantity of a drug or biological product associated with a billing and payment code (for example, a HCPCS Level II code), as established by CMS).

Step 3: By reference country, aggregate gross sales amount, in local currency, for all applicable international analogs. Gross sales amount must be rounded to 5 decimal places. Report what the local currency is.

Step 4: By reference country, aggregate net sales amount, in local currency, for all applicable international analogs. Net sales amount must be rounded to 5 decimal places. Report what the local currency is.

Step 5: By reference country, calculate the average net to gross ratio, in local currency, for each reference country:

a. Sum the gross sales amount for all net price levels of all applicable international analogs.

b. Sum the net sales amount for all net price levels for all applicable international analogs.

c. Divide the sum determined in Step 5b by the sum determined in Step 5a, resulting in the average net-to-gross-ratio per reference country. Round the average net-to-gross-ratio to 5 decimal places.

Step 6: By reference country, convert the net sales amount, in local currency, to U.S. dollars. Divide the net sales, in local currency, by, the exchange rate to convert to U.S. dollars and round to 5 decimal places.

Step 7: By reference country, calculate the per unit volume-weighted net price.

a. Multiply the net sales, in U.S. dollars, by the volume in HCPCS billing unit for each applicable international analog.

b. Add together the sums determined in Step 7a.

c. Sum together the volume sold in HCPCS billing units for all applicable international analogs.

- Divide the sum determined in Step 7b by the sum determined in Step 7c, resulting in the average volume-weighted net price per HCPCS billing unit per reference country and round to 5 decimal places.

Step 8: Calculate the across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit for all applicable international analogs to a GLOBE Model drug across all reference countries.

a. Per reference country, multiply the average volume-weighted net price calculated in Step 7d by the applicable GDP (PPP) adjuster per applicable ASP calendar quarter (to be published by CMS in supplemental document).

b. Per reference country, multiply the sum in Step 8a by the sum in Step 7c (total volume sold in HCPCS billing unit for all applicable international analogs).

c. Sum together the amounts in Step 8b and divide by the total billing units for all applicable international analogs in all reference countries, resulting in the across country average volume-weighted GDP (PPP) adjusted net price per HCPCS billing unit for all applicable international analogs to a GLOBE Model drug across all reference countries. Round the across country average volume-weighted GDP (PPP) adjusted net price per HCPCS billing unit for all reference countries to 3 decimal places.

c. Exchange Rate Considerations

For both options for submitting net pricing data elements, we are proposing that certain data elements would be submitted in U.S. dollars and the manufacturer would report the exchange rate for the currency conversion rounded to 3 decimal places, which CMS proposes would mean the conversion rate used by the manufacturer to convert from the currency of each reference country to U.S. dollars for data included in the submission. We propose manufacturers use either the World Bank Atlas (for a conversion method in lieu of a straight exchange rate),[128] IMF exchange rates data,[129] the Federal Reserve Bank foreign exchange rates,[130] or exchange rates from country-specific sources to identify the average exchange rate. If the data source chosen uses an exchange rate frequency that is less than annual (for example, daily, weekly, monthly, quarterly), the exchange rate for the currency conversion would correspond to an average exchange rate of the chosen frequency for the applicable ASP calendar quarter during which international sales occurred. We also propose manufacturers use the same exchange rate for currency conversion for all applicable international analogs, as defined in 42 CFR 513.600, in a reference country. In other words, all net pricing data in a reference country must use the same exchange rate. We also propose that once an exchange rate data source is identified that the manufacturer continues to use the same data source for all subsequent data submissions, unless the data source is no longer available, and that the exchange rate data source is reported with each voluntary submission. This approach is necessary so that a manufacturer's submitted international net pricing data per GLOBE Model drug is in a consistent format and CMS would be able to combine the data appropriately for purposes of testing an alternative rebate calculation methodology. We solicit feedback on other data sources manufacturers would consider for currency conversion; the methods that would be used; the challenges that might arise; and any other pertinent information related to this topic.

d. Attestation and Submission

While manufacturer reporting is voluntary, submitted data must meet completeness, and validity standards in proposed 42 CFR 513.610 and must be determined by CMS to be an applicable submission in order to be used by CMS to identify the per unit Method II GLOBE benchmark for a GLOBE Model drug for an applicable calendar quarter, as discussed in section II.G.2.b. of this proposed rule. In 42 CFR 513.610, we propose that if the manufacturer is electing to submit international drug net pricing data, the data must be submitted within 30 days after the end of the applicable ASP calendar quarter and the data that is contained within the submission must correspond to the applicable ASP calendar quarter. As such, we propose that an authorized representative, on behalf the manufacturer, provide an attestation that the submissions are accurate and complete to the manufacturer's knowledge, prepared in compliance with the requirements specified under § 513.610 (including, but not limited to the requirements for basic data elements and streamlined or limited option), and that the authorized representative has the authority to make such attestation on behalf of the manufacturer. Authorized representatives for the

[128] *The World Bank Atlas Method: Detailed Methodology, World Bank,* Available at *https://datahelpdesk.worldbank.org/knowledgebase/articles/378832-the-world-bank-atlas-method-detailed-methodology* (Last accessed Sept. 24, 2025).

[129] *IMF Data Explorer: Exchange Rate Data (4.0.1), International Monetary Fund,* Available at *https://data.imf.org/en/Data-Explorer?datasetUrn=IMF.STA:ER(4.0.1)* (Last accessed Sept. 24, 2025).

[130] *Foreign Exchange Rates—G.5A Annual, Board of Governors of the Federal Reserve System* (Jan. 6, 2025), Available at *https://www.federalreserve.gov/releases/g5a/current/* (Last accessed Sept. 24, 2025).

manufacturer must provide their contact information and attest as such. We propose the authorized representatives must be legally authorized to bind the manufacturer to the terms and conditions contained within the data agreement. The authorized representatives are also designated by a manufacturer to submit data, manage all related communications, and attest to the completeness and accuracy of the submission on the manufacturer's behalf. We propose that authorized representatives must specify if they are a third-party organization that is submitting data on behalf of the manufacturer. We propose that a data submission would not be considered complete if it does not include all requirements of attestation such as contact information of the authorized representative, whether a third-party organization is submitting on behalf of the manufacturer, and the attestation itself. The submission would also be considered incomplete if the required basic data elements defined in 42 CFR 513.610 and the required net pricing data elements in the selected streamlined or limited option, as defined in 42 CFR 513.600, are missing, or if the basic data elements and net pricing data elements do not correspond to the applicable ASP calendar quarter that is submitted.

In 42 CFR 513.610, we propose that the attestation and data submission process would occur through a CMS designated system. We intend to designate the CMS Health Plan and Management System (HPMS), which is currently used for Manufacturer Discount Program reporting, reporting for the Medicare Drug Price Negotiation Program, and for the Medicare Part B Drug Inflation Rebate Program. Leveraging existing technology and systems would facilitate executing the GLOBE Model data agreements and attestations, submitting data templates for the various data submission pathways, and provide a method for protecting submitted information. While we intend to designate HPMS, we may designate a different CMS system for submission, if necessary.

We propose that, pursuant to an effectuated GLOBE Model data agreement, CMS would 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 42 CFR 513.210 and 42 CFR 513.500 regarding the determination and implementation of the GLOBE Model rebate amount, the GLOBE Model beneficiary coinsurance, and adjusted Medicare payment amount.

We also propose a manufacturer selects one submission option for net pricing data elements, either limited or streamlined, for all applicable international analogs to a GLOBE Model drug. That is, for all applicable international analogs to a GLOBE Model drug for an applicable ASP calendar quarter, the manufacturer could not use one submission option for net pricing data elements for some of the reference countries and a different submission option for net pricing data elements for other reference countries for which international net pricing and sales data is submitted. Similarly, the manufacturer would continue to use the same submission option for net pricing data elements (either streamlined or limited) to submit all their international net pricing data for that GLOBE Model drug for subsequent applicable ASP calendar quarters. That is, once the manufacturer chooses to voluntarily submit international net pricing data, the manufacturer must continue to do so for the duration of the GLOBE Model so long as sales of applicable international analogs have occurred. This approach is necessary so that a manufacturer's submitted international net pricing data per GLOBE Model drug is in a consistent format and that CMS would be able to combine the data appropriately for purposes of testing an alternative rebate calculation methodology. We also propose that CMS reserves the right to terminate the data agreement if a manufacturer chooses to stop submitting voluntary international net pricing even when sales of the applicable international analogs have occurred. If the data agreement has been terminated, we propose the per unit Method I international benchmark is used for the GLOBE Model drug for the remainder of the model duration.

e. Corrections and Resubmissions

We recognize errors may occur during a manufacturer's submission of international pricing data and are proposing to allow corrections of a submission within 30 days of the submission deadline. For example, if a manufacturer submits international net pricing data for the applicable ASP calendar quarter ending December 31, 2026, to CMS no later than January 30, 2027, in accordance with the requirements for submission of such data, the manufacturer would be allowed to correct the submitted data by submitting a full replacement data submission and attestation for that applicable ASP calendar quarter to CMS (in accordance with the requirements for submitting corrected data) no later than March 1, 2027. We propose to limit the timeframe for submission of corrected international net pricing data to CMS for an applicable ASP calendar quarter to 30 days after the deadline for the initial submission to potentially allow CMS to revise the GLOBE Model beneficiary coinsurance percentage for applicable GLOBE Model drugs prior to the start of the applicable quarter. CMS must complete the calculation of the GLOBE Model beneficiary coinsurance percentage approximately 30 days prior to the start of an applicable quarter. Therefore, allowing 30 days for manufacturers to submit corrected international net pricing data to CMS is the maximum amount of time that could be permitted for such correction and also allow CMS a small window of time to recalculate the GLOBE Model beneficiary coinsurance percentage and make the results available within the Medicare Part B claims processing systems timely.

f. Alternatives Considered

We considered offering a more comprehensive option for manufacturers. Under this option, in addition to the data elements noted in the streamlined and limited options, manufacturers would have been required to submit more granular information and a greater number of data elements. Specifically, in addition to submitting net sales amount at the net price level, manufacturers would be required to submit the corresponding amount of any discounts, rebates, or other price concessions for each net sales amount at the net price level. As part of the submission, manufacturers would also submit an across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit in U.S. dollars across all the applicable international analogs corresponding to the GLOBE Model drug and across all the reference countries where the applicable international analogs are sold. However, we decided not to offer this option due to concerns of manufacturer and CMS reporting burden.

We also considered offering an option that allows manufacturers to submit for the entire set of applicable international analogs that correspond to a GLOBE Model drug, the total gross revenue, total net revenue, and total volume for each reference country. Under this potential option, manufacturers could combine the gross revenue, net revenue, and volume across all the applicable international analogs and report this to CMS along with other necessary data elements (volume weighted average net

price by reference country and across country volume weighted average GDP (PPP) adjusted net price). However, we decided against including this option in the proposal because our ability to verify this information would be limited. We also considered whether manufacturers would be required to calculate the volume weighted-average net price for each reference country and the across country volume-weighted GDP (PPP) adjusted net price per HCPCS billing unit or whether CMS would calculate these values. We decided against the policy of CMS calculating values because we believe that the burden related to doing the calculations given the other data elements that are required is minimal. In addition, we considered whether to require the manufacturer to also identify the lowest net price among the set of reference countries for the set of applicable international analogs that correspond to a GLOBE Model drug. However, as this information is already part of the submission, we did not believe it was necessary. We seek feedback on these policies.

In addition, we considered providing manufacturers the set of applicable international analogs for which they must submit the international net pricing data. However, we believe that manufacturers have this information, and it would not be burdensome to them to identify the set of applicable international analogs that are sold in the reference countries. We also considered the possibility of accepting a submission without the full set of applicable international analogs included in the submission and using the data that is submitted along with existing information to calculate an updated benchmark. However, we decided against this approach because of concerns about combining different data sources and whether it would be logical to do so. We also considered allowing manufacturers to submit an explanation for why they cannot provide pricing information for the full set of applicable international analogs for all reference countries where they are sold and for CMS to review the explanation to determine if this meets the requirement of an applicable submission. However, we believe manufacturers have access to pricing information for where their drugs or biological products are sold and can make a reasonable assumption of their net to gross ratio. We seek feedback on our proposed policy as well as the alternatives presented, including whether CMS should provide the set of applicable international analogs for which data would be submitted for each corresponding GLOBE Model drug.

We recognize the complexities inherent in international pharmaceutical markets, including variations in strengths, forms, and routes of administration; packaging differences; and diverse relationships between U.S. and international entities responsible for product marketing and distribution. For these reasons, we also considered only requesting this data for the set of applicable international analogs that correspond to a GLOBE Model drug that are sold directly by the manufacturer and not by any other subsidiary or company in the reference countries. We also considered an option where manufacturers would only submit the data for the set of applicable international analogs that they directly sell in the reference countries. However, we believe that manufacturers have relationships with subsidiaries, wholesalers, and other businesses involved in selling the set of applicable international analogs in the reference countries and can obtain the requested data under this option. We were also concerned that allowing manufacturers to only submit for applicable international analogs sold directly by the manufacturer would potentially result in manufacturers choosing which applicable international analogs to sale directly and which ones to be sold by other entities to reduce the manufacturer's GLOBE Model rebate liability. We balanced multiple policy priorities, including administrative burden for manufacturers and CMS; the need for complete and verifiable data submissions; and potential concerns that may arise from disclosing detailed international drug pricing information. CMS welcomes feedback on our proposed policy, the alternatives presented, and situations in which manufacturers may find it challenging to report the proposed net pricing information to CMS.

We also considered two alternatives for exchange rate for currency conversion. In the first option considered, CMS would not specify which exchange rate data source to use, allowing manufacturers maximum flexibility. In the second option, we considered publishing the exchange rate for currency conversion on the GLOBE Model website that would align to the applicable ASP calendar quarter, which would provide the most data standardization. We considered these alternatives and believed allowing maximum flexibility would lead to significant data standardization issues that may pose a challenge in testing an alternative rebate calculation methodology. We also believed that while the second option would provide for maximum data standardization it would limit manufacturer's ability to determine the most appropriate exchange rate and data source for when the sale of the applicable international analog occurred. As such, we believe our approach of allowing manufacturers to choose within a set of exchange rate data sources but requiring manufacturers to use the same data source within a reference country and for subsequent submission of the drugs, balances the need for flexibility and data standardization.

In addition, we also considered alternatives such as a longer timeline, 90 days after the end of the applicable ASP calendar quarter, for initial submission of international drug net pricing data as manufacturers may need additional time for reconciliation of pricing data after the end of the applicable ASP calendar quarter. We understand that manufacturers' processes and timelines for data gathering, calculations and reporting may vary widely by manufacturer, applicable international analog, reference country, and distribution arrangements. CMS balanced the timing needed to calculate the GLOBE Model beneficiary coinsurance percentage and manufacturers' process and timelines for data gathering and we believe that manufacturers would be able to make reasonable assumptions of nets sales based on historical data. Therefore, we believe requiring initial data submission to occur within 30 days after the end of the applicable ASP calendar quarter provides sufficient time for manufacturers to assess any reasonable assumptions needed for net sales reporting.

We also considered allowing manufacturers up to one year after initial data submission to correct data and account for any delayed price concessions such as clawbacks. As such, CMS would invoice manufacturers for any additional rebates identified after this corrected data submission, but would be unable to update the GLOBE Model beneficiary coinsurance percentage without reprocessing paid claims to apply retrospective changes to the coinsurance percentage which would be administratively burdensome for GLOBE Model beneficiaries, healthcare providers that submitted claims for GLOBE Model drugs that were furnished to GLOBE Model beneficiaries, CMS, and supplemental insurers, as well as confusing for impacted beneficiaries which could increase beneficiary requests for assistance through 1–800–Medicare and

from their healthcare providers. We considered this alternative and decided that since manufacturers are only required to report average net-to-gross price ratios and because most manufacturers likely have an estimate of expected clawbacks and other price concessions with data lag from historical data, manufacturers could make a reasonable assumption on their average net-to-gross ratio. We seek comments on whether the proposed timeline provides sufficient timing for manufacturers to submit pricing data (for example, clawbacks or other types of price concessions), whether manufacturers have sufficient information to make a reasonable assumption on their average net-to-gross ratio within the reported timelines proposed for attestation, and if there are other types of reasonable assumptions manufacturers may make to meet the proposed submission requirements.

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

As part of the GLOBE Model design, in 42 CFR 513.210, CMS proposes to test an alternative calculation for beneficiary coinsurance for GLOBE Model eligible beneficiaries who receive a GLOBE Model drug for which separate Medicare Part B payment is allowed. In general, for a separately payable Part B drug, the basic allowable charges that a participating provider or supplier may charge the beneficiary are the Part B annual deductible and 20 percent of the Medicare allowed amount in excess of that deductible, subject to the limitation described in 42 CFR 419.41(c)(4)(1) when applicable (that is, in certain circumstances, such as under the OPPS, beneficiary coinsurance does not exceed the inpatient deductible amount).[131] In the case of a Part B rebatable drug, the basic allowable charges that a participating provider or supplier may charge the beneficiary are the Part B annual deductible and 20 percent of the inflation-adjusted payment amount for the rebatable drug in excess of that deductible, which is applied as a percent to the payment amount for such calendar quarter, as set forth in 42 CFR 489.30(b)(6).

For the GLOBE Model, we propose to calculate the GLOBE Model beneficiary coinsurance adjustment for GLOBE Model drugs with respect to an applicable calendar quarter using a methodology that is similar to the coinsurance adjustment under the Medicare Part B Drug Inflation Rebate Program as set forth in 42 CFR 427.201. Specifically, we propose that, for a GLOBE Model drug for an applicable calendar quarter, to determine if the GLOBE Model beneficiary coinsurance adjustment applies, CMS would compare the payment amount, as set forth in 42 CFR 427.201(b)(3) (that is, CMS would use the published payment amount in quarterly pricing files published by CMS as the *payment amount* in this determination), to the *per unit GLOBE Model benchmark amount* as set forth in proposed 42 CFR 513.400. If the *payment amount* exceeds the *per unit GLOBE Model benchmark amount,* the GLOBE Model beneficiary coinsurance adjustment would apply and *the GLOBE Model beneficiary coinsurance* would be calculated by multiplying the *per unit GLOBE Model benchmark amount* by 0.20. To apply this amount as a percent to the *payment amount* for an applicable calendar quarter, we propose that CMS would then calculate the *GLOBE Model beneficiary coinsurance percentage* by dividing the result by the *payment amount* and rounding the result to the third decimal place.

If the *payment amount* does not exceed the *per unit GLOBE Model benchmark amount,* we propose that the GLOBE Model beneficiary coinsurance adjustment would not apply. In such cases, the GLOBE Model beneficiary coinsurance would be calculated using the non-model coinsurance to ensure that beneficiary liability for a GLOBE Model beneficiary is not greater than it would be absent the model. We note that, in such cases, the non-model coinsurance would likely equal the usual coinsurance (that is, 20 percent of the Medicare Part B allowed amount, assuming no other beneficiary liability would apply, as set forth in 42 CFR 489.30(b)(1)) because such cases would occur when neither the GLOBE Model beneficiary coinsurance nor a coinsurance reduction under the Medicare Part B Drug Rebate Program would apply.

CMS would determine and apply the *GLOBE Model beneficiary coinsurance percentage* to the payment amount when processing a claim for a separately payable GLOBE Model drug that was furnished to a GLOBE Model eligible beneficiary on a date of service within the applicable calendar quarter. CMS' calculation and application of the *GLOBE Model beneficiary coinsurance percentage* would not be subject to appeal.

Using the illustrative data for Method I presented in Table 6, the illustrative payment amount of $44.42 exceeds the illustrative *per unit GLOBE Model benchmark amount* of $16.16). In this case, the illustrative *GLOBE Model beneficiary coinsurance* would be $3.23, calculated by multiplying the *per unit GLOBE Model benchmark amount* by 0.20. The illustrative *GLOBE Model beneficiary coinsurance percentage* would then be 7.2 percent, which is the result of dividing $3.23 by the illustrative *payment amount* of $44.42.

Using illustrative 2024 data, calculations for the Method I benchmark estimated that for 73 percent of the illustrative GLOBE Model drugs, the beneficiary coinsurance would be reduced between 10 and 20 percent. Further, our analysis showed that for 17 percent of the illustrative GLOBE Model drugs, the beneficiary coinsurance would be reduced between 0 and 10 percent. For the remaining 10 percent of illustrative GLOBE Model drugs, there would not have been a change in the coinsurance as a result of being in the model.

In conjunction with testing an alternative calculation for beneficiary coinsurance, we propose that 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 as set forth in 42 CFR 410.152(m) and, for hospital outpatient department services, 42 CFR 419.41(e). That is, when the GLOBE Model beneficiary coinsurance adjustment applies, we propose that the Medicare payment amount (the adjusted Medicare payment amount) would be equal to the allowed amount for the GLOBE Model drug minus the product of the *GLOBE Model beneficiary coinsurance percentage* and the allowed amount, assuming no other claim adjustment applies. For example, if the Medicare Part B allowed amount under the GLOBE Model is $100 and the GLOBE Model beneficiary coinsurance percentage is 10 percent (instead of the usual 20 percent), the Medicare Part B program payment to the provider or supplier would be adjusted and would be $90 (instead of the usual $80) and the beneficiary financial responsibility would be $10. The formula in this example is $\$100 - (0.100 \times \$100) = \$90$.

We note that claims for any Part B rebatable drug that is excluded from the GLOBE Model for an applicable calendar quarter or is not separately payable would not be subject to the GLOBE Model beneficiary coinsurance percentage and payment adjustment.

We welcome comments on this proposed approach for testing an alternative calculation for beneficiary

[131] A non-participating supplier can bill the beneficiary for an extra 15 percent beyond the 20 percent coinsurance.

coinsurance and the Medicare Part B payment for GLOBE Model drugs that are furnished to GLOBE Model eligible beneficiaries during an applicable calendar quarter during the model performance period.

8. Proposed Approach for GLOBE Model Rebates Reports, Invoicing, and Reconciliation

In this section of this proposed rule and in proposed 42 CFR 513 subpart H, we present two alternative approaches for how CMS would invoice manufacturers for GLOBE Model rebates. After considering future comment on this proposed rule, CMS intends to adopt one of these approaches, or a similar approach that emerges from CMS' consideration of comments and further analysis of the alternatives and establish corresponding regulatory text. Hence, although this proposed rule includes two options for proposed invoicing processes in subpart H, CMS has only described one option within the regulatory text and only intends to include one option in a final rule that would establish the GLOBE Model.

One option we considered is called the ''*combined*'' approach. Under a *combined* approach, using the waiver authority under section 1115A of the Act, CMS would delay Medicare Part B Drug Inflation Rebate Program Preliminary Rebate Reports for all manufacturers by up to 2 months and would provide a combined report to all manufacturers of Part B rebatable drugs for both the Medicare Part B Drug Inflation Rebate Program and the GLOBE Model. The combined report would show, in one report, the information included in a Medicare Part B Drug Inflation Rebate Program Rebate Report as specified in 42 CFR 427.501 and further discussed in section II.G.8.a. of this proposed rule. Because there would be a single combined report and rebate amount due, we propose that the Suggestion of Error process specified in 42 CFR 427.503 would be used such that manufacturers would use one submission if the manufacturer believes that there is a mathematical error or errors to be corrected before the Rebate Report or a subsequent reconciliation of the rebate amount due for both the Medicare Part B Drug Inflation Rebate Program and the GLOBE Model (if any), is finalized. We note that, as discussed in section II.G.4. of this proposed rule, the *total GLOBE Model rebate amount* invoiced would be an incremental amount (the *incremental GLOBE Model rebate amount*), which represents the amount of the GLOBE Model rebate that is in excess of the rebate amount for the Medicare Part B Drug Inflation Rebate Program that applies to the *total number of GLOBE Model billing units.*

The combined approach would present information in a single report which may enhance transparency for manufacturers of GLOBE Model drugs. In a single report, GLOBE Model Rebate Report information would not appear in Rebate Reports for Part B rebatable drugs that are not GLOBE Model drugs. For CMS, the increased operational complexity of combining data from the Inflation Rebate Program and the GLOBE Model into a single report would lengthen the time necessary for creating Preliminary Rebate Reports for all manufacturers of Part B rebatable drugs, which, correspondingly, would extend the time following the end of an applicable calendar quarter for manufacturers to pay rebates.

Another option we considered is called the ''*incremental*'' approach. Under the *incremental* approach, GLOBE Model reports and invoicing would not disrupt the Medicare Part B Drug Inflation Rebate Program reports and invoicing timelines. This approach would use a separate report and invoicing process that would run approximately two months after the Medicare Part B Drug Inflation Rebate Program reports and would invoice manufacturers of GLOBE Model drugs for the incremental GLOBE Model rebate amount due as set forth in 42 CFR 513.500(b). Under this two-stage process, the Medicare Part B Drug Inflation Rebate Program reports would show information specified for that program and the GLOBE Model reports would show information specific to the model as proposed in 42 CFR 513.710 and further discussed in section II.G.8.b. of this proposed rule. In 42 CFR 513.710(b), we propose that a GLOBE Model Preliminary Rebate Report would be provided to each manufacturer of a GLOBE Model drug at least 1 month prior to the issuance of the GLOBE Model Rebate Report which would be provided no later than 8 months after the end of each applicable calendar quarter.

Consistent with our proposed timing of invoicing activities described later in this section, the GLOBE Model Preliminary Rebate Report would reflect any revisions identified through the Suggestion of Error process specified in 42 CFR 427.503 related to the Medicare Part B Drug Inflation Rebate Program Rebate Report, and the GLOBE Model Rebate Report (or subsequent GLOBE Model report) would reflect such revisions as applicable. In addition, because there would be separate reports, in 42 CFR 513.720, we propose a separate Suggestion of Error process such that a manufacturer would submit its Suggestion of Error within 10 calendar days from the date of receipt of a GLOBE Model Preliminary Rebate Report (or a report detailing the preliminary reconciliation of a GLOBE Model rebate amount) for the applicable calendar quarter, using a method and process established by CMS, if the manufacturer believes that there is a mathematical error or errors to be corrected before the GLOBE Model Rebate Report or a subsequent reconciliation of the GLOBE Model rebate amount, as applicable, is finalized.

The incremental approach using a two-step reporting and invoicing process and separate Suggestion of Error process could facilitate administrative efficiencies for CMS and manufacturers of GLOBE Model drugs compared to the combined approach. Separate reports could avoid potential confusion for manufacturers of Part B rebatable drugs that are not GLOBE Model drugs.

Under each approach CMS would need to calculate the *incremental per unit GLOBE Model rebate amount* for an applicable calendar quarter after the Part B rebate amount has been calculated as set forth in 42 CFR 427.301, CMS would need additional time following the end of an applicable calendar quarter for providing incremental GLOBE Model Rebate Reports to manufacturers of GLOBE Model drugs and, similarly, for manufacturers to pay rebates. We estimate that the extended time would be about the same under either the combined or incremental approach, and the amount of additional time that would be necessary would be about two months.

At 42 CFR 513.700, we propose, that ''date of receipt'' would have the same meaning as set forth in 42 CFR 513.500. This term would be applicable to both options discussed in this section of this proposed rule.

We welcome feedback on these proposed approaches for reports and reconciliation and potential refinements to them as well as potential alternative approaches that would support efficient testing and evaluation of the GLOBE Model and transparency for manufacturers while minimizing adverse impacts on manufacturers of Part B rebatable drugs and CMS' systems, operations, and financial resources.

The following sections describe the proposed reports under the combined and incremental approaches in more detail.

a. Proposed Changes to the Rebate Report and Reconciliation Under the Combined Approach

Under a combined approach for rebate invoicing, to operate the GLOBE Model in a streamlined efficient manner, we propose that the total GLOBE Model rebate amount due would be invoiced to the manufacturer using the Medicare Part B Drug Inflation Rebate Program rebate report processes with some minor changes to convey GLOBE Model information within one Preliminary Rebate Report (and subsequent reports) for an applicable calendar quarter and allow CMS more time to make reports available to manufacturers.

Specifically, we propose to waive 42 CFR 427.501(c) to the extent necessary such that CMS would provide each manufacturer of a Part B rebatable drug a Rebate Report that is the invoice for the total rebate amount due under both the Medicare Part B Drug Inflation Rebate Program and the GLOBE Model (if applicable), if any, no later than 8 months after the end of each applicable calendar quarter instead of 6 months after the end of each applicable calendar quarter. The extended timeline would apply to all Part B rebatable drugs and manufacturers not just those that are GLOBE Model drugs and GLOBE Model participants. We do not believe that it would be feasible to extend the timeframe solely for GLOBE Model drugs and GLOBE Model participants because CMS confirms the identification of GLOBE Model drugs and the manufacturer(s) of such drugs as CMS completes the steps to compile all Rebate Reports and the additional GLOBE Model considerations would increase the level of effort and time necessary for CMS to complete all rebate calculations and report generation steps.

In addition, we propose to waive 42 CFR 427.501 to the extent necessary to include GLOBE Model rebate information within the Rebate Report (and subsequent reports). We propose that, for a calendar quarter, a Preliminary Rebate Report (and subsequent related rebate reports) would include the information set forth in 42 CFR 427.501(b)(1) as well as GLOBE Model information specified in new 42 CFR 427.520(b)(2), which we propose would include but not be limited to the following: the NDC(s) billing and payment codes identified for the GLOBE Model drug as determined by CMS; the total number of GLOBE Model billing units as set forth in 42 CFR 513.520; the total number of billing units as determined under 42 CFR 427.303; the per unit Method I GLOBE Model benchmark (as described in section II.G.2.a. of this proposed rule and identified under 42 CFR 513.410); the per unit Method II GLOBE Model benchmark, if available (as described in section II.G.2.b. of this proposed rule and identified under 42 CFR 513.420); the per unit GLOBE Model benchmark amount as set forth in 42 CFR 513.400; the per unit GLOBE Model rebate amount as set forth in 42 CFR 513.510(a); the incremental per unit GLOBE Model rebate amount as set forth in 42 CFR 513.510(b); the applicable calendar quarter specified amount as determined under 42 CFR 427.302(b); the amount, if any, by which the specified amount as determined under 42 CFR 427.302(b) exceeds the inflation-adjusted payment amount as determined under 42 CFR 427.302(g) for the Part B rebatable drug for the applicable calendar quarter as set forth in 42 CFR 427.302; the total GLOBE Model rebate amount as set forth in 42 CFR 513.500; the incremental GLOBE Model rebate amount due as set forth in 42 CFR 513.500; any applied reductions as determined under 42 CFR 513 subpart F; the proportion of manufacturer-reported ASP units, if applicable; and the reduced incremental GLOBE Model rebate amount, if any. The total rebate amount due would be the combined rebate amount due under both the GLOBE Model and the Medicare Part B Drug Inflation Rebate Program. The GLOBE Model information specified at proposed 42 CFR 513.710(b)(1) would only be populated in Preliminary Rebate Reports (and subsequent related rebate reports) for manufacturers of GLOBE Model drugs. For a Rebate Report for a manufacturer of a Part B rebatable drug that is not GLOBE Model drug for an applicable calendar quarter, the total rebate amount due would equal the amount specified in 42 CFR 427.501(b)(1)(ix) which is the rebate amount due as determined under the Medicare Part B Drug Inflation Rebate Program at 43 CFR 427.301(a).

We note that, while we propose to issue the Preliminary Rebate Reports 2 month later, under the combined invoicing approach, the cadence for rebate reports and reconciliation under 42 CFR 427.501(b) and (d) would be unchanged. For example, preliminary rebate reports would be issued 1 month before Rebate Reports. Similarly, payment of rebate amounts owed would be due no later than 11:59 p.m. Pacific Time (PT) on the 30th calendar day after the date of receipt of information regarding the total rebate amount. To specify how this cadence would apply to Rebate Reports, invoicing, and reconciliation, we propose several amendments to 42 CFR 427.501(b)(2), (c) and (d). Specifically, we propose that 42 CFR 427.501(c) would waive to the extent necessary that CMS would provide each manufacturer of a Part B rebatable drug no later than 8 months after the end of each applicable calendar quarter a GLOBE Model Rebate Report with the total GLOBE Model rebate amount due for a GLOBE Model drug for that applicable calendar quarter. We propose that 42 CFR 427.501(d)(1) would be applied such that CMS would perform one regular reconciliation of the rebate amount within 12 months of the date of receipt of the Rebate Report for each applicable calendar quarter. As discussed in section II.O. of this proposed rule, under the combined approach, we propose to use the waiver authority under section 1115A of the Act, to the extent necessary to delay Medicare Part B Drug Inflation Rebate Program invoicing for manufacturers of GLOBE Model drugs by up to 2 months.

We propose the GLOBE Model information would be added to the Preliminary Rebate Reports, Rebate Reports, and Reconciliation Rebate Reports for an applicable calendar quarter under 42 CFR 427 subpart F. Because the Suggestion of Error process specified in 42 CFR 427.503 would apply to the GLOBE Model rebate information included in the Preliminary Rebate Report or Preliminary Reconciliation Rebate Report, manufacturers would use one submission if the manufacturer believes that there is a mathematical error or errors to be corrected before the Rebate Report or a subsequent Reconciliation Rebate Report, as applicable, is finalized, and as such we are not proposing a separate Suggestion of Error process for the GLOBE Model information under the combined approach.

If the combined approach is adopted for the GLOBE Model, CMS would inform manufacturers of the revised Rebate Report format by posting information on the CMS website and issuing a memorandum to all manufacturers of Part B rebatable drugs.

b. Proposed Changes to the Rebate Report and Reconciliation Under the Incremental Approach

Under the incremental approach, the GLOBE Model rebate amount would be invoiced to the manufacturer using a process that would be separate from, but harmonized with, the Medicare Part B Drug Inflation Rebate Program rebate invoicing process. As such, in 42 CFR 513.710 and 42 CFR 513.720, we propose regulatory text for GLOBE

Model Rebate Reports and reconciliation, including a Suggestion of Error process, that aligns as applicable with the Medicare Part B Drug Inflation Rebate Program as set forth at 42 CFR 427 subpart F. The Medicare Part B Drug Inflation Rebate Program reporting and reconciliation would continue as specified under 42 CFR 427 subpart F.

In 42 CFR 513.710(c), for the GLOBE Model rebate reporting activities, we propose that CMS would provide each manufacturer of a GLOBE Model drug a GLOBE Model Rebate Report no later than 8 months after the end of each applicable calendar quarter. For a calendar quarter, the GLOBE Model Preliminary Rebate Report would include the information set forth in 42 CFR 513.710(b)(1), including the following: the NDC(s) billing and payment codes identified for the GLOBE Model drug as determined by CMS; the total number of GLOBE Model billing units as set forth in 42 CFR 513.520; the per unit Method I GLOBE Model benchmark as identified under 42 CFR 513.410; the per unit Method II GLOBE Model benchmark as identified under 42 CFR 513.420; the per unit GLOBE Model benchmark amount as set forth in 42 CFR 513.400; the per unit GLOBE Model rebate amount as set forth in 42 CFR 513.510; the incremental per unit GLOBE Model rebate amount as set forth in 42 CFR 513.510; the applicable calendar quarter specified amount as determined under 42 CFR 427.302(b), the amount, if any, by which the specified amount as determined under 42 CFR 427.302(b) exceeds the inflation-adjusted payment amount as determined under 42 CFR 427.302(g) for the Part B rebatable drug for the applicable calendar quarter as set forth in 42 CFR 427.302; the amount, if any, by which the specified amount as determined under 42 CFR 427.302(b) exceeds the per unit GLOBE Model rebate amount as determined under 42 CFR 513.510 for the GLOBE Model drug for the applicable calendar quarter as set forth in 42 CFR 513.500; the total GLOBE Model rebate amount as set forth in 42 CFR 513.500; the incremental GLOBE Model rebate amount as set forth in 42 CFR 513.500; the proportion of manufacturer-reported ASP units, if applicable; any applied reductions as determined under 42 CFR 513 subpart F; and the reduced incremental GLOBE model rebate amount, if applicable.

In 42 CFR 513.710, we propose that the incremental GLOBE Model rebate amount would be invoiced to the manufacturer using a process that would be harmonized with, but separate from, the Medicare Part B Drug Inflation Rebate Program rebate invoicing process. First, in accordance with 42 CFR 427.501(c), CMS would provide each manufacturer of a Part B rebatable drug a Rebate Report that is the invoice for the rebate amount due for a Part B rebatable drug under the Medicare Part B Drug Inflation Rebate Program (if any) no later than 6 months after the end of each applicable calendar quarter. For an applicable calendar quarter, the Rebate Report includes the information set forth in 42 CFR 427.501(b)(1), including the total number of billing units as determined under 42 CFR 427.303 and the rebate amount due as determined under 42 CFR 427.301(a), if any. Second, via an additional invoice that is specific to the GLOBE Model for an applicable calendar quarter, we propose that CMS would provide each manufacturer of a GLOBE Model drug a GLOBE Model Rebate Report that would be the invoice for the incremental GLOBE Model rebate amount (if any) which, when considered with the rebate amount already invoiced under the Rebate Report for the Medicare Part B Drug Inflation Rebate Program, reconciles the rebate amount due under the GLOBE Model to the total GLOBE Model amount. The incremental amount due (and invoiced on the GLOBE Model Rebate Report) would be calculated by multiplying the incremental per unit rebate amount by the total number of GLOBE Model billing units as proposed under 42 CFR 513.520. The amount that would be reflected in the second GLOBE Model-specific *incremental* invoice for a GLOBE Model drug for a manufacturer would be the additional amount owed within 30 days of receipt of the GLOBE Model rebate report. The GLOBE Model also adopts the reconciliation approach under the Medicare Part B Drug Inflation Rebate Program specified at 42 CFR 427.501(d). That is, within 12 months of the issuance of the GLOBE Model Rebate Report, a report of the reconciled incremental GLOBE Model rebate amount will be provided to each manufacturer of a GLOBE Model drug to account for certain updates (for example, updates to the GLOBE Model billing units or restatement of inputs to the specified amount under 42 CFR 427.302(b)) that may affect the GLOBE Model rebate amount calculation. One month prior to the issuance of this report with the reconciled incremental GLOBE Model rebate amount, CMS will conduct a preliminary reconciliation of the incremental GLOBE Model rebate amount as set forth in proposed 42 CFR 5137.710(d). CMS would provide the GLOBE Model report to manufacturers of GLOBE Model drugs 2 months after the Medicare Part B Drug Inflation Rebate Program provides a report for the applicable calendar quarter. Under the Medicare Part B Drug Inflation Rebate Program, for an applicable calendar quarter, there are four reports. Table 9 shows the four reports for an applicable calendar quarter, the timing for each report, and an example of how the timing for these reports would occur for the first applicable calendar quarter during performance year 1 of the GLOBE Model assuming the proposed model start on October 1, 2026.

TABLE 9: ILLUSTRATION OF THE PROPOSED TWO-STEP INVOICING TIMELINE FOR GLOBE MODEL REBATE AMOUNTS: EXAMPLE FOR APPLICABLE CALENDAR QUARTER OCTOBER – DECEMBER 2026

First Invoice Medicare Part B Drug Inflation Rebate Program			Second (Incremental) Invoice GLOBE Model		
Report	**Report Provided By**	**Example Timeline**	**Report**	**Report Provided By**	**Example Timeline**
Preliminary Rebate Report (See 42 CFR 427.501(b))	At least 1 month prior to the issuance of the Rebate Report	May 31, 2027	GLOBE Model Preliminary Rebate Report (See 42 CFR 513.710(b)	At least 1 month prior to the issuance of the GLOBE Model Rebate Report	July 31, 2027
Rebate Report (See 42 CFR 427.501(c))	No later than 6 months after the end of each applicable calendar quarter	June 30, 2027	GLOBE Model Rebate Report (See 42 CFR 513.710(c)	No later than 8 months after the end of each applicable calendar quarter	August 31, 2027
Rebate Report – Preliminary Reconciliation (See 42 CFR 427.501(d)(1)(i))	At least 1 month prior to the issuance of a report with the reconciled rebate amount	May 31, 2028	Rebate Report – Preliminary Reconciliation (See 42 CFR 513.710(d(1)(i)	At least 1 month prior to the issuance of a report with the reconciled rebate amount	July 31, 2028
Rebate Report – Regular Reconciliation (See 42 CFR 427.501(d)(1))	Within 12 months of the issuance of the Rebate Report	June 30, 2028	Rebate Report – Regular Reconciliation (See 42 CFR 513.710(d)(1)	Within 12 months of the date of issuance of the GLOBE Model Rebate Report	August 31, 2028

We propose that GLOBE Model rebate invoicing would occur after invoicing under the Medicare Part B Drug Inflation Rebate Program to create a unified framework for testing the GLOBE Model while maintaining harmonization between the model and non-model activities. We believe that up to 2 months would be a reasonable timeframe during which CMS would gather the necessary information to calculate the incremental GLOBE Model rebate amount due and perform data quality checks prior to providing each manufacturer of a GLOBE Model drug a GLOBE Model Rebate Report that would be the invoice for the incremental GLOBE Model rebate amount due (if any). We are proposing to harmonize the model and non-model activities, including the proposed incremental GLOBE Model invoicing approach, to maintain consistency and transparency for manufacturers with respect to the Medicare Part B Drug Inflation Rebate Program while minimizing administrative impacts on manufacturers and complexity for CMS operations of the Medicare Part B Drug Inflation Rebate Program during the GLOBE Model test.

As discussed in section II.G.4.d. of this proposed rule and proposed at 42 CFR 513.500, we propose to, when applicable, reduce the incremental GLOBE Model rebate amount for drugs in shortage and/or when there is a severe supply chain disruption or likely shortage, if applicable. Under the incremental approach, CMS would apply any reductions as determined under sections 42 CFR 427.401 and 42 CFR 427.402 to the total GLOBE Model rebate amount due such that the GLOBE Model rebate amount due would reflect such reductions (if applicable). In addition, we propose that CMS would provide a GLOBE Model Rebate Report for each GLOBE Model drug for each applicable calendar quarter even in cases when the incremental per unit GLOBE Model rebate amount equals zero.

If the incremental approach is adopted for the GLOBE Model, CMS would establish a GLOBE Model Rebate Report format that would be similar to the current Rebate Report format and would inform manufacturers of the GLOBE Model Rebate Report format by posting information on the CMS website and issuing a memorandum to all manufacturers of Part B rebatable drugs.

c. Proposed Suggestion of Error Process Under the Incremental Approach

In 42 CFR 513.720, we propose a Suggestion of Error process for the GLOBE Model such that a manufacturer would submit its Suggestion of Error to CMS, for its discretionary consideration, for the applicable calendar quarter within 10 calendar days from the date of receipt of a GLOBE Model Preliminary Rebate Report or a GLOBE Model Preliminary Reconciliation Rebate Report using a method and process established by CMS if the manufacturer believes that there is a mathematical error or errors to be corrected before the GLOBE Model Rebate Report or a subsequent GLOBE Model Reconciliation Rebate Report, as applicable, is finalized. CMS would make available a method for a manufacturer to submit a Suggestion of Error for GLOBE Model reports that would be substantially similar to the method used for the Medicare Part B Drug Inflation Rebate Program. Further, we propose that CMS would include any revisions to the calculation of the GLOBE Model rebate amount, if determined necessary by CMS based on the manufacturer's Suggestion of Error, prior to providing the GLOBE Model Rebate Report or any GLOBE Model Reconciliation Rebate Report, if applicable. CMS would notify the manufacturer whether CMS revised its calculation of the rebate amount based on the Suggestion of Error. CMS notes that the scope of the Suggestion of Error process set forth in 42 CFR 513.720 would be limited to GLOBE Model information and any corrections would not impact the information in the Reconciliation Rebate Report as set forth in 42 CFR 427.501(d)(ii).

We welcome comment on our proposal for a separate Suggestion of Error process that would be included for the incremental approach if such approach is adopted for the model.

H. Proposed Program Compliance Requirements and Enforcement

1. Enforcement Action

a. Enforcement of GLOBE Model Rebate Amount Payments by Manufacturers

As described in section II.J. of this proposed rule, CMS proposes that the manufacturer of a GLOBE Model drug would be required to pay the incremental GLOBE Model rebate amount by 11:59 p.m. Eastern Time on the 30th calendar day after receipt of the GLOBE Model Rebate Report.

Manufacturer payment of GLOBE Model rebate amounts is critical to model test integrity; without these payments, there would be limited ability to test potential savings to the Federal Supplementary Medical Insurance Trust Fund or impacts to quality of care. Given that CMS would reduce coinsurance for GLOBE Model

eligible beneficiaries who have received a GLOBE Model drug, CMS must collect GLOBE Model rebate amounts in order to recoup what it has spent on GLOBE model drugs where it paid more than 80 percent of the allowed amount. CMS would need to terminate the GLOBE Model given the statutory requirement in section 1115(A)(b)(3) of the Act to terminate or modify models that are not expected to reduce spending (or those that improve the quality of care while reducing spending). Given the importance of these rebates, CMS may utilize available civil money penalty (CMP) authority at section 1847A(i)(7) of the Act or section 1128A of the Act to ensure timely compliance with payment of GLOBE Model rebate amounts due.

Consistent with the Medicare Part B Drug Inflation Rebate Program and the regulations at 42 CFR 427.600 and 513.800, CMS proposes that manufacturers of a GLOBE Model drug that have failed to timely pay the incremental GLOBE Model rebate amount would be subject to a CMP in an amount equal to at least 125 percent of the incremental GLOBE Model rebate amount for such GLOBE Model drug and applicable calendar quarter which would be in addition to any unpaid incremental GLOBE Model rebate amount due. However, this GLOBE Model CMP is separate from and in addition to any civil money penalty assessed under 42 CFR 427.600.

CMS further proposes to rely on the general CMP authority in section 1128A of the Act as codified in 42 CFR part 423, subpart T. Specifically, section 1128A(a)(8) of the Act allows a CMP to be imposed against anyone who ''knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim for payment for items or services furnished under a Federal health care program.'' CMS believes that any manufacturer that knowingly fails to comply with GLOBE Model requirements as set forth in a regulation that establishes the GLOBE Model, including provisions in the GLOBE Model data agreement, could be subject to a CMP in addition to any incremental GLOBE Model rebate amount due.

If CMS assesses a CMP for a manufacturer, the manufacturer would be held responsible for paying the incremental GLOBE Model rebate amount of any CMP amount imposed, and any amount imposed for late payment. The CMP payment would be due within 60 days after the date of notice of imposition of the CMP according to section 1128A of the Act.

In the event of non-payment of any portion of the total GLOBE Model rebate amount, CMS considered other potential enforcement approaches. For example, CMS could refer manufacturers to the Department of Justice (DOJ) for breach of contract or false certification, Department of the Treasury for their use of the Debt Management or Recovery Offset Programs, or the Department of Health and Human Services' (HHS') Office of Inspector General (OIG) for use of their CMP authority and for further review and investigation. However, given the importance of recovering GLOBE Model rebate amounts due from manufacturers, CMS believes it would be appropriate to pursue CMPs in order to enforce payments of the total GLOBE Model rebate amount.

In the event that a manufacturer declares bankruptcy, as described in Title 11 of the United States Code, and as a result of the bankruptcy, fails to pay either the full GLOBE Model rebate amount owed or the total sum of CMP imposed, or both, the government intends to reserve the right to file a proof of claim with the bankruptcy court to recover the unpaid amount of the GLOBE Model rebate amount and/or CMP owed by the manufacturer as set forth in 42 CFR 513.800.

We propose to codify civil money penalty and appeals procedures for GLOBE Model rebate amounts at 42 CFR part 513, subpart I.

b. Other Enforcement Actions

We propose that CMS could impose one or more enforcement actions such as CMP or terminating the data agreement if CMS determines that the following has occurred, which is not an exhaustive list:

- The GLOBE participant has submitted false data or made false representations, warranties, or certifications in connection with any aspect of the GLOBE Model.
- The GLOBE participant is subject to investigation or action by HHS (including the HHS–OIG, CMS, or FDA) or the DOJ due to an allegation of fraud or significant misconduct, including being subject to the filing of a complaint or filing of a criminal charge, being subject to an indictment, being named as a defendant in a False Claims Act qui tam matter in which the Federal Government has intervened, or similar action.

We propose that CMS may take one or more of the following enforcement actions if CMS determines that one or more of the grounds for enforcement action described in section H.1. of this proposed rule had taken place:

- Suspending or terminating the data agreement with the manufacturer.
- Require the manufacturer to provide additional requested information to CMS or its designees.
- Subject the manufacturer to additional monitoring, auditing, or both.

As part of the Innovation Center's monitoring and assessment of the impact of models tested under the authority of section 1115A of the Act, CMS has a special interest in ensuring that these model tests do not interfere with the program integrity interests of the Medicare program. For this reason, CMS monitors actions of GLOBE participants for compliance with model terms, as well as other Medicare program rules. When CMS becomes aware of noncompliance with these requirements, it is necessary for CMS to have the ability to impose certain administrative enforcement actions on a noncompliant model participant. We seek comment on these proposed provisions regarding the proposed grounds for enforcement actions, enforcement actions generally, and whether additional types of enforcement action would be appropriate.

I. Proposed Collection of GLOBE Model Rebate Amounts

1. Proposed Systems To Collect GLOBE Model Rebate Amounts

In 42 CFR 513.740, we propose that the deadline and process for payment of rebate amounts, including rebate amounts owed by a manufacturer, failure to pay a rebate amount, and potential refunds to a manufacturer, as articulated in 42 CFR 427.505 would apply to GLOBE Model rebate amounts calculated under the GLOBE Model. The process for manufacturer access to rebate reports as codified in 42 CFR 427.504 would apply to Rebate Reports including GLOBE Model rebate amounts (that is, combined rebate amounts, under the combined invoicing approach described in section II.G.8. of the proposed rule and incremental GLOBE model rebate amounts under the incremental invoicing approach described in section II.G.8. of the proposed rule, as applicable) calculated under the GLOBE Model, including any report of reconciled rebate amounts. In addition, we propose that the date of receipt, 30 days after which payment is due, as codified in 42 CFR 427.500, would be the calendar day following the day on which a report of a GLOBE Model rebate amount (as set forth in 42 CFR 513.510) is made available to the manufacturer of a GLOBE Model drug by CMS.

J. Proposed Quality Measures

1. General

Consistent with the evaluation provisions of section 1115A(b)(4) of the Act, CMS proposes utilizing quality measures to monitor and evaluate whether quality of care, including as measured through patient-level outcomes, changes as a result of the proposed alternative Part B inflation rebate amount calculation approach for GLOBE Model drugs. Payments to manufacturers or providers would not be adjusted based on quality of care. CMS would consider multiple domains of monitoring as outlined below, including but not limited to out-of-pocket costs, utilization of care, and access to GLOBE Model drugs.

2. Collection of Quality Measures

CMS proposes utilizing claims-based measures or existing national surveys, such as the Medicare Current Beneficiary Survey, when possible, to monitor the quality of care in a way that directly reflects patient-level factors. These may include measures to monitor—

- Part B drug utilization and prescribing patterns—such as changes in medication treatment, or cessation of treatment earlier than expected given disease course;
- Out-of-pocket costs for Part B drugs that were administered—comparing costs for beneficiaries with and without supplemental prescription drug coverage based on available data;
- Frequency and regularity of administration of Part B drugs, such as inappropriate gaps between administration of infusions or injections;
- Changes in site of service for a beneficiary receiving administration of Part B drugs;
- Changes in site of service for outpatient clinic appointments;
- Changes in prescriber of the Part B drug; and
- Downstream health care utilization, such as hospitalizations or emergency room visits.

CMS may also find it necessary to supplement claims-based measures with voluntary surveys of providers who administer Part B drugs to assess variables including but not limited to changes in: (1) perceived prescribing practices as a result of this alternative payment approach; (2) site of service for administration of clinician-administered drugs; and (3) interactions between patient and provider.

When developing this proposed quality strategy, CMS considered a range of quality measures, including high-value prescribing of efficacious Part B drugs, medication management, barriers to access, medication adherence, patient experience of care measures, and drug-related adverse events.

CMS does not anticipate this test of a new payment approach would impact high value prescribing as the payment incentive directly to the prescribers is equivalent between the intervention and control group (ASP +6 percent).

Accurate measurement of medication management and medication adherence for Part B clinician-administered drugs is challenging because dosing schedules are variable, clinical assessment is required, and insurance claims lack sufficient clinical context.[132] To limit additional burden upon beneficiaries, CMS proposes using existing national surveys wherever possible. If necessary to assess how the GLOBE Model has affected patient quality of care, CMS may consider implementing a beneficiary survey.

This proposed model does not test the efficacy of prescription drugs, but rather, it tests the impact of an alternative payment approach. Thus, CMS does not propose new monitoring of changes to drug-related adverse events. CMS would monitor changes in downstream health care utilization, such as changes in rates of emergency room visits, hospitalizations, or use of other clinical services. Any additional measures, including potentially beneficiary surveys, utilized by CMS would not add significant burden to GLOBE Model participants or beneficiaries.

CMS welcomes comments on the proposed quality measures above to monitor changes in the quality of care that may result from this alternative Part B inflation rebate amount calculation approach.

K. Proposed Beneficiary Protections

1. General

CMS recognizes stakeholders may have concerns over potential disruptions to beneficiary access to Medicare Part B drugs, including those that are GLOBE Model drugs, as a result of the GLOBE Model changing financial incentives for manufacturers. To alleviate these concerns, CMS has considered various options to protect beneficiary access to Medicare Part B drugs during the model performance period.

One potential option CMS has considered is creating a reporting system where stakeholders, such as providers or beneficiaries, could notify CMS that a particular drug has become harder to source or obtain after the implementation of the GLOBE Model. A reporting system such as this could allow CMS to gather information to inform potential follow-up investigations to determine if any drug access issues are occurring. As such, CMS proposes setting up a GLOBE Model reporting system open to providers and beneficiaries to notify CMS that a particular drug has become harder to source or obtain. CMS also proposes to conduct investigations as appropriate based on information reported to the system, including but not limited to requesting additional information from the submitter and conducting additional analyses to determine whether the report requires further action from CMS or other governmental entities. One possibility for how this system could work is including GLOBE Model reporting within the 1–800–Medicare system. Additionally, CMS could develop an email inbox to receive reports from providers and beneficiaries. CMS may develop multiple ways to receive reports. Instructions for how to report, using one or more methods, would be posted on the CMS website for awareness. CMS could also consider making beneficiaries aware of the available reporting methods by sending letters to eligible GLOBE Model beneficiaries with reporting instructions.

CMS welcomes comments on a potential plan to build a GLOBE reporting and monitoring system for stakeholders and any other methods to protect beneficiaries.

2. Alternatives Considered

CMS Innovation Center models frequently include various policies to protect beneficiaries from any negative intended or unintended consequences of models. One of the most common forms of beneficiary protections CMS Innovation Center Models include are policies that allow beneficiaries to choose to be excluded from a model. These usually take the form of a letter sent to beneficiaries that would be included in the Innovation Center Model outlining what the model is and how it might impact beneficiaries. These letters then usually include a section allowing the beneficiary to opt-out of the model by changing to a provider not included in the model, or some other general opt-out mechanism.

[132] Lam WY, Fresco P. Medication Adherence Measures: An Overview. Biomed Res Int. 2015:217047. *https://pmc.ncbi.nlm.nih.gov/articles/PMC4619779/.*

CMS has considered including a beneficiary opt-out within the GLOBE Model as an additional protection for beneficiaries but has chosen to not move forward with a beneficiary opt-out at this time. While CMS acknowledges the GLOBE Model may affect drug access, CMS believes that the likelihood of reduced access is relatively low. GLOBE Model beneficiaries are expected to benefit from the program through lower coinsurance costs for GLOBE Model drugs, removing the potential for downside risk for beneficiaries. Not including a beneficiary opt-out would enhance the model test integrity and improve the generalizability of results, as there would not be a selection bias among beneficiaries who choose to remain in the model if an opt-out were offered. CMS believes that beneficiaries would benefit by being categorized as an elgible GLOBE Model beneficiary due to the potentially reduced coinsurance percentage that would apply for eligible GLOBE Model drugs for GLOBE Model beneficiaries.

CMS seeks comment on the decision not to include a beneficiary opt-out and whether variations of a beneficiary opt-out could be considered.

L. Proposed Monitoring and Compliance Actions

1. General Provisions: Monitoring and Compliance

The CMS Innovation Center has described general provisions for monitoring and compliance for CMS Innovation Center models at 42 CFR 512.150. However, we note that many of these provisions would not apply to the GLOBE Model, and the GLOBE Model is substantially different from other mandatory CMS Innovation Center models.

Instead, CMS intends to monitor for specific potential issues that could arise as part of the GLOBE Model. CMS intends to monitor for major changes in beneficiary access, as viewed through changes in site of care, provider, and other measures described in section II.J. of this proposed rule. CMS may also monitor changing list prices in the U.S. to determine whether any changes to model policies or duration could be necessary in future performance periods. CMS may also consider monitoring impacts on drug innovation, research & development, and timing of drugs coming to market in the U.S. CMS also proposes to collaborate with the Food & Drug Administration (FDA) to review shortage lists and determine whether the number of drugs or length of time on the shortage list changes over time. To the extent that CMS identifies an issue through regular monitoring that would require a change to model policies or duration under section 1115A(b)(3)(B) of the Act, CMS would take necessary action to change a model policy or model duration based on its finding.

2. Appeals Process

CMSI proposes that the appeals processes established in 42 CFR 427.600, subpart T would apply. Additionally, the enforcement provisions of section 1847A(i)(8) of the Act and the judicial review section 1847A(j) of the Act would apply.

We seek comment on our proposal to apply administrative procedures established in 42 CFR 427.600, subpart T, along with judicial review provisions of section 1847A(i)(8) and (j) of the Act.

M. Interaction With Other Models and Programs

1. Approach for Overlap With Other Models

In designing each CMS Innovation Center model, CMS considers potential overlap between a new model and other ongoing and potential models and programs. Based on the type of overlap, such as participating entity, health care provider or beneficiary, operating rules may be established for whether or not entities, health care providers and beneficiaries can be part of both models as well as how to handle overlap when it occurs. These policies help to ensure that the evaluation of model impact is not compromised by issues of model overlap and that double counting of health care providers, beneficiaries and dollars across different models does not occur.

As discussed in section II.F. of this proposed rule, CMS is proposing to test the GLOBE Model in selected geographic areas because we believe that this approach would best allow the model evaluation to observe the impacts of the model. We considered whether additional design modifications, such as testing models in different geographic areas, or operational adjustments would be necessary for a robust test of the GLOBE Model in situations where ongoing and potential models and programs would also apply and concluded that none were warranted at this time because we intend for the GLOBE Model monitoring activities and evaluation to observe for potential behavioral changes (such as in prescribing or patterns of care) and other potential impacts on non-model aspects of the Medicare program and other models and programs. For example, as discussed in section II.J. of this proposed rule, we propose to monitor for prescribing shifts and potential impacts on beneficiaries' access to care. If, during implementation of the proposed GLOBE Model, we were to observe unintended impacts on beneficiaries or model operations (for example, in GLOBE Model geographic areas we observe an increase in Part D utilization of clinician-administered drugs), we intend to propose appropriate operational adjustments to the GLOBE Model through notice and comment rulemaking.

In developing the proposed GLOBE Model, CMS conducted an internal review of which models and programs could have potential overlap with the GLOBE Model. As a result of our review, we expect there may be situations where an eligible GLOBE Model beneficiary who receives a GLOBE Model drug would also be assigned, aligned, or attributed to another Innovation Center model or CMS program or initiative. Overlap could also occur among health care providers and suppliers, health plans, prescription drug plans, and other entities that participate in such models, programs or initiatives. We do not believe that health care provider or beneficiary overlap between the GLOBE Model and other models, programs and initiatives would impact our ability to conduct the GLOBE Model evaluation or interpret findings. Therefore, we are not proposing adjustments to the GLOBE Model when there is overlap of health care providers that prescribe, pharmacies and other entities that furnish or dispense, or beneficiaries who receive GLOBE Model drugs. Instead, other CMS Innovation Center models and CMS programs and initiatives, as determined by CMS, would make adjustments as necessary to accommodate the GLOBE Model test and maintain the integrity of such models, programs and initiatives. For example, the Enhancing Oncology Model (EOM) [133] uses standardized payment amounts [134] and, as applicable, other adjustments to ensure that expenditures included in EOM calculations (such as benchmarks and performance year expenditures) reflect amounts that would have been paid by Medicare in the absence of other CMS

[133] For information about the EOM, see: *https://www.cms.gov/priorities/innovation/innovation-models/enhancing-oncology-model*.

[134] Standardized payments also exclude geographic differences and certain Medicare payment adjustments (for example, graduate medical education payments) to make Medicare payments comparable across providers nationwide. For more information, please see the CMS Payment Standardization Overview provided by the Research Data Assistance Center (ResDAC).

initiatives, and that payments or recoupments are not double counted. Specifically, EOM uses standardized allowed amounts in calculations that include Part B drug claims. The Medicare Part B allowed amount represents the Medicare payment limit before beneficiary cost sharing liability is applied. Therefore, the proposed GLOBE Model beneficiary coinsurance percentage adjustment when applicable is not expected to impact EOM calculations. Other CMS Innovation Center models and CMS programs also use standard payment amounts in calculations (for example, to calculate benchmarks, target expenditures, total cost of care, and shared savings) and would also not be expected to be impacted by claims that would be paid under the proposed GLOBE Model, and the proposed reduced beneficiary coinsurance was applied. Of note, some existing models and programs would not have overlap at the health care practitioner or participant level and do not impact manufacturers due to the way in which the model or program operates and makes payments.

In response to the proposed GLOBE Model beneficiary coinsurance adjustment policy discussed in section II.G.7. of this proposed rule, health care providers and beneficiaries may increase use of GLOBE Model drugs that qualify for lower coinsurance and/or manufacturers may adjust the sales price of GLOBE Model drugs. To the extent that changes in drug prices and/or beneficiary coinsurance amounts result in more appropriate provision of care, other CMS Innovation Center models and CMS programs and initiatives that reward efficient use of Medicare and Medicaid services could experience additional impacts from the design of such models, programs and initiatives because of overlap with the proposed GLOBE Model.

We anticipate model overlap may occur between the proposed GLOBE Model and future CMS models or programs not yet implemented. If the proposed GLOBE Model is finalized, CMS would take the GLOBE Model into consideration in the development of future model designs to address potential impacts of overlap with the GLOBE Model.

In summary, we are not proposing to modify or adjust any CMS Innovation Center model or CMS program or initiative where model overlap with the proposed GLOBE Model would occur. If, in the future, CMS determines a modification or adjustment to the GLOBE Model or other CMS Innovation Center model or CMS program or initiative is necessary for purposes of testing the GLOBE Model or other CMS Innovation Center model or to operate a CMS program or initiative, CMS would pursue such modification or adjustment at such time through the appropriate mechanisms, for example, modifications or adjustments to the GLOBE Model would be pursued through notice and comment rulemaking whereas it might be appropriate for modifications or adjustments to other CMS Innovation Center models or CMS programs and initiatives to be pursued through updates to model policies and data agreements, or program participation criteria or requirements.

We seek comments on our proposed approach to address overlap between the proposed GLOBE Model and other ongoing or future CMS Innovation Center models and CMS programs as described in this section of this proposed rule. We also seek comment on the potential need for any specific modifications or adjustments to the proposed GLOBE Model that would be necessary to support a robust model test of the proposed GLOBE Model or other CMS Innovation Center model. We also welcome comments on the potential ways the proposed GLOBE Model may impact CMS programs and initiatives and the potential need for modifications or adjustments to the proposed GLOBE Model that may be necessary to minimize overlap impacts.

2. Quality Payment Program

The proposed GLOBE Model would not qualify as an Alternative Payment Model (APM) under the Quality Payment Program (QPP) or as a Merit-based Incentive Payment System (MIPS) Alternative Payment Model (MIPS APM).[135] Specifically, the proposed GLOBE Model participants would be manufacturers of GLOBE Model drugs, and those entities are not health care providers and do not qualify to participate in the QPP or MIPS APM. Medicare allowed amounts for claims for GLOBE Model drugs submitted by health care providers that are eligible for participation in the QPP would not be changed under the proposed GLOBE Model. Therefore, the cost element of the QPP would not be impacted by the proposed GLOBE Model.

N. Interaction With Other Federal Programs

The proposed GLOBE Model may have impacts on other federal programs, such as Medicaid, the 340B Program, the Veterans Health Administration, the Department of Defense, the Public Health Service, the Coast Guard, and Medicare.

1. Impact on Medicaid

a. Impact on Medicaid ''Best Price''

With respect to single source or innovator multiple source drugs (which Medicaid recognizes to include biologicals), the term ''Medicaid Best Price'' is the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, non-profit entity or governmental entity within the U.S. with certain exclusions. That is, a manufacturer's best price determination represents the lowest price available from the manufacturer during a rebate period (a quarter) to best price eligible entities or purchasers in the U.S. only. In accordance with section 1927(c)(1)(C)(ii)(I) of the Act, a manufacturer's best price determination is inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates other than rebates under section 1927 of the Act, section 1847A(i) of the Act, or section 1860D–14B of the Act. Because proposed GLOBE Model rebates would be paid by manufacturers pursuant to section 1847A(i) of the Act, the proposed GLOBE Model rebates themselves would not be included in the manufacturer's best price determination.

We expect that the proposed GLOBE Model would lead manufacturers to seek to adjust prices in order to lower the amount of GLOBE Model rebates they would owe. In addition, awareness of the proposed GLOBE Model would likely drive an increase in purchasers' interest in obtaining lower drug prices from manufacturers. The model may indirectly impact a manufacturer's best price to the extent that a manufacturers' U.S. best price would be lower than what it would be otherwise. In other words, if during the course of the GLOBE Model, market forces result in manufacturers reducing prices available to purchasers and such prices are included in a manufacturer's determination of best price, a manufacturer's best price could potentially be lower and possibly increase Medicaid rebates. This is particularly possible because the proposed GLOBE Model rebates would be based in part on pricing outside of the U.S., which are typically lower than prices in the U.S., and may impact the prices made available by the manufacturer in the U.S.

[135] For more information about APMs and MIPS APMs see *https://qpp.cms.gov/apms/overview.*

b. Impact on Average Manufacturer Price (AMP)

AMP is defined at section 1927(k)(1) of the Act. Generally, AMP is determined based on the average price paid to the manufacturer for a covered outpatient drug in the U.S. by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer with certain exclusions. The proposed GLOBE Model would focus on certain Part B rebatable drugs. Because Part B rebatable drugs are typically furnished in the outpatient setting and these drugs are most likely injected or infused, the AMP for GLOBE Model drugs that are identified as 5i drugs [136] may be impacted by the model. The AMP computation for 5i drugs includes sales that are not generally dispensed through retail community pharmacies (see section 1927(k)(1)(B)(i)(IV) of the Act, 42 CFR 447.504(d)), such as sales to physicians, pharmacy benefit managers (PBMs) and hospitals.

Because proposed GLOBE Model rebates would be paid by manufacturers pursuant to section 1847A(i) of the Act, the GLOBE Model rebates themselves would not be included in a manufacturer's AMP for a GLOBE Model drug in accordance with section 1927(k)(1)(B)(i)(VII) of the Act. If the manufacturer lowers prices for GLOBE Model drugs in the U.S., the manufacturer's AMP for a GLOBE Model drug may be lower. If a drug's AMP decreases, it may result in potentially lowering the applicable Medicaid drug rebate paid (the rebate, in part, is based on a percentage of AMP). However, as previously discussed in section VI.D. of this proposed rule, the GLOBE Model may also have indirect impacts that could lower a manufacturer's best price for a GLOBE Model drug. The resulting effect on the Medicaid drug rebate would depend upon the relationship of any AMP change and any best price change.

We also note that if the AMP for a GLOBE Model drug is lowered it may be more likely that, in accordance with section 1847A(d) of the Act, the Inspector General may find that the ASP for a GLOBE Model drug exceeds the AMP for such drug, and that, in accordance with section 1847A(d)(3)(C)(ii) of the Act, the circumstances in which 103 percent of AMP is substituted for the ASP-based price in CMS' determination of the payment allowance for such drug would occur.

[136] Inhalation, infusion, instilled, implanted or injectable drugs.

2. Interaction With 340B Program

The Health Resources and Services Administration (HRSA) administers the 340B Drug Pricing Program that allows certain hospitals and other health care providers (''covered entities'') to obtain discounted prices on ''covered outpatient drugs'' (as defined at 1927(k)(2) of the Act) from drug manufacturers. HRSA calculates a 340B ceiling price for each covered outpatient drug, which represents the maximum price a manufacturer can charge a covered entity for the drug that is provided to an eligible patient. Several types of hospitals as well as clinics that receive certain federal grants from the HHS may enroll in the 340B program as covered entities. Billing units associated with claims for GLOBE Model drugs that are submitted with a 340B modifier and paid for under Part B would be excluded from the total GLOBE Model rebate amount in accordance with 42 CFR 427.303(1) as discussed in section II.G.4. of this proposed rule.

a. Impact on 340B Ceiling Price

Covered entities that enroll in the 340B Program can purchase covered outpatient drugs at no more than a ''ceiling price,'' which is calculated as AMP minus Medicaid unit rebate amount.[137] We note that some 340B hospitals can obtain covered outpatient drugs at less than the ceiling price. Since the Medicaid unit rebate amount is based partly on AMP minus best price, to the extent the proposed GLOBE Model may indirectly affect a drug's AMP and best price, the 340B prices would be affected.

3. Interaction With Medicare

a. Medicare Part B

As discussed in section VI.D. of this proposed rule, we believe the proposed GLOBE Model would result in lower net Medicare spending for GLOBE Model drugs, including lower beneficiary cost-sharing, and in overall reduced Federal Supplementary Medical Insurance Trust Fund expenditures, which in turn could lower Medicare FFS expenditures and beneficiaries' Part B premiums. We estimate that total Medicare Part B FFS savings would amount to $8.4 billion over the model test period and that there would be additional beneficiary premium savings of $1.4 billion over the model test period.

As discussed in section VI.D. of this proposed rule, manufacturers' ASPs for GLOBE Model drugs may be higher or lower than they otherwise would be absent the proposed GLOBE Model. In turn, Medicare Part B FFS payments (before sequestration) to providers and suppliers for GLOBE Model drugs could be higher or lower than what the payments would have been absent the model. We note that, consistent with section 1927(c)(1)(C)(ii)(I) of the Act and section 1847A(c)(3) of the Act, because the GLOBE Model rebate amounts are rebates under section 1847A(i) of the Act, manufacturers would not include GLOBE Model rebates in the calculation of Medicaid Best Price and the manufacturer's average sales price.

We note that if the AMP for a GLOBE Model Part B drug is lowered it may be more likely that, in accordance with section 1847A of the Act, the Inspector General may find that the ASP for a GLOBE Model drug exceeds the AMP for such drug, and that the circumstances in which 103 percent of AMP is substituted for ASP in CMS' determination of the payment allowance for such drug would occur.

b. Medicare Advantage

Medicare Advantage (MA) plans and beneficiaries enrolled in MA plans would not be included in the proposed GLOBE Model. We note that when MA plans pay non-contracted, out of network providers who have administered a GLOBE Model drug to an enrollee, the amount paid would continue to be based on the Medicare FFS payment amount (that is, the amount that MA plans would pay to these providers would reflect the non-model payment amount) and the beneficiary coinsurance must not exceed 50 percent of the plan's total financial liability or the non-model Medicare FFS allowed amount per 42 CFR 422.100(f)(6)(i). When MA plans pay contracted, in-network providers who have administered a GLOBE Model drug to an enrollee, beneficiary coinsurance must not exceed the coinsurance percentage listed in the applicable non-model quarterly ASP file), consistent with the requirements of 42 CFR 422.100(j)(1).

As discussed in section IV.B. of this proposed rule, we expect the proposed GLOBE Model would lower overall net Medicare FFS expenditures; that is, Medicare Part B net payment amounts for GLOBE Model drugs would be lower than such payment would be absent the model, and the model would result in an overall reduction in Medicare expenditures. The overall decrease in Medicare FFS expenditures would be considered in determining the historical FFS claims experience for calculating the rates for plan service areas.

[137] For more information about the 340B ceiling price calculation see *https://340bpricingsubmissions.hrsa.gov/Help/Manufacturer/Pricing%20Formulas/Pricing%20Formulas.htm.*

Payments to MA organizations may be lower than they would be absent the model, resulting from lower MA benchmarks and bids. At a high level, the FFS component of the non-ESRD MA rates is based on the product of the projected national per-capita spending and a county-level relative cost index. Thus, if the proposed GLOBE Model is finalized, the MA rate book calculations would reflect changes in actual FFS spending due to the impact of the GLOBE Model. We note that this approach is consistent with treatment of payments made under other CMS Innovation Center models and the Medicare Shared Savings Program.

As discussed in section IV.D. of this proposed rule, we estimate that MA benchmarks and bids may be lower, resulting in $10.4 billion in savings over the model period. In turn, MA plans may reduce supplemental benefits and increase MA beneficiary out-of-pocket costs. We note that there is much uncertainty around the assumptions for this estimate.

O. Medicare Program Waivers

1. Overview

We believe it may be necessary to waive certain requirements of title XVIII of the Act for the testing of the GLOBE Model. We propose to issue these waivers using our waiver authority under section 1115A(d)(1) of the Act. Section 1115A(d)(1) of the Act provides authority for the Secretary to waive such requirements of title XVIII of the Act as may be necessary solely for the purposes of carrying out section 1115A of the Act with respect to testing models described in sections 1115A(b) of the Act. This provision affords broad authority for the Secretary to waive statutory Medicare program requirements as necessary to carry out the provisions of section 1115A of the Act with respect to testing models.

We welcome comments on other possible waivers under section 1115A of the Act of certain Medicare program rules beyond those specifically discussed in this proposed rule that might be necessary to test this model. We would consider the comments received during the public comment period and may make future proposals regarding program rule waivers during the course of the model test.

2. Waiver of the Calculation of the Rebate Amount

In proposed 42 CFR 513.1000(a), we propose to waive program requirements that are necessary solely for the purposes of testing the GLOBE Model. Specifically, we propose to waive the Medicare Part B inflation rebate calculation provisions, as described in section 1847A(i)(3) of the Act and 42 CFR 427.302 and 42 CFR 427.301, which describes the calculation of the rebate amount. We believe this is necessary in order to implement the proposed alternative calculation for the GLOBE Model rebate amount as described in section II.G. of this proposed rule. We seek comment on our proposed waiver of the Medicare Part B inflation rebate calculation provisions as described in section 1847A(i)(3) of the Act.

We believe that section 1115A of the Act is broad and grants us significant flexibility in the design and implementation of new models. Further, section 1115A(b)(2)(A) the Act provides the Secretary with broad authority to test alternative payment models where ''there is evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures.'' We believe this supports our implementation of the GLOBE Model test and innovative payment models. This model test modifies the Part B inflation rebate amount calculation for GLOBE Model drugs using international drug pricing information to identify a benchmark that reflects prices paid in a set of economically comparable countries. CMS expects these modifications would reduce program expenditures for Medicare Part B while preserving or enhancing beneficiaries' quality of care. Further, the Secretary has the authority under section 1115A(d)(1) of the Act to waive certain Medicare and Medicaid statutory requirements ''as may be as may be necessary solely for purposes of carrying out this section with respect to testing models.''

As such, we believe the proposed waiver of the Medicare Part B inflation rebate amount calculation provisions section 1847A(i)(3) of the Act is necessary in order to implement the proposed alternative calculation for the rebate amount as described in section II.G. of this proposed rule. Specifically, we believe waiving the existing calculation for the rebate amount under section 1847A(i)(3) of the Act as part of the GLOBE Model is necessary in order to implement an alternative calculation for the rebate amount using international pricing information.

We seek comment on our proposed waiver of the Medicare Part B inflation rebate amount calculation provisions as described in section 1847A(i)(3) of the Act.

3. Waiver of Timing Requirements

In proposed 42 CFR 513.1000(b), we propose to waive program requirements that are necessary solely for the purposes of testing the GLOBE Model. As described in section II.G.8. of this proposed rule, we are considering two proposals for invoicing GLOBE Model rebate amounts. Under both approaches, we propose to waive section 1847A(i)(1) of the Act and instead we propose the following deadlines, effective dates, and time period requirements for the GLOBE Model under either option.

For the *combined* invoicing approach, we note that the increased operational complexity would lengthen the time necessary for creating Rebate Reports, which would extend the time following the end of an applicable calendar quarter for manufacturers to pay rebates. As described in section II.G.8. of this proposed rule, we propose that no later than 8 months after the end of each calendar quarter beginning October 1, 2026, CMS would, for all Part B rebatable drugs and for each GLOBE Model Drug, report to the manufacturer the information described in section II.G.8. of this proposed rule and the information in 42 CFR 427.501. We also propose, for each calendar quarter beginning on or after October 1, 2026, the GLOBE manufacturer of a GLOBE Model Drug shall, for such drug, not later than 30 days after the date of receipt of the information for such calendar quarter, provide to CMS the total GLOBE Model rebate amount as set forth in 42 CFR 513.520 for such drug for such calendar quarter.

For the *incremental* invoicing approach, we note that the Preliminary Rebate Reports and Rebate Reports issued as part of the Medicare Part B Drug Inflation Rebate Program must necessarily be delivered before the GLOBE Model Preliminary Rebate Report and GLOBE Model Rebate Report can be issued. As such, we similarly propose that for each calendar quarter we propose that no later than 8 months after the end of each calendar quarter beginning October 1, 2026, CMS would, for each GLOBE Model Drug, report to the manufacturer the information described in section II.G.8. of this proposed rule. We also propose, for each calendar quarter beginning on or after October 1, 2026, the GLOBE manufacturer of a GLOBE Model drug must, for such drug, not later than 30 days after the date of receipt of the information for such calendar quarter, provide to CMS the total GLOBE Model rebate amount as set forth in 42 CFR 513.520 for such drug for such calendar quarter.

As described in section II.G. of this proposed rule, we believe these waivers are necessary to implement the GLOBE Model on the timeline proposed herein given various operational considerations necessary to calculate GLOBE Model rebate amounts. Under the combined invoicing approach, we believe that by issuing Rebate Reports 2 months later than specified in section 1847A(i)(a)(1) of the Act, CMS would be able to both calculate the necessary information for a comprehensive Rebate Report as well as align with the need to provide information about Medicare Part B drug inflation rebate amounts and GLOBE Model rebate amounts to GLOBE Manufacturers timely. As such, under the combined invoicing approach we propose waiving section 1847A(i)(1)(A) of the Act to the extent necessary to allow CMS to issue Rebate Reports no later than 8 months after the end of a calendar quarter during the GLOBE Model performance period. Under the incremental invoicing approach, we believe that delivering the incremental GLOBE Model Rebate Report 2 months later than specified in section 1847A(i)(a)(1) of the Act, CMS would be able to conduct the necessary calculations in order to provide the information needed for the incremental GLOBE Model Rebate Report. As such, under the incremental invoicing approach, we propose waiving section 1847A(i)(1)(A) of the Act to the extent necessary to allow CMS to provide the rebate amount information to manufacturers.

We seek comments on our proposed waiver of section 1847A(i)(1) of the Act.

4. Waivers of Section 1833 of the Act (Payment of Benefits)

As described in section II.E.6. of this proposed rule, we intend to implement an alternative calculation for beneficiary coinsurance and, in conjunction with this calculation, adjust the Medicare payment for the GLOBE Model drug claim. Accordingly, we believe it would be necessary to waive sections 1833(a)(1), 1833(a)(1)(S), 1833(a)(1)(EE), and 1833(t) of the Act in order to implement these changes as they relate to payment to providers and beneficiary coinsurance amount. In addition, we believe it would be necessary to waive provisions in 42 CFR 410.152(m), 419.41(e), 489.30(b)(1), and 489.30(b)(6). Without these waivers, CMS would not be able to carry out the model test of implementing an alternative calculation for beneficiary coinsurance and correspondingly adjust the Medicare payment for the GLOBE Model drug claim in the same manner as under the Medicare Part B Drug Inflation Rebate Program.

P. Evaluation

We would conduct an evaluation of the proposed GLOBE Model, as required under section 1115A(b)(4) of the Act. The evaluation would analyze the quality of care furnished under the model and the changes in spending under Medicare by reason of the model. The evaluation would include the collection of representative information from manufacturers of GLOBE Model drugs, drug purchasers, providers, and beneficiaries. The collection and analysis of these data would inform how the GLOBE Model might function if it were certified and expanded nationally.

All Innovation Center models, which would include the GLOBE Model, are rigorously evaluated on their ability to improve quality without increasing costs or reduce costs without reducing quality. In addition, we routinely evaluate monitoring data from Innovation Center models for potential unintended consequences that run counter to the stated objective of lowering costs without adversely affecting quality of care. The design and evaluation methods, the data collection methods, key evaluation research questions, the evaluation period and anticipated reports for the GLOBE Model are outlined as follows.

1. Evaluation Methods

The evaluation methodology accounts for GLOBE's innovative payment model that modifies the Part B inflation rebate amount calculation for certain Part B rebatable drugs that are single source drugs and sole source biological products to account for prices paid in economically comparable countries. CMS expects this would reduce program expenditures for Medicare Part B while preserving or enhancing beneficiaries' quality of care. The evaluation would employ a design to provide evidence that the proposed intervention would reduce the cost of these drugs and would maintain or enhance the quality of care for Medicare beneficiaries. The first objective would be to estimate the change in the net savings to Medicare due to the model intervention. The second objective would be to examine any changes to the quality of care and out-of-pocket costs of Part B rebatable drugs for the cohort of beneficiaries subject to the model intervention compared to a comparison cohort of eligible beneficiaries not randomized to the model intervention.

The impact of the model would be measured by comparing the change in key outcomes in GLOBE Model regions to non-selected regions. We are considering several populations of interest for the GLOBE Model evaluation, such as Medicare beneficiaries who are likely to receive one of the Part B rebatable drugs based on recent diagnoses and/or prior treatment and populations defined by recent diagnoses (for example, those diagnosed with cancer, rheumatoid arthritis, ophthalmologic conditions) and/or prior treatment to capture the model's impact on beneficiaries directly affected by the changes due to the model.

Medicare spending would be examined in terms of total Part B drug spending for Part B rebatable drugs, total Part B drug spending for any Part B drugs, total Parts A and B spending, and potentially other spending measures for specific types of health care services (for example, inpatient hospital spending). The evaluation of the model's impact on quality of care would examine beneficiary out of pocket spending and drug access, measured by utilization (for example, rates of any use and duration of use) of both Part B drugs (including Part B rebatable drugs, GLOBE Model drugs, and other Part B drugs) and Part D drugs (particularly, for Part D drugs that can substitute for Part B rebatable drugs). We would also examine non-drug health care utilization that may change because of the GLOBE Model to estimate any impacts on access to care. Examples of other non-drug health care utilization include hospitalizations, emergency department visits, and condition specific utilization related to a given subgroup of beneficiaries. The impact estimates would reflect the collective effect of the GLOBE Model's changes to Medicare payments and beneficiary cost-sharing for GLOBE Part B rebatable drugs.

2. Data Collection Methods

We are considering multiple sources of data to evaluate the effects of the GLOBE Model. We expect to base much of our analysis on secondary data sources such as Medicare enrollment and claims data. Beneficiary level claims data would be analyzed to estimate expenditures in total and by type of drug and service. We would examine other sources of data that may include rebate or provider discount information, and international pricing data.

For Part B drugs, we would analyze data on drug utilization patterns, pricing, and expenditures in the original ''fee-for-service'' Medicare program. We would give strong preference to existing surveys and available data collected for

other purposes and would consider CMS evaluation contractor administered site visits, interviews or surveys with selected manufacturers, physicians/practitioners, wholesale drug purchasers, and beneficiaries necessary to measure quality of care. These qualitative sources would provide information that would help us understand better the dynamics and interactions occurring among the stakeholders in the GLOBE Model that cannot be estimated using the proposed secondary data sources.

3. Key Evaluation Research Questions

Our evaluation research questions are structured to assess the impact of the GLOBE Model on reducing Medicare expenditures and preserving or enhancing quality of care. To the extent possible, we would explore how net savings, if any, were related to specific aspects of the payment test, such as how the alternative benchmarks were identified (42 CFR 513.410 and 42 CFR 513.420, Identification of the per unit Method I GLOBE Model benchmark and Identification of the per unit Method II GLOBE Model benchmark, respectively), characteristics of the GLOBE Model drugs, manufacturers, and beneficiaries, and other secondary analyses. Our key evaluation questions would include, but are not limited to, the following:

- Medicare Payments. Did the GLOBE Model result in net savings to Medicare, and if so, how?
- Market Impact. How did manufacturer behavior change in response to the GLOBE Model? Is there evidence of broader changes to the pharmaceutical market, such as changes in the supply of drugs or to drug pricing?
- Quality. What was the impact of the GLOBE Model on the patient's quality of care? Did beneficiaries' cost sharing or access to drugs change under the model, and if so, how? Were there changes in drug or other health service utilization patterns that can be attributed to the model? Were there shifts in utilization from Part B to Part D drugs?
- Unintended Consequences. Did the GLOBE Model result in unintended consequences?

The GLOBE Model evaluation would gather evidence to inform certification through a rigorous, evidence-based process to determine how this model would perform if expanded nationally across the Medicare program. The evaluation would provide evidence to demonstrate if the model achieved its goals during the test period. It would also assess if the results were generalizable at a national scale and financially and operationally sustainable.

4. Evaluation Period and Anticipated Reports

As proposed, the GLOBE Model would have a 7-year test period, including a 5-year performance period and a 7-year payment period beginning on October 1, 2026. The evaluation period would encompass the entire test period, with a baseline period of up to 3 years prior. Continued evaluation after the test period is necessary to assess the impact of the GLOBE Model on reducing Medicare expenditures and preserving or enhancing quality of care. We plan to evaluate the GLOBE Model on a continuous basis and release public evaluation reports annually.

We recognize that interim results are subject to changing policies and issues such as sample size and market fluctuations. Hence, while CMS intends to conduct periodic summaries to offer useful insight during the model test, a final analysis after the end of the model test period would be important for ultimately synthesizing and validating results.

If during our evaluation, results indicate statistically significant savings while preserving or enhancing the quality of care, the Secretary could recommend legislative action to facilitate the development or expansion of the model or a portion of the model.

III. Collection of Information Requirements

Section 1115A of the Act authorizes the CMS Innovation Center to test innovative payment and service delivery models that preserve or enhance the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program beneficiaries while reducing program expenditures. As stated in section 1115A(d)(3) of the Act, Chapter 35 of title 44, United States Code, shall not apply to the testing and evaluation of models under section 1115A of the Act. As a result, the information collection requirements contained in this proposed rule need not be reviewed by the Office of Management and Budget.

IV. Preliminary Regulatory Impact Analysis

A. Statement of Need

As discussed in section I.B. of this proposed rule, studies have revealed that U.S. prices for prescription drugs are 422 percent higher than other countries.[138] Further, CMS data and other studies show that Medicare Part B FFS drug spending[139] has grown by 85.8 percent ($18.7 billion)[140] from 2014 to 2021 with the standard monthly Medicare Part B premium for beneficiaries increasing by 41.5 percent ($104.90[141] to $148.50,[142]) and that the pace of growth has varied across disease categories. For example, according to a recent report,[143] drugs classified in immunology, oncology, rheumatology, endocrinology and ophthalmology are among the top 20 therapeutic classes based on spending or prescriptions volume in the United States and drugs in these categories have shown notable growth between 2023 and 2024. This trend is also observed in Medicare Part B FFS drugs, where these five therapeutic classes represent at least $24 billion in Medicare Part B FFS allowed charges in 2024.[144] [145] [146] Under the IRA, some Medicare beneficiaries have seen savings for some drugs,[147] but recent surveys revealed that Medicare beneficiaries continue to experience challenges in access to medication due to cost.[148] [149] [150] [151] Further, according to

[138] Assistant Secretary for Planning and Evaluation. Comparing Prescription Drugs in the U.S. and Other Countries: Prices and Availability. Contractor Project Report, February 2024. Available at: *https://aspe.hhs.gov/sites/default/files/documents/f96a072f8f82f3ba546abd52bfcaeb57/aspe-cover-idr-pricing-availability.pdf.*

[139] Measured by drug allowed charges.

[140] Medicare Part B Drug Pricing, Office of the Assistant Secretary for Planning and Evaluation (June 9, 2023). Available at: *https://aspe.hhs.gov/sites/default/files/documents/fb7f647e32d57ce4672320b61a0a1443/aspe-medicare-part-b-drug-pricing.pdf.*

[141] CMS announces major savings for Medicare beneficiaries. Available at: *https://www.cms.gov/newsroom/press-releases/cms-announces-major-savings-medicare-beneficiaries.*

[142] 2021 Medicare Parts A & B Premiums and Deductibles. Available at: *https://www.cms.gov/newsroom/fact-sheets/2021-medicare-parts-b-premiums-and-deductibles.*

[143] HDA Research Foundation. HDA 96th Edition HDA Factbook. The Facts, Figures, and Trends in Healthcare (2025–2026). Available at: *https://www.hda.org/publications/.*

[144] CMS. Medicare Utilization for Medicare Part B FFS. Available at: *https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-fee-for-service-parts-a-b/medicare-utilization-part-b.*

[145] Dickson, S.R., and James, K.E. Treatments Associated with Manufacturer Payments to Ophthalmologists. *JAMA Health Forum,* 2023, 4 (9): e232951. doi:10.1001/jamahealthforum.2023.2951.

[146] Desai S., Sekimitsu, S., Rossin, E.J., Zebardast, N. Trends in Anti-Vascular Endothelial Growth Factor Original Medicare Part B Claims in the United States, 2014–2019. *Ophthalmic Epidemio,* 2024, 31(5): 468–477. doi: 10.1080/09286586.2024.2310854.

[147] HHS Announces Cost Savings for 64 Prescription Drugs Thanks to the Medicare Prescription drug Inflation Rebate Program established by the Biden-Harries Administration's Lower Cost Prescription Drug Law. CMS Newsroom, December 20, 2024. Available at: *https://www.cms.gov/newsroom/press-releases/hhs-announces-cost-savings-64-prescription-drugs-thanks-medicare-prescription-drug-inflation-rebate.*

[148] Nekui F, Galbraith AA, Briesacher BA, Zhang F, Soumerai SB, Ross-Degnan D, Gurwitz JH,

a report,[152] Medicare spending doubled between 2010 and 2023, increasing from $0.05 trillion to $1 trillion, and it is projected to reach nearly $2 trillion by 2033. Studies have also shown that increased high drug costs limit access to care and treatment that lead to worse health outcomes, including avoidable hospitalizations and premature death.[153] [154] CMS analysis of claims data shows that total Medicare spending in 2024 was $70.71 billion, and that almost two-thirds of this spending was attributed to Medicare Part B rebatable drugs. Separate data show that Medicare is the largest single purchaser of health care in the U.S., and accounts for 23 percent of total personal health care cost.[155] Further, data reveal that Medicare Part FFS program spending is highly concentrated among a small number of beneficiaries—the costliest 25 percent of beneficiaries accounted for 85 percent of Medicare spending.[156] The associated costs of medication non-adherence due to cost can be significant (up to $290 billion per year).[157]

This rulemaking is necessary to implement and test an innovative payment model that modifies the Part B inflation rebate amount for GLOBE Model drugs using international drug pricing information to reduce expenditures and improve quality of care. Specifically, as described in section II.G. of this proposed rule, the model test would include more than one method for identifying a benchmark amount for the modified rebate calculation and the model evaluation would assess the impacts of using different sources for international drug pricing information. CMS expects that the innovative alternative rebate calculation would reduce Medicare expenditures and beneficiary coinsurance amounts for Medicare Part B while preserving or enhancing beneficiaries' quality of care.

As detailed in sections II.A. through D. of this proposed rule, the proposed GLOBE Model would establish a 7-year GLOBE Model alternative payment test for a subset of separately payable Medicare Part B rebatable drugs that are furnished in the outpatient setting to Medicare beneficiaries who are in the cohort and that are paid under the GLOBE Model, or ''Globe Model drugs.'' As described in section II.E. of this proposed rule, and subject to certain exclusions as discussed in section II.B.2. of this proposed rule, participants would include manufacturers of GLOBE Model drugs. GLOBE Model participants would be subject to the participation requirements, as applicable, during the GLOBE Model test period as described in sections II.E. and II.G.6. of this proposed rule.

B. Overall Impact

We have examined the impacts of this proposed rule as required by *Executive Order 12866* on Regulatory Planning and Review (September 30, 1993); *Executive Order 13132,* ''Federalism''; *Executive Order 14192,* ''Unleashing Prosperity Through Deregulation''; the Regulatory Flexibility Act (RFA) (Pub. L. 96–354); section 1102(b) of the Act (impact on small rural hospitals); and section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (*Pub. L. 104–4*).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of $100 million or more, or adversely affect in a material way a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in E.O. 12866.

A regulatory impact analysis (RIA) must be prepared for a regulatory action that is significant under section 3(f)(1) of *E.O. 12866.* Based on our analysis, the Office of Information and Regulatory Affairs (OIRA) has determined this rulemaking is significant pursuant to section 3(f)(1) of *E.O. 12866.* Accordingly, we have prepared a regulatory impact analysis that presents the estimated costs and benefits associated with this proposed rulemaking.

C. Accounting Statement and Table

As required by OMB Circular A–4, (available at *https://trumpwhitehouse.archives.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf*) in Table 10, we have prepared an accounting statement showing the transfers and costs associated with the provisions of this proposed rule over a 7-year period versus a 10-year period reflecting the proposed 5-year performance period of the GLOBE Model beginning in October 2026 and the proposed 7-year payment period. This Table 10 was based on the analysis discussed in the ''Estimated Impacts of the Proposal'' section in this RIA. The costs for manufacturers to prepare submissions associated with voluntary net price reporting, discussed in section IV.D.3. of this proposed rule, was not directly included since after rounding, these costs are negligible. We estimate that the GLOBE Model would result in an overall savings of $8.4 billion in Medicare Part B FFS net spending during the model before accounting for changes in the Part B premium. In this estimate, we assume manufacturer behavior changes and beneficiary utilization changes. We also estimate savings for the MA program of $7.5 billion before accounting for changes in the Part B premium due to the way CMS calculates MA payments using Medicare FFS claims which would include claims paid under the

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Madden JM. *Cost-related Medication Nonadherence and Its Risk Factors Among Medicare Beneficiaries.* Medical Care. 2021;59(1):13–21. *https://doi.org/10.1097/MLR.0000000000001458.*

[149] Arnold Ventures, Commonwealth Fund, and PerryUndem. Drug Costs and Their Impact on Care. February 10, 2025. Available at: *https://www.arnoldventures.org/stories/drug-costs-and-their-impact-on-care.*

[150] Center for Opinion Research and I–MAK Survey. Understanding Americans' Top Concerns on Drug Pricing: Corporate Greed and Patent Reform. Available at: *https://www.i-mak.org/survey/.*

[151] Ehsan AN, Wu CA, Minasian A, et al. Financial Toxicity Among Patients With Breast Cancer Worldwide: A Systematic Review and Meta-analysis. JAMA Netw Open. 2023;6(2):e2255388. doi:10.1001/jamanetworkopen.2022.55388.

[152] MedPac. National Health Care and Medicare Spending. Section 1. National Health Care and Medicare Spending. July 2025. Available at: *https://www.medpac.gov/wp-content/uploads/2025/07/July2025_MedPAC_DataBook_Sec1_SEC.pdf.*

[153] Ehsan AN, Wu CA, Minasian A, et al. Financial Toxicity Among Patients With Breast Cancer Worldwide: A Systematic Review and Meta-analysis. JAMA Netw Open. 2023;6(2):e2255388. doi:10.1001/jamanetworkopen.2022.55388.

[154] Nekui F, Galbraith AA, Briesacher BA, Zhang F, Soumerai SB, Ross-Degnan D, Gurwitz JH, Madden JM. *Cost-related Medication Nonadherence and Its Risk Factors Among Medicare Beneficiaries.* Medical Care. 2021;59(1):13–21. *https://doi.org/10.1097/MLR.0000000000001458.*

[155] MedPac, Health Care Spending and the Medicare Program. A Data Book. July 2025. Available at: *https://www.medpac.gov/wp-content/uploads/2025/07/July2025_MedPAC_DataBook_SEC.pdf.*

[156] MedPac, Health Care Spending and the Medicare Program. A Data Book. July 2025. Available at: *https://www.medpac.gov/wp-content/uploads/2025/07/July2025_MedPAC_DataBook_SEC.pdf.*

[157] Cutler, R.L., Fernandez-Llimos, F., Frommer, M., Benrimoj, C, et al. Economic Impact of Medication Non-adherence by Disease Groups: A Systematic Review. *BMJ Open,* 2018, 8(1): e016982. DOI: 10.1136/bmjopen-2017–016982.

GLOBE Model beginning with rate setting for 2028, and savings for the Medicaid program of almost $1.0 billion, of which roughly $0.5 billion would be federal savings and roughly $0.3 billion would be state savings. When annualized over 2026 to 2032 we estimate that the GLOBE Model would result in an overall cost savings in Medicare Part B FFS net spending of approximately $2.3 billion at both the 3 and 7 percent rates of discount.

TABLE 10: ACCOUNTING STATEMENT: CLASSIFICATIONS OF ESTIMATED TRANSFERS AND COSTS FOR CONTRACT YEARS 2026 to 2032

Category	3% Discount Rate	7% Discount Rate
TRANSFERS ($millions)		
Annualized monetized transfers, in 2025 dollars, from Manufacturers to the Medicare and Medicaid Trust Funds ($millions)	**2,358.7**	**2,299.7**

D. Estimated Impacts of the Proposal

In this section we discuss the estimated overall impact of the proposed GLOBE Model on the Medicare and Medicaid programs. We also show the paperwork (information) burden.

1. Estimated Impacts to Medicare

The proposed GLOBE Model modifies the existing Part B inflation rebate amount calculation for certain rebatable drugs administered to beneficiaries under Medicare Part B. For beneficiaries in model geographic areas, the specified amount for model drugs would be compared to an international benchmark and the inflation-adjusted payment amount, with the manufacturer rebating any excess to CMS (referred to as the ''incremental GLOBE Model rebate amount'' as set forth in 42 CFR 513.510). The rebates would exclude units that are currently exempt from the existing Part B inflation rebate amount calculation, including 340B and most categories of dual eligible beneficiaries. Certain drugs may be excluded from the model based on therapeutic categories, spending thresholds, ineligibility for the Medicare Part B Drug Inflation Rebate Program, or competitive status within the market. These estimates assume that all manufacturers of proposed GLOBE Model drugs are included in this 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. The model does not change the Medicare Part B payment limit, including the add-on payment, which would remain at 6 percent of ASP for most Part B drugs. In developing our estimate of the potential Medicare savings of the model we started with 2024 Part B claims data for GLOBE Model drugs. CMS' Office of the Actuary (OACT) relied on CMS' Innovation Center for a list of drugs that would have been included in the model had the proposed model been tested based in 2024 data, and we estimate that GLOBE Model drugs would have comprised approximately 54 percent of non-dual, non-340B Part B FFS drug spending for 2024. The model excludes drugs that are paid based on a maximum fair price that has been negotiated through the Medicare Drug Price Negotiation Program; as drugs are selected for the negotiation program and have a payment limit that is based on a maximum fair price, we expect the proportion of drugs included in the GLOBE Model would decrease over time. We estimated which drugs would have an effective maximum fair price during the model performance period and reduced the model rebate to account for the exclusion of these drugs from the model. OACT's estimates of which drugs would be negotiated were developed independently, without input from Medicare Drug Rebate and Negotiation Group within CMS. By the end of the model window, we estimate that GLOBE Model drugs would comprise approximately 21 percent of non-dual, non-340B Part B FFS drug spending for 2024, which reflects the increased amount of spending expected to be subject to the Medicare Drug Price Negotiation Program over time. The model geographic areas would be selected to comprise 25 percent of Part B FFS beneficiaries further reducing the drug spending targeted by the GLOBE Model. Additionally, the numeric estimates of benefit savings (as displayed in Tables 11 and 12) in this analysis reflect the impacts of the incremental GLOBE Model rebate amount, which would be the amount CMS would collect in addition to what CMS collects through the Medicare Part B Drug Inflation Rebate Program.

To reflect the international benchmarks that would be used in the model we relied on international data furnished from IQVIA MIDAS, after adjustments for GDP and purchasing power parity. On average these international benchmarks were 71 percent below the 2024 ASPs for GLOBE Model drugs. This would reflect the upper limit of potential savings as we expect that manufacturers and other stakeholders may engage in a variety of responses that may impact the potential savings of the model.

Our first anticipated manufacturer reaction is to report their international net price data to CMS in cases where that data show higher prices than the Method I GLOBE Model benchmark. Under the GLOBE Model, manufacturers would be eligible to report net international pricing data, and if those prices are higher than the Method I benchmarks, the Method II benchmarks would become the applicable benchmark for the GLOBE Model rebate calculation. This effect would have an upward pressure on applicable benchmarks over time and would reduce the GLOBE Model rebate amounts paid by manufacturers.

Our estimate assumes that the manufacturer reporting would reduce the total GLOBE Model rebate amount by 35 percent by the end of the model test period. This assumption is informed by the average difference between the lowest reference country price and prices averaged over all reference countries (after adjustments for GDP and purchasing power parity) for GLOBE Model drugs (see Table 11).

TABLE 11: ESTIMATES USED TO INFORM THE ANTICIPATED MANUFACTURER REPORTING ASSUMPTION

HCPC Code	Method I Benchmark	GDP and PPP Adjusted Average of all Reference Countries
JYYYY	$100	$135

Manufacturers that increase prices in response to the model will likely need time to implement changes to the international prices. Accordingly, we phased this adjustment into our analysis, beginning with a 10 percent change to 2026 price data and reaching 35 percent in the 2029 price data. These factors are applied at an aggregate level to the rebates calculated under the Method I benchmarks. For example, the total GLOBE model rebate amount paid based on 2026 fourth quarter utilization using the Method I benchmark is reduced by 10 percent in our impacts to reflect this manufacturer response. Table 12 shows the percentage adjustment by performance year.

TABLE 12: ESTIMATED ADJUSTMENTS TO ACCOUNT FOR POTENTIAL INCREASE IN PRICES AS A MANUFACTURER RESPONSE

	2026	2027	2028	2029	2030	2031
Phase-in of Method II Benchmark Adjustment	-10%	-20%	-30%	-35%	-35%	-35%

We also anticipate that there would be some collaboration between manufacturers and providers to incentivize the increased use of white-bagging, where drugs would be reimbursed for under the Part D benefit while still being administered in an office/facility setting, allowing the manufacturer to avoid owing a GLOBE Model rebate amount for those units. We compared current total Part B drug spending for GLOBE Model drugs to comparable NDC's in the Part D program to identify drugs that have a high potential to be moved to the Part D benefit. Combined with assumptions about how much utilization would move, we estimate that this effect would further reduce total GLOBE Model rebate amounts by an additional 2.6 percent.

We also included an induced utilization effect reflecting the potential for increased use of drugs among FFS beneficiaries in model regions in response to lower cost sharing required for GLOBE Model drugs. As many FFS beneficiaries are either dual status or have supplemental prescription drug coverage, we estimate a relatively small 1.2 percent increase in total gross Part B drug spending on average in the first model year for beneficiaries in model geographic areas. This effect decays over time reflecting the lower expected total GLOBE Model rebate amounts over the life of the model.

After accounting for the above effects, we calculated the expected Medicare FFS benefit savings after accounting for reduced coinsurances for beneficiaries in model geographic areas. We then calculated the expected changes in MA benchmarks and the corresponding change in MA payments, under the assumption that the model would be incorporated into the contract year 2028 rate development. The total federal savings account for the fact that the beneficiaries share the lower estimated benefit payments through reduced Part B premiums. Table 13 represents the final estimated benefit savings and the proportion reflected in beneficiary Part B premiums versus federal government savings on a fiscal year cash basis. No impact is shown for 2033 due to payments in 2033 relating to reconciling prior payments, and the amount of this reconciliation is not known at this time.

TABLE 13: ESTIMATED IMPACTS TO MEDICARE

Medicare Impacts ($billions)	2026	2027	2028	2029	2030	2031	2032	Total
FFS Benefit Savings	0.0	0.0	2.2	1.9	1.7	1.5	1.1	8.4
Medicare Advantage Payment Savings	0.0	0.0	1.9	1.9	1.8	1.5	0.3	7.5
Premium Offset	0.0	0.0	1.0	1.0	0.9	0.7	0.4	4.0
Total Federal Savings	0.0	0.0	3.1	2.9	2.6	2.2	1.1	11.9

Note: Totals may not add up due to rounding.

In addition to changes from the model resulting in reduced MA benchmarks and bids, MA plans would likely need to reduce supplemental benefits as well. Since the MA plans that bid below their benchmarks are paid a portion of this difference as an MA rebate, it follows that a reduction in benchmarks reduce the MA rebates. MA plans use these rebates for supplemental benefits, such as premium reductions or reductions in beneficiary cost-sharing, which would increase MA beneficiary out-of-pocket costs.

The model would result in beneficiary savings by reducing the Part B premium for all beneficiaries. Additionally, FFS beneficiaries would see a reduced coinsurance on model drugs via the existing mechanism for adjusting the Part B coinsurance for drugs with a Medicare Part B drug inflation rebate amount. Table 14 shows impacts to beneficiaries on a calendar year basis.

TABLE 14: ESTIMATED IMPACTS TO MEDICARE BEBEFICIARIES

Beneficiary Impacts ($ billions)	2026	2027	2028	2029	2030	2031	Total
Cost Sharing Savings for FFS Beneficiaries	0.1	0.3	0.3	0.2	0.2	0.2	1.4
Supplemental Benefit Savings for MA Beneficiaries	0.0	0.0	-0.2	-0.2	-0.2	-0.1	-0.7
Premium Savings for FFS Beneficiaries	0.0	0.2	0.4	0.4	0.3	0.2	1.6
Premium Savings for MA Beneficiaries	0.0	0.5	1.1	0.9	0.8	0.6	3.9
Total Out-of-Pocket Savings	0.1	1.1	1.7	1.3	1.2	0.9	6.2

Note: Totals may not add up due to rounding.

We also considered the following responses but either determined their impact would be small or that we lacked sufficient data to quantify the level of impact they would have on GLOBE Model rebates:

- We expect that manufacturers with drugs selected for the Medicare Drug Price Negotiation Program would be less inclined to give discounts below the statutorily specified ceiling price. We expect this effect to be small based on the ceiling prices specified by the Inflation Reduction Act of 2022 for Part B drugs.
- As 340B units are excluded from the GLOBE Model rebate amount, we would expect manufacturers to incentivize the increased utilization of these units. However, we do not believe there is much potential for this shift as most model drugs have a relatively low proportion of 340B units currently and the difference between 340B pricing and the benchmark prices for the model are unknown.
- As a change in list prices for model drugs would shift the balance between the GLOBE Model rebate amount and the Medicare Part B inflation rebate amount, there are incentives for manufacturers to raise list prices across all payers to counteract the lost revenue from the model. This reaction could create additional effects on Medicaid or Federal Marketplace spending. The likelihood of this response increases the higher the spending is for a given drug outside of Medicare. We welcome comments on the probability and magnitude of this response to inform future analysis.
- Since drugs with an MFP that applies would be excluded from the model, we might expect manufacturers would try to change their pricing to become eligible for the Medicare Drug Price Negotiation Program if they see it being more favorable for their reimbursement. Given the criteria for being selected for the Medicare Drug Price Negotiation Program, we believe it would be difficult for manufacturers to achieve this. Additionally, the model does not impact reimbursement for all FFS beneficiaries as negotiations would, so this response would require dramatic pricing differences to be favorable to manufacturers.
- The GLOBE Model does not include MA plans and so manufacturers may be inclined to assist in efforts to increase MA enrollment if they find MA reimbursement would be higher than Medicare FFS. It is not clear how much more favorable MA reimbursement would be for manufacturers and so we have not included this in our estimates. We seek comment on the potential response from manufacturers and corresponding impacts to MA plan enrollment and reimbursement to inform future analysis.

2. Estimated Impacts to Medicaid

Medicaid savings of the GLOBE Model would be reflected via the reduced cost sharing and premiums that Medicaid pays on behalf of dual beneficiaries in the model geographic areas. Based on historical experience we expect that 30 percent of the reduced cost sharing would come from dual beneficiaries, with the federal government retaining 57 percent of those savings and states retaining the rest. Based on historical experience we expect that approximately 19 percent of the Part B premiums are paid by Medicaid on behalf of dual beneficiaries, with the federal government retaining 57 percent of those savings and states retaining the rest. Table 15 shows Medicaid impacts on a calendar year cash basis.

TABLE 15: ESTIMATED IMPACTS TO MEDICAID

Medicaid Impacts ($billions)	2026	2027	2028	2029	2030	2031	Total
Federal Cost Sharing Savings	0.0	0.1	0.0	0.0	0.0	0.0	0.2
State Cost Sharing Savings	0.0	0.1	0.0	0.0	0.0	0.0	0.1
Federal Premium Savings	0.0	0.1	0.1	0.1	0.1	0.1	0.5
State Premium Savings	0.0	0.0	0.1	0.1	0.1	0.0	0.3
Total Medicaid Savings	0.0	0.2	0.3	0.2	0.2	0.1	1.0

Note: Totals may not add up due to rounding.

3. Negligibility of Paperwork (Information) Burden

As discussed in section III. of this proposed rule, Chapter 35 of title 44, United States Code, does not apply to the testing and evaluation of models under section 1115A of the Act. That is, models are exempt from paperwork (information) burden requirements. Nevertheless, and for discussional purposes only, we briefly review the main paperwork burden of this proposed rule and show it is negligible. The main information burden arises from voluntary manufacturer-reported submission of international net pricing information. The analysis of cost is summarized in Tables 16 and 17 with line items explained afterwards. Table 16 presents an analysis of items for which we have an experience basis for

quantification. Table 17 discusses other items affecting the cost of submission requirements for which CMS has no prior experience on which to base quantification. To meaningfully deal with this, we assume each item would increase the total quantifiable burden by some factor; a range of factors is presented to account for our lack of precise quantification.

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TABLE 16: DISCUSSION OF QUANTIFIABLE BURDEN FOR SUBMISSION

Line ID	Description	2026	2027 - 2030	2031
(1)	Number of manufacturers	40	40	40
(2)	Quarters per year	4	4	4
(3)	Hours/Preparation	20	10	10
(4)	Hours/Submission`	6	3	3
(5)=(2)*((3)+(4))	Total hours per period per manufacturer	104	52	52
(6)–(1)*(5)	Total unadjusted aggregate hours for full period	4160	2080	2080
(7)	Percent applied for period	0.25	1	0.75
(8)=(6)*(7)	Total aggregate hours for period	1040	2080	1560
(9a)	Mean wage (Administrative Assistants)(43-6014)	$22.90	$22.90	$22.90
(9b)	Mean wage (Health Service Managers)(11-9111)	$66.22	$66.22	$66.22
(9c)	Mean wage (Software Developers, Programmers, Testers) (15-1250)	$65.34	$65.34	$65.34
(9d)	Mean wage (Lawyers) (23-1011)	$87.86	$87.86	$87.86
(9e)	Mean wage (Pharmacists)(29-1051)	$65.97	$65.97	$65.97
(9f)=2/13*((9a - (9e)) +3/13*(9a)	Average weighted hourly wage for five professions	$52.71	$52.71	$52.71
(10)	Factor for fringe benefits/Overtime	2	2	2
(11)=(9)*(10)	Adjusted mean wage	$105.43	$105.43	$105.43
(12)=(11)*(8)	Total Estimated Cost	$109,645	$219,290	$164,467
(13)=sum of row (12) with a weight of 4 for years for 2027-2030	Total Cost 5 Years	$1,151,270	$1,151,270	$1,151,270

We next explain the various line items in sequential order.

Line Item 1: To receive coverage of their drugs by Medicare, manufacturers

must comply with the requirements of 42 U.S.C. 1396r–8,42 U.S.C. 256b, 38 U.S.C. 8126. As a subset of these manufacturers could be impacted by the GLOBE Model, we obtained a list of manufacturers, designated by labeler codes, of Medicare Part B rebatable drugs in 2024 as of June 2025. This list was based on initial, non-final data and there were 61 unique labeler codes on that list. Based on a hypothetical analysis of how many manufacturers would participate in the GLOBE Model using 2024 data, we concluded that the GLOBE Model would only apply to a subset of manufacturers of Part B rebatable drugs given the drug inclusions and exclusions described in section II.B. of this proposed rule. As a conservative estimate meant to include more manufacturers than likely would participate in the GLOBE Model, we used 40 manufacturers. This number is used for the initial estimate in Table 16, reflecting quantifiable information. A second table, Table 17, addresses the reasonable assumption that this number would fluctuate from year to year.

Line Items 3 and 4: The hours required for submission are split between preparation, including reading rules, gathering data, and so forth, and actual submission. We used similar estimates of submission to CMS from a Supporting Statement of the Manufacturer Submission of Average Sales Price (ASP) for Medicare Part B Drugs and Biologicals and Supporting Regulations in 42 CFR 414.800–806 (CMS–10110, OMB 0938–0921) from 2023. The supporting document listed 10 hours for preparation and 3 hours for submission. However, we believe that extra hours would be required for the first year, and in the absence of more reliable data we simply doubled the 10 and 3.

Line Item 7: The GLOBE Model performance period, during which manufacturers could choose to report, is proposed to last from October 2026 through September 2031. Hence, in 2026, the model performance period includes only 1 calendar quarter (25 percent of the year) and in 2031 the model performance period includes 3 calendar quarters (75 percent of the year).

Lines 9a through 9f: The $21.90 is the mean wage obtained from the Bureau of Labor Statistics website for Secretaries and Administrative Assistants, Occupational Code 43–6014, for the latest year available at this time, 2024. Note that CMS still uses mean wages even though many agencies use median wages. However, replacing the mean by the median would not change the conclusion of negligibility. 43–6014 is the same occupational title used for estimates in OMB 0938–0921. However, we determined that this approach (using only administrative assistants) was overly simplified. While administrative assistants are appropriate staff for the 3 hours submission, we assume the preparation would involve a team of administrative assistants, health care managers, software engineers, lawyers, and pharmacists. The mean hourly wage of these staff for 2024 are displayed along with their occupational titles and code. The wages of these five staff are combined to produce a single mean hourly wage for the team. In the absence of further data, the weights assume that all five staff work equally in the 10 hours of preparation resulting in 2 hours per staff. The administrative staff exclusively work during the 3 hours of submission. Thus, the weights are five-thirteenths for administrative staff and two-thirteenths for each of the other staff.

Line 10: Per HHS guidance,[158] CMS uses a factor of 2 to account for overtime and fringe benefits.

We next turn to items for which we have no basis on which to quantify. The total analysis is presented in Table 17. As noted in Table 17, there are two non-quantifiable issues that have to be addressed.

New and departing participants: Each year, the group of GLOBE Model participants may change based on whether their drug meets the criteria for inclusion in the GLOBE Model. We have no way of estimating with accuracy whether a given manufacturer would be included or excluded in the GLOBE Model. If we assume 4 new manufacturers, then bottom line estimates from Table 16 would increase 10 percent (4/40). This is a low estimate. In an alternative scenario, the number of participants might increase as much as 50 percent corresponding to a factor of 1.5; although this is unlikely, it helps define a range of possible costs.

19 Countries: If a manufacturer were to opt to report manufacturer-submitted data, they would do so for a set of reference countries, up to 19 countries as discussed in section II.G.1.e. of this proposed rule. The 10 hours of preparation assumed in Table 16 provides time for each GLOBE Model participant to address marketing, pricing, and licensing requirements. But likely, this is different for different countries. We do not have enough information to quantify this. We approach the extra time as a factor by which we increase cost. For example, assuming that half the countries require the same preparation time, we would multiply the bottom line cost burden by a factor of 9.5 (19/2). On the other hand, if data on licensing, marketing, and pricing for each individual country are readily available, it might only require an extra 2 hours of work resulting in an increase of 1.15 (2/13). We take these as the low and high estimates and insert an intermediate estimate.

To obtain a range of adjusted bottom line estimates we multiply the factors together. For example, as discussed previously, if half the countries require the same amount of work (resulting in a factor of 9.5) and if the number of participants increases 50 percent (resulting in a factor of 1.5) then we multiply the bottom line number from Table 10, $1,151,270 by 14.25 (1.5 * 9.5) and obtain a high cost burden of $16,405,603 million as shown in Table 17. As shown on the bottom line of Table 17, the resulting range of estimates of cost burden is between roughly $1.5 million and $16.5 million.

[158] ASPE. Guidelines for Regulatory Impact Analysis, 2016. Available at: *https://aspe.hhs.gov/sites/default/files/private/pdf/242926/HHS_RIAGuidance.pdf.*

TABLE 17: ADJUSTING COST BURDEN TO ACCOUNT FOR NON-QUANTIFIABLE ISSUES

LINE ID	Description	Low Factor	Intermediate Factor	High Factor
(1)	19 countries	1.16	5	9.5
(2)	New and departing participants	1.1	1.3	1.5
(3)=(1)*(2)	Product of factors	1.276	6.5	14.25
(4) (From Table 14)	Quantifiable burden	$1,151,270	$1,151,270	$1,151,270
(5)=(4)*(3)	Range of possible adjusted cost burdens	$1,469,021	$7,483,258	$16,405,603

Notes: (1) The GLOBE Model as proposed in this proposed rule would include 19 countries as part of the set of reference countries. For a discussion of the low and high factors or for a discussion of new and departing GLOBE Model participants see the paragraph immediately preceding Table 17.

E. Initial Regulatory Flexibility Analysis

The Regulatory Flexibility Act (RFA) requires agencies to analyze options for regulatory relief for small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Individuals and states are not included in the definition of a small entity. The RFA requires that CMS analyze regulatory options for small businesses and other entities unless CMS certifies that a rule would not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the proposed rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities.

HHS considers a significant impact on a substantial number of small entities, to be one with a 3 percent revenue effect on 5 percent of small entities.[159] As discussed in section II. of this proposed rule, manufacturers that are GLOBE Model participants would pay GLOBE Model rebates to the Medicare Part B account in the Federal Supplementary Medical Insurance Trust Fund if the amount specified in section 1847A(i)(3)(A)(ii)(I) of the Act for a GLOBE Model drug exceeds a benchmark amount that would be based on available international drug pricing information (as described in section II.G.1. of this proposed rule), and would not be less than any rebate owed under the Medicare Part B Drug Inflation Rebate Program. Our analysis shows that the proposed rule, would impact 7 percent of small entities, and the impact is estimated to represent up to 2.6 percent of the small entities' annual revenue in the United States. Given the uncertainty on manufacturer response and available data, CMS concludes that this proposed rule, if finalized as proposed, would have a significant economic impact on a substantial number of small entities. This analysis, as well as other sections in this proposed rule, serves as the Regulatory Flexibility Analysis, as required by the RFA.

1. Description and Number of Affected Small Entities

We use the North American Industry Classification System (NAICS) to identify the industry potentially affected by the proposed rule. We also use the Small Business Administration (SBA) size standards to identify small entities.[160] The SBA considers any ''Pharmaceutical Preparation Manufacturing'' firm (NAICS code 325412) with fewer than 1,300 employees as a small business.

We use financial and employment information publicly available on annual reports published on companies' websites or submitted to the Securities and Exchange Commission (SEC) for 2024 to identify revenue and employment information for the potentially affected companies. Most companies self-identified as ''global'' and provided information separately for their global consolidated business and for the United States. For purposes of this analysis, we use revenue and employment size information based on data reported for the United States. We used the Internal Revenue Service's yearly average currency exchange rates for 2024 to convert revenue information into U.S. dollars when this information was provided in a foreign currency.[161]

We identified 30 manufacturers that would be associated with 61 GLOBE Model drugs. Using the financial data, we determined that two of the 30 manufacturers are subsidiaries of larger companies. For purposes of this analysis, we consider the impact on the 28 unique parent companies. Table 18 shows that 7 percent of the affected manufacturers would be considered small based on the SBA definition.[162] In 2024, the total company revenue in the United States for these small companies exceeded $2 billion (the average U.S. revenue per small company exceeded $1 billion). These companies accounted for about 0.45 percent ($2,045/$456,292) of the total U.S. revenue among the 28 affected entities. The potential GLOBE Model drugs associated with these small entities are classified as immunological agents and antineoplastics for which there are at least a dozen other drugs that are in the same therapeutic class as determined by the number of HCPCS Level II codes in the USP DC classification category used for this analysis. Further, based on CMS expertise the potential GLOBE Model drugs associated with these small entities have therapeutically equivalent substitutes.

[159] Department of Health and Human Services. Guidance on Proper Consideration of Small Entities in Rulemaking of the U.S. Department of Health and Human Services, 2003. Available at: *https://aspe.hhs.gov/reports/proper-consideration-small-entities-rulemakings-us-dhhs.*

[160] Small Business Administration. Table of Size Standards, Available at: *https://www.sba.gov/document/support-table-size-standards.*

[161] Internal Revenue Service. Yearly average currency exchange rates. Available at: *https://www.irs.gov/individuals/international-taxpayers/yearly-average-currency-exchange-rates.*

[162] Using data on the total number of employees inside and outside the U.S., the estimated percent of small entities is 3.5 percent.

TABLE 18: NUMBER OF SMALL ENTITIES BY EMPLOYMENT SIZE AND REVENUE, 2024

Company Size	Total Number of Employees in the U.S.	Percent of Unique Companies	Total Global Revenue ($million)	Total U.S. Revenue ($million)	Average U.S. Revenue per Company ($million)
Small	1300 or fewer	7%	$4,649.87	$2,045.11	$1,022.56
Large	1300+	93%	$786,811.00	$454,246.70	$17,471.03
Total		100%	$791,460.88	$456,291.81	$16,296.14

2. Description of the Potential Impacts on Small Entities

CMS anticipates that payments to CMS in the form of GLOBE Model rebate amounts, as set forth in 42 CFR 513.500 of this proposed rule, would represent the largest impact to small entities. We estimate the impact using two approaches. Under the first approach, we use available data to estimate an average GLOBE Model rebate per company ($26 million), including both large and small manufacturers. Using this estimate as an upper bound, we estimate that GLOBE Model rebates could represent up to 2.6 percent of a small entity's average revenue in the U.S. ($26 million/$1 billion). In the second approach we assume that 1.64 percent of the estimated incremental GLOBE Model rebate amount would be associated with small entities, and then estimate the potential incremental GLOBE Model rebate amount for the small entities affected. The estimate of 1.64 percent was derived separately from OACT's analysis because OACT's overall estimates in the RIA represent aggregates across all companies. Using this estimate, and OACT's estimate of the total incurred calendar year GLOBE Model rebates, we estimate the incremental GLOBE Model rebate amounts would range from $0.00 to $49.37 million for small entities over the model performance period. Table 17 presents the estimated incremental GLOBE rebate amounts for small entities and the corresponding impact on total revenue. Based on our analysis and using available data on total revenue and estimated incremental GLOBE Model rebates, CMS estimates that the estimated incremental GLOBE Model rebate amounts would represent up to 2.4 percent of small entities' total revenue, as measured in terms of revenue in the U.S. The administrative costs involved with reading and understanding this proposed rule are not included in these estimates. However, as noted in the RIA, these costs are estimated to be negligible.

CMS notes that these estimates are based on available data which could change in the future and as such, the estimated impacts could vary. Specifically, the estimates are based on the current status of rebatable drugs, employment and revenue information using 2024 or other available data as of the publication of this proposed rule. Given this uncertainty, CMS concludes that the proposed rule, if finalized as proposed, would have a significant impact on a substantial number of small entities. CMS welcome comments on our conclusion, approach, assumptions, and data used to estimate these impacts.

TABLE 19: ESTIMATED IMPACT ON SMALL ENTITIES

Description	2026	2027	2028	2029	2030	2031	2032
Estimated Incremental GLOBE Model Rebate Amount for Small Entities ($millions)	12.59	49.37	45.88	35.88	32.08	23.70	0.00
Estimated Total GLOBE Model Rebate for Small Entities as Percent of Total U.S. Revenue of Small Entities	0.6%	2.4%	2.2%	1.8%	1.6%	1.2%	0.0%

As discussed previously, we also considered other responses, including limited price reductions for drugs selected for the Medicare Drug Price Negotiation Program, increased utilization of 340B units, changes in list pricing information, changes in incentives to participate in the Medicare Drug Price Negotiation Program, impacts to MA plans and Medicaid, and either determined their impact to be small or that there was insufficient data to properly quantify their impact. We note that there is much uncertainty around the assumptions for these estimates. We welcome comments on our estimate of significantly affected small manufacturers and the magnitude of estimated effects. We also welcome comments on adjustments to the GLOBE Model that could be considered while preserving the innovative approach to payment in the GLOBE Model.

3. Alternatives To Minimize the Impact on Small Entities

CMS considered the following alternatives to minimize the impact on small entities: (1) establishing a different spending threshold; (2) establishing an exemption process; and (3) establishing different compliance dates.

- *Spending threshold:* As discussed in section II.B. of this proposed rule, CMS is proposing to include drugs or biological products that meet the proposed definition of a GLOBE Model drug which would include a subset of Part B rebatable drugs that: (1) have the listed USP DC categories in Table 3 of this proposed rule; (2) are single source drugs or sole source biological products; (3) have a HCPCS Level II code with Medicare Part B FFS spending greater than $100 million over a 12-month period; and (4) are not excluded from the GLOBE Model as proposed in 42 CFR 513.130(c). Based on the third criterion, CMS is excluding from the GLOBE Model those drugs with relative share of spending costs to drug spending lower than $100 million. This spending threshold applies to all

manufacturers irrespective of size. While lowering the spending threshold increases the number of drugs that could be included in the GLOBE Model, it also increases the number of small manufacturers that could potentially be impacted. For this reason, CMS proposes not to select a lower threshold. Further, increasing the threshold reduces both the number of small and large manufacturers and the number of drugs in the GLOBE Model. For example, a threshold of $125 million would exclude eight manufacturers including six large manufacturers (they employ more than 5,000 employees in the United States). Further, setting a threshold above $186 million would exclude all identified small manufacturers as well as 16 drugs manufactured by large manufacturers and would result in a total of 50 included drugs. Selecting a different spending threshold higher than $100 million would also reduce the estimated savings to the Medicare program and to beneficiaries and thereby shift the focus of the model test and limit the ability to evaluate the experiences of manufacturers of drugs with diverse characteristics.

- *Exempting small entities:* As discussed in section II.B.2. of this proposed rule, to avoid interactions with other initiatives and programs that focus on manufacturers of Medicare Part B drugs, CMS would exclude drugs assigned to HCPCS Level II codes when the Medicare Part B payment limit is based on a maximum fair price for drugs separately payable under Medicare Part B. Because small and large manufacturers could potentially be eligible for this proposed exclusion, we do not believe that additional processes for exemptions are needed. CMS seeks comments on other factors or considerations regarding exemptions for small entities.
- *Compliance dates:* CMS also considered the flexibility of providing different compliance dates to small manufacturers. While creating significantly different compliance dates could provide more time for small manufacturers to comply, it could interfere with the statutory requirement of evaluating the model to determine whether savings have occurred.

In summary, because the purpose of the GLOBE Model is to test an innovative payment model that modifies the Medicare Part B inflation rebate amount calculation for GLOBE Model drugs using international drug pricing information to identify a benchmark that reflects prices paid in economically comparable countries, which CMS expects would reduce program expenditures for Medicare Part B while preserving or enhancing beneficiaries' quality of care, CMS therefore declined to propose the alternatives considered. We welcome comments on the alternatives considered as well as other factors that could be considered to mitigate the impact on small manufacturers.

F. Effects on Small Rural Hospitals

Section 1102(b) of the Act requires CMS to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has 100 or fewer beds.

Providers and suppliers who furnish GLOBE Model drugs to Medicare FFS beneficiaries who are in the model cohort would not be GLOBE Model participants and would continue to buy and bill for GLOBE Model drugs as usual and receive separate payment under Medicare Part B if applicable. These providers and suppliers include hospital outpatient departments, physician practices, ambulatory surgical centers, pharmacies enrolled as durable medical equipment (DME) suppliers, and certain other provider and supplier types. When the GLOBE Model reduced beneficiary coinsurance applies, the portion of Medicare Part B allowed amount for a GLOBE Model drug paid by Medicare would be greater than the usual 80 percent. For example, if the Medicare Part B allowed amount under the GLOBE Model is $100 and the GLOBE Model beneficiary coinsurance percentage is 10 percent (instead of the usual 20 percent), the Medicare Part B program payment to the provider or supplier would be adjusted and would be $90 (instead of the usual $80) and the beneficiary financial responsibility would be $10.

According to 2025 data from the American Hospital Association [163] there are 6,093 hospitals in the United States. Using data from 2021 and 2025, we estimate that there are 1,524 small rural hospitals in the United States.[164] This represents 25 percent of all U.S. hospitals. We estimate that very small rural hospitals, those with up to 25 beds, represent almost 60 percent (or 869) of all small rural hospitals, followed by hospitals with 25–50 beds (N=331) and 51–100 beds (N=323). It has been estimated that rural hospitals represent about 10.8 percent of the total share of Medicare Part B spending,[165] and that Medical Part B spending in all hospitals represented about 41 percent of total Part B spending in 2022 ($19.3 billion/$46.9 billion).[166] Assuming that these percentages have remained relatively unchanged, we estimate that slightly less than 4 percent ($1.71 billion) of total Medicare Part B drug allowed charges in 2024 are associated with very small rural providers and suppliers.[167] The small rural hospitals are not expected to experience drug payment reductions and overall payment reductions similar to urban hospitals. As noted previously, CMS anticipates that there would be some collaboration between manufacturers and providers to incentivize the increased use of white-bagging. However, small rural hospitals are not expected to experience increased use of white-bagging as for these facilities white-bagging may already be a reasonable solution.[168] We tentatively conclude that this proposed rule, if finalized as proposed, would not have a significant impact on small rural hospitals. We seek comments on this conclusion, as well as data or other factors that have not been considered.

G. Unfunded Mandates Reform Act (UMRA)

Section 202 of UMRA also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation.

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[163] American Hospital Association. Fast Facts on U.S. Hospitals, 2025. Available at: *https://www.aha.org/system/files/media/file/2025/01/Fast-Facts-on-US-Hospitals-2025.pdf.*

[164] American Hospital Association. Fast Facts on U.S. Rural Hospitals, 2023. Available at: *https://www.aha.org/system/files/media/file/2023/12/Fast-Fact-on-US-Rural-Hospitals-2023-Infographic.pdf.*

[165] Avalere Health. CMS Site-neutral Payments Affect Share of Spending, January 10, 2024. Available at: *https://advisory.avalerehealth.com/insights/cms-site-neutral-payments-affect-small-share-of-spending.*

[166] MedPac. July 2025 Data Book Section 10: Prescription Drugs, Data Book, July 17, 2025. Available at: *https://www.medpac.gov/document/july-2025-data-book-section-10-prescription-drugs/.*

[167] We estimate the Medicare Part B spending for rural hospitals is 2024 is $2.053 billion (=$46.18 billion times 41 percent times 10.8 percent), and that the Medicare Part B spending for small rural hospitals is $1.74 billion (=$2.053 times 1524 divided by 1796, where $2.05 (in billions) represents the estimated Medicare Part B spending in 2024, 0.108 represents the share of Medicare Part B spending for rural hospitals, 1524 is the number of small rural hospitals, 1796 is the number of rural hospitals.

[168] American Hospital Association. Health Insurer Specialty Pharmacy Policies Threaten Patient Quality of Care, March 2021. Available at: *https://www.aha.org/system/files/media/file/2021/03/AOMarch8white-bagging-0221.pdf.*

In 2025, that threshold is approximately $187 million. This proposed rule would not impose a mandate that would result in the expenditure by State, local, and Tribal Governments, in the aggregate, or by the private sector, of more than $187 million in any one year. However, this proposed rule, if finalized as proposed, would result in additional impacts that we do not quantify associated with changes in behavior. We request comments, including on the potential magnitude of this impact and the extent to which it is a funded or unfunded mandate.

H. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. Since this proposed rule does not impose any substantial costs on State or local governments, preempt State law or have federalism implications, the requirements of Executive Order 13132 are not applicable.

I. Unleashing Prosperity Through Deregulation

E.O. 14192, titled ''Unleashing Prosperity Through Deregulation,'' was issued on January 31, 2025, and requires that ''any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations.''

V. Response to Comments

Because of the large number of public comments we normally receive on documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on December 10, 2025.

List of Subjects in 42 CFR Part 513

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV by adding part 513 to read as follows:

SUBCHAPTER H—HEALTH CARE INFRASTRUCTURE AND MODEL PROGRAMS

PART 513—Global Benchmark for Efficient Drug Pricing (GLOBE) Model

Sec.

Authority: 42 U.S.C.1302, 1315(a), and 1395hh.

Subpart A—General Provisions

§ 513.1 Basis, scope, duration, and severability.

(a) *Basis.* This part implements the test of the Global Benchmark for Efficient Drug Pricing (GLOBE) Model under section 1115A of the Act. Except as specifically noted in this part, the regulations under this part do not affect payment, coverage, program integrity, or any other requirements that otherwise apply to providers of services, suppliers, and manufacturers under this chapter.

(b) *Scope.* This part sets forth the following:

(1) The manufacturers required to participate in the GLOBE Model and applicable requirements including, but not limited to, the requirement for manufacturers of GLOBE Model drugs to pay GLOBE Model rebates to the Federal Supplementary Insurance Trust Fund for each calendar quarter during the model performance period when a GLOBE Model rebate is owed in accordance with 42 CFR 513.510.

(2) The beneficiaries included in the GLOBE Model.

(3) The Part B rebatable drugs included in the GLOBE Model.

(4) The methodologies for establishing the GLOBE Model rebate amount.

(5) The methodologies for establishing the GLOBE Model beneficiary coinsurance percentage.

(6) The methodologies for establishing the Medicare Part B payment to providers of services and suppliers when the GLOBE Model beneficiary coinsurance percentage applies.

(c) *Duration.* The GLOBE Model has a 7-year test period consisting of a 5-year performance period and a 7-year payment period.

(1) The first performance year begins on October 1, 2026, and the final performance year ends on September 30, 2031, unless sooner terminated in accordance with 42 CFR 513.1500.

(2) The first payment year begins on October 1, 2026, and the final payment year ends on September 30, 2033, unless sooner terminated in accordance with 42 CFR 513.1500.

(d) *Severability.* Were any provision of this part to be held invalid or unenforceable by its terms, or as applied to any person or circumstance, these provisions would be severable from this part and the invalidity or unenforceability would not affect the remainder thereof or any other part of this subchapter or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances.

§ 513.20 Definitions.

For the purpose of this part the following definitions are applicable unless otherwise stated:

Across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit means a volume-weighted average for all reference countries of GDP (PPP) adjusted net prices, where the weights are the volume in HCPCS billing units for each reference country, in U.S dollars from international drug net pricing data from an applicable submission.

Add-on percentage amount means the amount of payment for a drug or biological product determined in accordance with section 1847A(b)(1)(B) of the Act above the drug or biological product's average sales price, expressed as a percentage of the average sales price or the wholesale acquisition cost.

Allowed charges has the same meaning set forth in 42 CFR 427.20.

Applicable ASP calendar quarter means the period that is 2 calendar quarters prior to the applicable calendar quarter.

Applicable calendar quarter has the same meaning set forth in 42 CFR 427.20.

Applicable threshold percentage means the percentage specified in 42 CFR 513.400.

Average sales price (ASP) has the same meaning set forth in 42 CFR 427.20.

Billing and payment code has the same meaning set forth in 42 CFR 427.20.

Billing unit has the same meaning set forth in 42 CFR 427.20.

Biosimilar biological product for the United States has the same meaning set forth in 42 CFR 427.20

International biosimilar biological product means a biological product approved or licensed in a reference country under that reference country's regulatory framework under a pathway similar to section 351(k) of the PHS Act in the U.S.

Country-level price means the unadjusted country-level price for a GLOBE Model drug at the unit of measurement delineated in the HCPCS Level II code descriptor as calculated in accordance with 42 CFR 513.410.

Currently in shortage has the same meaning set forth in 42 CFR 427.400.

Date of receipt has the same meaning as set forth in 42 CFR 427.500.

Drug shortage or shortage has the same meaning set forth in 42 CFR 427.400.

Eligible manufacturer means the manufacturer of a separately payable Medicare Part B rebatable single source drug or biological (as defined in section 1847A(c)(6)(D) of the Act) that could be a GLOBE Model drug during the model performance period.

Final action claim has the same meaning set forth in 42 CFR 427.20.

FDA stands for Food and Drug Administration.

GDP stands for gross domestic product.

GDP (PPP) adjuster means the country specific adjuster as calculated in accordance with 42 CFR 513.430.

GLOBE Model-adjusted beneficiary coinsurance percentage means the applicable coinsurance percentage as determined under 42 CFR 513.210.

GLOBE Model benchmark amount means the amount calculated in accordance with 42 CFR 513.400.

GLOBE Model beneficiary means a Medicare beneficiary who has been identified by CMS for inclusion in the model and added to the model cohort for some or a portion of the GLOBE Model performance period as set forth in 42 CFR 513.120.

GLOBE Model billing units means the billing units of the GLOBE Model drug furnished to a GLOBE Model beneficiary during the applicable calendar quarter, as identified by CMS as set forth in 42 CFR 513.520.

GLOBE Model drug means Medicare Part B rebatable drug described by a HCPCS Level II code included on the GLOBE Model Drug HCPCS Level II Codes List specified in 42 CFR 513.130(c).

GLOBE Model eligible beneficiary means a Medicare beneficiary meeting the criteria in 42 CFR 513.120(b)(1).

GLOBE Model Eligible Beneficiary List means the list recording the assignment of Medicare beneficiaries as eligible for the model cohort in accordance with 42 CFR 513.120(b)(1).

GLOBE Model geographic areas means the set of ZIP Codes identified in accordance with 42 CFR 513.110.

GLOBE Model participant means a manufacturer of a GLOBE Model drug that is required to participate in the GLOBE Model in accordance with 42 CFR 513.100.

GLOBE Model payment period means the 7-year period of time beginning on October 1, 2027, through September 30, 2033, as specified in 42 CFR 513.1(c).

GLOBE Model performance period means the 5-year period of time beginning on October 1, 2026, through September 30, 2031, as specified in 42 CFR 513.1(c).

GLOBE Model rebate amount means the amount that is calculated in accordance with 42 CFR 513.510 for a Part B rebatable drug.

HCPCS stands for Healthcare Common Procedure Coding System.

HCPCS billing units are the standardized measurement quantities (such as milligrams, milliliters, or individual items) used to determine how medical services, procedures, supplies, and drugs are quantified and billed for reimbursement under the Healthcare Common Procedure Coding System, where the billing quantity is calculated by dividing the total amount administered or provided by the unit of measurement defined for that specific HCPCS Level II code.

HCPCS dosage means the quantity of drug represented in one HCPCS billing unit, which is the identifiable quantity of a drug or biological product associated with a billing and payment code (for example, a HCPCS Level II code), as established by CMS.

Inflation-adjusted payment amount means the amount determined under 42 CFR 427.302(g).

International generic means for a drug approved and marketed in a non-U.S. country under that non-U.S. country's regulatory framework under a pathway similar to section 505(j) of the FD&C Act in the U.S.

International net pricing information means the data specified in 42 CFR 513.610.

International originator drug means an original biological product or drug approved or licensed in a non-U.S. country under that non-U.S. country's regulatory framework under a pathway similar to 351(k) of the PHS Act or approved under a pathway similar to section 505(c) of the FD&A Act in the U.S.

List price means the manufacturer's price (also known as the ex-factory price or undiscounted price offered by a manufacturer to a purchaser) at the presentation level for a calendar quarter (expressed U.S. currency).

Manufacturer has the meaning as set forth in section 1847A(c)(6)(A) of the Act and 42 CFR 427.20.

Manufacturer average sale price information means the information

described in sections 1927(b)(3)(A)(iii) and 1847A(f)(2)(A) of the Act.

Manufacturer's average sales price has the same meaning as under 42 CFR 414.902 and means the price calculated and reported by a manufacturer under 42 CFR 414 Subpart J.

Maximum fair price has the same meaning as specified in section 1191(c)(3) of the Act.

Method I GLOBE Model benchmark means the lowest country-level price of the countries specified in 42 CFR 513.310 for a GLOBE Model drug as determined in 42 CFR 513.410.

Method II GLOBE Model benchmark means the volume-weighted average of the manufacturer's net pricing for sales within a set of countries specified in 42 CFR 513.310 for a GLOBE Model drug as determined in 42 CFR 513.420.

Natural disaster has the same meaning set forth in 42 CFR 427.400.

Net sales price means the total net sales divided by the number of units sold for a calendar quarter (expressed in U.S. currency).

OECD means Organisation for Economic Co-operation and Development.

Other unique or unexpected event has the same meaning set forth in 42 CFR 427.400.

Part B rebatable drug has the same meaning as identified in 42 CFR 427.20.

Payment year means a 12-month period beginning on October 1 and ending on September 30 during the GLOBE Model test period.

Plasma-derived product has the same meaning set forth in 42 CFR 427.400

Performance year means a 12-month period beginning on October 1 and ending on September 30 during the first 5 years of the GLOBE Model test period.

Presentation level means, for a scientific and nonproprietary name, a unique combination of dosage form, strength, route of administration, pack size, and packaging sold in a reference country.

Presentation unit means the product represented at the presentation level, unless otherwise specified by CMS to account for situations where labeling indicates that the quantity of drug product represented by the presentation level varies.

Provider means a ''provider of services'' as defined under section 1861(u) of the Act and codified at 42 CFR 400.202 of this chapter.

Reference country means a country that is identified under 42 CFR 513.310(b).

Reference product means an FDA-licensed biological product approved under section 351(a) of the Public Health Service Act against which a biosimilar biological product is evaluated in an application submitted to the FDA under section 351(k) of the Public Health Service Act.

Severe supply chain disruption has the same meaning set forth in 42 CFR 427.400.

Single source drug or biological product has the same meaning set forth in 42 CFR 427.20.

Sold or marketed has the same meaning set forth in 42 CFR 427.20.

Sole source biological means a biological product licensed by the FDA in under a BLA under section 351(a) of the PHS Act and that, at time of evaluating for inclusion into the GLOBE Model for each applicable ASP calendar quarter, is not the reference biological product, as defined in section 1847A(c)(6)(I) of the Act, for a biosimilar biological product licensed by the FDA in a BLA under section 351(k) of the PHSA Act. The biosimilar biological product must be recognized in the FDA's Purple Book and be identified as sold or marketed in FDA's NDC Directory. At the time of evaluating inclusion in the GLOBE Model for each applicable ASP calendar quarter, CMS uses FDA's NDC Directory, including historical information from NDC Directory files such as discontinued, delisted, and expired listings, provided by the FDA or published on the FDA website to identify whether the biosimilar biological product is being sold or marketed for purposes of the GLOBE Model.

Specified amount has the same meaning set forth in 42 CFR 427.20.

Supplier means a supplier as defined in section 1861(d) of the Act and codified at 42 CFR 400.202 of this chapter.

Unit has the same meaning set forth in 42 CFR 427.20.

U.S. originator drug means the original biologic and drug developed and licensed or approved via section 351(a) of the Public Health Services Act or submitted under section 505(b) and approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). U.S. originator drugs are also sometimes called brand name drugs, reference listed drug, or reference products.

U.S. stands for United States.

ZIP Code means a trademark of the United States Postal Service (USPS) created to coordinate mail handling and delivery. The USPS assigns ZIP Code ranges to regional post offices, which in turn assign ZIP Codes to delivery routes.

ZIP Code Tabulation Areas (ZCTAs) means approximate area representations of USPS five-digit Zonal Improvement Plan (ZIP) Code service routes that the Census Bureau creates using whole blocks to present statistical data from censuses and surveys.

Subpart B—Inclusion in the GLOBE Model

§ 513.100 GLOBE Model participants.

(a) *GLOBE Model participants.* The GLOBE Model requires participation by all manufacturers of GLOBE Model drugs.

(b) *GLOBE Model participant requirements during the GLOBE Model performance period.* During the GLOBE Model performance period described in 42 CFR 513.1(c), GLOBE Model participants must do all of the following:

(1) Adhere to the GLOBE Model rebate invoicing and payment instructions in subpart H of this part and as established by CMS and its contractors responsible for providing GLOBE Model rebate reports and invoices, and processing GLOBE Model rebates, including without limitation those described in 42 CFR 513.500, to ensure appropriate and accurate GLOBE Model rebate payments.

(2) Participate in GLOBE Model monitoring and evaluation activities in accordance with 42 CFR 403.1110(b), including collecting and reporting of ''protected health information'' as the Secretary determines is necessary to monitor and evaluate the GLOBE Model.

(3) If electing to submit international drug net pricing data, adhere to the requirements set forth in 42 CFR 513.610 and the GLOBE Model data agreement (42 CFR 513.620).

(c) *GLOBE Model participant requirements prior to performance period 1.* If electing to submit international drug net pricing data for the applicable ASP calendar quarter beginning April 1, 2025, a GLOBE Model participant must adhere to the requirements set forth in 42 CFR 513.610 and the GLOBE Model data agreement (42 CFR 513.620).

(d) *GLOBE Model participant audit, record access, and record retention requirements and model termination.*

(1) *Right to audit.* The Federal Government, including CMS, HHS, and the Comptroller General, or their designees, has the right to audit, inspect, investigate, and evaluate any documents and other evidence regarding implementation of the GLOBE Model.

(2) *Access to records.* The GLOBE manufacturer must maintain and give the Federal government, including CMS, HHS, and the Comptroller General, or their designees, access to all such documents and other sufficient

evidence to enable the audit, evaluation, inspection, or investigation of the implementation of the GLOBE Model, including without limitation, documents and other evidence regarding all the following:

(i) The accuracy of voluntarily submitted data reported to CMS as set forth in 42 CFR 513.610 for the GLOBE Model.

(ii) Other CMS-identified program integrity issues.

(3) *Record retention.* The GLOBE manufacturer must maintain the documents and other evidence described in paragraph (d)(2) of this section for a period of 6 years from the last GLOBE Model rebate payment for the GLOBE manufacturer under the GLOBE Model or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless—

(i) CMS determines that there is a special need to retain a particular record or group of records for a longer period and notifies the manufacturer at least 30 days before the normal disposition date; or

(ii) There has been a termination, dispute, or allegation of fraud or similar fault against the manufacturer in which case the records must be maintained for an additional 6 years from the date of any resulting final resolution of the termination, dispute, or allegation of fraud or similar fault.

(4) *Termination of the GLOBE Model.*

(i) CMS may terminate the GLOBE Model for reasons including, but not limited to, the following:

(A) CMS determines that it no longer has the funds to support the GLOBE Model.

(B) CMS terminates the model in accordance with section 1115A(b)(3)(B) of the Act.

(ii) If CMS terminates the GLOBE Model, CMS provides written notice to the model participants specifying the grounds for model termination and the effective date of the termination.

(iii) As specified in section 1115A(d)(2) of the Act, termination of the model in accordance with section 1115A(b)(3)(B) of the Act is not subject to administrative or judicial review.

§ 513.110 GLOBE Model geographic areas.

(a) *Identification of GLOBE Model geographic areas.*

The GLOBE Model geographic areas are identified by ZIP Codes in the United States, excluding U.S. territories that are aligned with ZCTAs that are randomly selected by CMS no later than 60 calendar days prior to the start of the model performance period. During the model performance period, if a ZIP Code that is within the GLOBE Model geographic areas is split or redesignated, the new ZIP Code is not get reassigned to a GLOBE Model geographic area.

(b) *Selection process.* (1) The identified geographic areas are selected randomly based on the total Medicare population and expenditures, including Part B drug expenditures balanced on Medicare beneficiary population and Medicare expenditures nationwide.

(2) The identified GLOBE Model geographic areas must include ZIP Codes where approximately 25 percent of Medicare Part B FFS beneficiaries have an address of record as set forth in 42 CFR 513.120.

(c) No later than 30 calendar days in advance of model start, CMS provides a table on the GLOBE Model website that lists the GLOBE model geographic areas by ZIP code.

§ 513.120 Identification of GLOBE Model beneficiaries and comparison group.

(a) *General.* (1) The identification of GLOBE Model eligible beneficiaries and the comparison group is performed solely by CMS at certain points in time as determined by CMS and is not subject to review.

(2) CMS determines when the list of GLOBE Model eligible beneficiaries is created and updated, and the Medicare claims processing systems are updated with the most recent list of GLOBE Model eligible beneficiaries, the timing of such updates is not subject to review.

(3) For purposes of identifying a beneficiary's address in paragraph (b), CMS uses the beneficiary's address as recorded in CMS's Medicare Beneficiary Database (MBD), System No. 09–70–0536, as determined by CMS.

(b) *Initial assignment of beneficiaries as eligible for the Model cohort or comparison group.* Subject to paragraph (d) of this section, approximately 30 days prior to model start using available Medicare program administrative information as determined by CMS, CMS—

(1) Identifies the Medicare beneficiaries who are enrolled in Medicare Part B, have Traditional Medicare Part B as their primary payer, and have an address of record within the GLOBE Model geographic areas selected for inclusion in the model at model start (as identified by CMS under 42 CFR 513.110(c)), and adds such beneficiaries to the GLOBE Model Eligible Beneficiary List.

(2) Identifies Medicare beneficiaries who are enrolled in Medicare Part B, have Traditional Medicare Part B as their primary payer, and do not have an address of record within the GLOBE Model geographic areas selected for inclusion in the model, and assigns such beneficiaries as eligible for the comparison group.

(c) *GLOBE Model Eligible Beneficiary List Updates.* Subject to paragraph (d) of this section, periodically (not more frequently than weekly), using available Medicare program administrative information as determined by CMS, CMS identifies the Medicare beneficiaries—

(1) Who are enrolled in Medicare Part B, have Traditional Medicare Part B as their primary payer, and have an address of record within the GLOBE Model geographic areas selected for inclusion (as identified by CMS under 42 CFR 513.110(c)), are not yet included on the GLOBE Model Eligible Beneficiary List, and are not assigned as eligible for the comparison group. CMS adds such beneficiaries to the GLOBE Model Eligible Beneficiary List at the next cohort update; and

(2) On the GLOBE Model Eligible Beneficiary List who no longer meet the criteria for a GLOBE Model eligible beneficiary and removes such beneficiaries from the GLOBE Model Eligible Beneficiary List at the next update.

(d) *Beneficiary exclusions.* Subject to paragraph (d)(3) of this section, the following are not eligible for assignment to the GLOBE Model Eligible Beneficiary List or comparison group:

(1) Beneficiaries who do not have Medicare Part B FFS as their primary payer; and

(2) Beneficiaries who are enrolled in a MA plan, section 1876 cost plan, section 1833 healthcare prepayment plans, or who have other group health coverage that is a primary payer (such as employer-sponsored health insurance).

(3) Beneficiaries who are identified by CMS as eligible for inclusion in the comparison group prior to model start remain eligible for the comparison group as determined by CMS.

(e) *GLOBE Model Beneficiaries.* GLOBE Model eligible beneficiaries who are furnished a GLOBE Model drug during the model performance period for which separate payment is made are GLOBE Model beneficiaries as determined by CMS.

§ 513.130 GLOBE Model drugs and excluded drugs.

(a) [Reserved.]

(b) *GLOBE Model drugs.* GLOBE Model drugs include Part B rebatable drugs (as identified by the applicable billing and payment code) in accordance with 42 CFR 427.101(a)(1)(ii) of this chapter that meet the following criteria:

(1) Drugs or biological products listed as antigout agents, antineoplastics, blood products and modifiers, central nervous system agents, immunological agents, metabolic bone disease agents, or ophthalmic agents as specified in the United States Pharmacopeia Drug Classification (USP DC) category.

(i) CMS identifies drugs or biological products that are Part B rebatable drugs at the start of the GLOBE Model as antigout agents, antineoplastics, blood products and modifiers, central nervous system agents, immunological agents, metabolic bone disease agents, or ophthalmic agents using the United States Pharmacopeia Drug Classification published in 2025 (USP DC 2025).

(ii) CMS identifies drugs or biological products that were not Part B rebatable drugs at the start of the GLOBE Model, but subsequently become Part B rebatable drugs, as antigout agents, antineoplastics, blood products and modifiers, central nervous system agents, immunological agents, metabolic bone disease agents, or ophthalmic agents identified using the latest, publicly available United States Pharmacopeia Drug Classification to identify their category.

(iii) CMS adds new USP DC categories that stem from the USP DC categories listed in § 513.130(b)(1) to the GLOBE Model inclusion criteria. CMS may make this determination based on a review of USP revision bulletins, revision histories, and corresponding change log information published by USP.

(2) Single source drugs or sole source biological products.

(3) Drug or biological products with total Medicare Part B FFS allowed charges greater than $100 million over a 12-month period (as determined by CMS under paragraph (d) of this section) ending 6 months prior to the start of the applicable calendar quarter.

(i) This criterion is met if the drug or biological product meets this requirement (as determined by CMS under paragraph (d) of this section) at least one time during the duration of the GLOBE Model. If the drug or biological product meets this criterion for an applicable calendar quarter it continues to meet this criterion for subsequent applicable calendar quarters even if the Medicare Part B FFS allowed charges falls below $100 million over a 12-month period ending 6 months prior to the start of the subsequent applicable calendar quarters.

(4) Drug or biological products that are not excluded from the GLOBE Model under paragraph (c) of this section.

(c) *Exclusions.* (1) The following are excluded from the GLOBE Model:

(i) A Part B rebatable drug for applicable calendar quarters prior to the first applicable calendar quarter for which CMS identifies a specified amount under 42 CFR 427.302(b).

(ii) A Part B rebatable drug for which a maximum fair price under the Medicare Drug Price Negotiation Program is in effect.

(iii) A drug or biological product that is no longer a Part B rebatable drug during the duration of the GLOBE Model is removed for the applicable calendar quarter in which it is no longer a Part B rebatable drug.

(d) *Medicare Part B FFS allowed charges.* For a GLOBE Model drug for an applicable calendar quarter, CMS calculates the total Medicare Part B FFS allowed charges for a consecutive 12-month period ending 6 months prior to the start of the applicable calendar quarter as follows:

(1) CMS identifies the Medicare Part B FFS final action claims with dates of service within the consecutive 12-month period ending 6 months prior to the start of the applicable calendar quarter that have separately payable allowed charges greater than $0 for any billing and payment code used to describe the GLOBE Model drug.

(2) For the claims identified in paragraph (d)(1) of this section, CMS sums the allowed charges.

(e) *GLOBE Model Drug HCPCS Level II Codes List.* (1) Subject to paragraph (d)(2) of this section, prior to an applicable calendar quarter, CMS creates the GLOBE Model Drug HCPCS Level II Codes List for that applicable calendar quarter as follows:

(i) CMS adds all separately payable HCPCS Level II codes for a GLOBE Model drug identified in accordance with paragraphs (b) and (c) of this section to the GLOBE Model Drug HCPCS Level II Codes List for that applicable calendar quarter.

(ii) CMS identifies a United States Pharmacopeia Drug Classification Category for each HCPCS Level II code.

(A) HCPCS Level II codes included in the initial GLOBE Model Drug HCPCS Level II Codes List retain their USP DC category for the entire model duration.

(B) New HCPCS Level II codes that were not in the previously published GLOBE Model Drug HCPCS Level II Codes List is assigned a United States Pharmacopeia Drug Classification category at the time of identification of the new HCPCS Level II codes for a GLOBE Model drug, based on the United States Pharmacopeia Drug Classification available then. After identification, the new HCPCS Level II codes retain their category for the remainder of the model duration.

(2) *Revisions.* As applicable, CMS revises the GLOBE Model Drug HCPCS Level II Codes List for an applicable calendar quarter to correct errors as determined by CMS.

(3) *Publication.* CMS makes the GLOBE Model Drug HCPCS Level II Codes List for an applicable calendar quarter available on the CMS GLOBE Model website.

Subpart C—Coinsurance Adjustment and Adjusted Medicare Payment for GLOBE Model Drugs

§ 513.200 Definitions.

As used in this subpart, the following definitions apply:

GLOBE Model beneficiary coinsurance percentage means the applicable coinsurance percentage as determined under this subpart.

Per unit GLOBE Model benchmark amount means the sum of the product of the per unit GLOBE Model benchmark as set forth in 42 CFR 513.400, the applicable threshold percentage, and the add-on percentage amount as set forth in 42 CFR 513.400(c).

§ 513.210 Computation of GLOBE Model beneficiary coinsurance adjustment and adjusted Medicare payment for GLOBE Model drugs.

(a) *General.* CMS uses the methodology set forth in this section to calculate the GLOBE Model beneficiary coinsurance, the GLOBE Model beneficiary coinsurance percentage and associated adjusted Medicare payment for GLOBE Model drugs.

(b) *Calculation of GLOBE Model beneficiary coinsurance adjustment.* To calculate and determine if the GLOBE Model beneficiary coinsurance adjustment applies for separately payable units of GLOBE Model drugs furnished to a GLOBE Model beneficiary with respect to an applicable calendar quarter, CMS compares the payment amount as set forth in 42 CFR 427.201(b)(3) to the per unit GLOBE Model benchmark amount as set forth in 42 CFR 513.400.

(1) If the payment amount exceeds the per unit GLOBE Model benchmark amount, the GLOBE Model beneficiary coinsurance adjustment applies and the GLOBE Model beneficiary coinsurance is calculated by multiplying the per unit GLOBE Model benchmark amount by 0.20. In such case, the GLOBE Model beneficiary coinsurance is applied as a percent to the payment amount and the GLOBE Model beneficiary coinsurance percentage is calculated by dividing the GLOBE Model beneficiary coinsurance

by the payment amount and rounding to the third decimal place.

(2) If the payment amount does not exceed the per unit GLOBE Model benchmark amount, the adjustment to the beneficiary coinsurance set forth in paragraph (b)(1) of this section is not applied. In such case, the GLOBE Model beneficiary coinsurance is the coinsurance amount computed as set forth in 42 CFR 419.41(e) or 42 CFR 489.30(b)(1) as applicable.

(c) *Identification of the adjusted Medicare payment amount.* When the GLOBE Model beneficiary coinsurance adjustment applies, CMS calculates the adjusted Medicare payment amount for a GLOBE Model drug for an applicable calendar quarter as follows.

(1) *Calculation of the adjusted Medicare payment amount.* The product of the allowed amount multiplied by the GLOBE Model beneficiary coinsurance percentage is subtracted from the allowed amount. Subject to paragraph (c)(2) of this section, the result equals the adjusted Medicare payment amount.

(2*) Limitation.* The adjusted Medicare payment amount is subject to other claims adjustments and the Part B deductible.

(d) *Exclusions.* Any Part B rebatable drug that is excluded from the GLOBE Model for an applicable calendar quarter is not subject to the GLOBE Model beneficiary coinsurance adjustment set forth in paragraph (b) of this section and the adjusted Medicare payment amount set forth in paragraph (c) of this section.

Subpart D—GLOBE Model Data Sources

§ 513.300 Definitions

As used in this subpart, the following definitions apply:

Real GDP per capita means, for a country, the total gross domestic product based on purchasing power parity (PPP) divided by the total population for the same year as estimated and available in the U.S. Central Intelligence Agency (CIA) World Factbook.

Annual real GDP means, for a country, the total gross domestic product based on purchasing power parity (PPP) for a given year as estimated and available in the U.S. Central Intelligence Agency (CIA) World Factbook.

§ 513.310 Included international data.

(a) *General.* CMS uses international drug pricing information from data sources, available to CMS at least 60 business days prior to the start of an applicable calendar quarter, meeting the requirements in paragraphs (c) and (d) of this section, for countries in the set of reference countries identified in paragraph (b) of this section.

(b) *Set of reference countries.*

(1) Subject to paragraph (b)(6) of this section, CMS uses available international drug pricing information for countries that were non-U.S. OECD member countries as of October 1, 2025 with a real GDP per capita that is at least 60 percent of the U.S. real GDP per capita and an annual real GDP of at least $400 billion, as determined by CMS in accordance with this paragraph (b).

(2) Subject to the limitation specified in paragraph (b)(4) of this section, the real GDP per capita for a country is the most recent estimate of real GDP per capita based on purchasing power parity for that country for the year 2024 using data available in the U.S. Central Intelligence Agency (CIA) World Factbook as of October 1, 2025.

(3) Subject to the limitation specified in paragraph (b)(4) of this section, the annual real GDP for a country is the most recent estimate of annual real GDP based on purchasing power parity for that country for the year 2024 available in the U.S. Central Intelligence Agency (CIA) World Factbook as of October 1, 2025.

(4) The country's real GDP per capita and annual real GDP, and the U.S. real GDP per capita selected from the CIA World Factbook must be for the same calendar year and for the year 2024.

(5) CMS identifies countries with a real GDP per capita that is at least 60 percent of the U.S. GDP per capita by dividing the real GDP per capita for a country by the U.S. real GDP per capita and assessing the results.

(6) CMS identifies the set of reference countries for the GLOBE Model performance period prior to the start of performance year 1 using the U.S. CIA World Factbook data as available on October 1, 2025. The set of reference countries includes all of the following:

(i)Australia.
(ii) Austria.
(iii) Belgium.
(iv) Canada.
(v) Czechia.
(vi) Denmark.
(vii) France.
(viii) Germany.
(ix) Ireland.
(x) Israel.
(xi) Italy.
(xii) Japan.
(xiii) Netherlands.
(xiv) Norway.
(xv) South Korea.
(xvi) Spain.
(xvii) Sweden.
(xviii) Switzerland.
(xix) The United Kingdom.

(c) *Identification of available international data* sources *used to identify the per unit Method I GLOBE Model benchmark.*

(1) *General.* For purposes of selecting a data source for each GLOBE Model drug for an applicable calendar quarter for a reference country, CMS identifies available international drug pricing information data sources for the GLOBE Model drug, by aligning the GLOBE Model drug's assigned HCPCS Level II code long description (including dosage form) with the data sources' standardized method for identifying scientific names or nonproprietary names, dosage form, route of administration, other details within the billing and payment code long description, as applicable.

(i) CMS obtains data from one or more international drug pricing information data sources for purposes of identifying available international drug pricing information for the countries specified in paragraph (b) of this section.

(ii) The data sources must, as determined by CMS use a standardized method for identifying all of the following:

(A) Drugs across countries within that data source, such as using internationally recognized scientific and nonproprietary product names.

(B) Dosage form and route of administration across countries within the data source that at a minimum distinguishes among injectable, oral, and other forms of a drug, and other details within the billing and payment code long description, as applicable, such as using an internationally recognized nomenclature for pharmaceutical forms like the New Form Code classification

(C) Strength or concentration across countries within that data source, and they are expressed in internationally recognized measures such as milligrams or milliliters.

(D) U.S. originator drug, international originator drug, non-originator U.S. drug, and non-originator international drug using a drug's regulatory approval pathway across countries within that data source, that at a minimum distinguishes international generics and international biosimilar biological products

(iv) Contain at a minimum one of the following international drug pricing data information and utilizes a standard method across countries, including the following:

(A) List prices across countries within the data source (expressed in U.S. currency) and its corresponding volume, meaning quantity of units (for example,

number of items, packages or units sold).

(B) Sales data, which may be based on ex-manufacturer prices (sometimes called ex-factory prices) that represent actual or calculated prices paid to the manufacturer by wholesalers and other distributors across countries within the data source (expressed in U.S. currency) and its corresponding volume, meaning quantity of units (for example, number of items, packages or units sold).

(C) Retail prices that represent actual or calculated sales for retail purchasers, or prices paid by other purchasers in the distribution channels across countries within the data source (expressed in U.S. currency and its corresponding volume data, meaning quantity of units (for example, number of items, packages or units sold).

(D) List prices across countries within the data source (expressed in U.S. currency).

(E) Sales data, which may be based on ex-manufacturer prices (sometimes called ex-factory prices) that represent actual or calculated prices paid to the manufacturer by wholesalers and other distributors across countries within the data source (expressed in U.S. currency).

(F) Retail prices that represent actual or calculated sales for retail purchasers, or prices paid by other purchasers in the distribution channels across countries within the data source (expressed in U.S. currency).

(v) Have mechanisms in place to maintain, update, validate, and correct, if necessary, the information on international drug pricing in the data source on at least a quarterly basis.

(vi) Be maintained by an organization that seeks to limit the lag inherent in data to no more than 90 days from the end of the calendar quarter for which drug pricing information is compiled to the time that the organization makes updates available to users of the data source.

(2) *Selection of data source.* Subject to paragraphs (c)(1) and (c)(3) of this section, for each GLOBE Model drug for an applicable calendar quarter, CMS selects a data source using the following hierarchy and uses this data source, if available, to identify the per unit Method I GLOBE Model benchmark as described in 42 CFR 513.400(b).

(i) The data source contains drug specific sales and volume data for the applicable ASP calendar quarter from at least one country described in paragraph (b) of this section.

(ii) Except as noted in paragraph (c)(2)(iii) of this section, the data source does not have drug specific sales and volume data for the applicable ASP calendar quarter, but contains drug specific sales and volume data for any prior ASP calendar quarter beginning on or after April 1, 2025 from at least one country described in paragraph (b) of this section. If sales and volume data from a prior ASP calendar quarter are used, CMS uses sales and volume data from the most recent ASP calendar quarter for which both sales and volume data are available.

(iii) The extracted data used by CMS to identify the most recent per unit Method I GLOBE Model benchmark available in a document posted on the GLOBE Model website, including extracted data with drug specific sales and volume data from January 1, 2024 to December 31, 2024 from at least one country described in paragraph (b) of this section.

(iv) The data source contains drug specific ex-manufacturer price data for the applicable ASP calendar quarter from at least one country described in paragraph (b) of this section.

(v) The data source contains drug specific list price data (for example, the price made available to wholesalers) for the applicable ASP calendar quarter from at least one country described in paragraph (b) of this section.

(3) If there is more than one data source for a GLOBE Model drug, CMS selects the data source at the highest level of the hierarchy that contains information from the highest number of countries described in paragraph (b) of this section and, if available, incorporates discounts, rebates, and other price concessions into its drug pricing information. CMS does not use more than one data source for a GLOBE drug across countries.

(d) *Identification of available manufacturer-submitted international net pricing information used to identify the per unit Method II GLOBE Model benchmark.*

(1) *General.* Subject to 42 CFR 513.610 and the GLOBE Model data agreement (42 CFR 513.620), for each GLOBE Model drug for an applicable calendar quarter as set forth in 42 CFR 513.20, CMS assesses manufacturer-submitted international net pricing information for the applicable ASP calendar quarter that was accepted in accordance with 42 CFR 513.610.

(2) *Determining availability of international net pricing information.* For purposes of identifying available manufacturer-submitted international drug pricing information for the countries specified in paragraph (b) of this section for a GLOBE Model drug for an applicable calendar quarter, CMS uses the following steps:

(i) CMS identifies the accepted manufacturer-submitted international net pricing information for the applicable ASP calendar quarter (as set forth in 42 CFR 513.20) that aligns with a GLOBE Model drug's HCPCS Level II code long descriptor (including scientific or nonproprietary name, dosage form, route of administration (if applicable), and other details within the billing and payment code long description), as determined by CMS.

(ii) When there is accepted international net pricing information (or, if applicable, an attestation stating that there was no reportable international net pricing information) from each eligible manufacturer of the GLOBE Model drug, using the accepted international net pricing information identified in paragraph (d)(2)(ii)(A) of this section, CMS identifies presentation level information that includes, as determined by CMS—

(A) Complete international drug product information that is consistent with the reported total quantity of drug in the pack size;

(B) International net pricing and sales data for at least one of the countries specified in paragraph (b) of this section; and

(C) The presentation level information is not for an international generic or international biosimilar biological product (as applicable for data for a country).

(iii) CMS deems the presentation level information to be complete and valid per 42 CFR 513.610.

(3) *Limitation.* If CMS determines that manufacturer-submitted international drug pricing information is not complete and valid per 42 CFR 513.610, then the presentation level information is not available for purposes of 42 CFR 513.520.

Subpart E—Determination of the Per Unit GLOBE Benchmark Amount

§ 513.400 Identification of the per unit GLOBE Model benchmark amount.

(a) *General.* The result of calculations in this subpart E are rounded to the fifth decimal place except for the calculation in paragraph (c)(4) which are rounded to the third decimal place.

(b) *Identification of the per unit GLOBE Model benchmark.* Subject to available information as determined by CMS and paragraph (b)(3), for each applicable calendar quarter, CMS identifies and designates the greater of the following as the per unit GLOBE Model benchmark:

(1) The per unit Method I GLOBE Model benchmark (as determined in 42 CFR 513.410).

(2) The per unit Method II GLOBE Model benchmark (as determined in 42 CFR 513.420), as available, as the per unit GLOBE Model benchmark for a GLOBE Model drug for the applicable calendar quarter.

(3) *Limitation.* If CMS determines that neither a per unit Method I GLOBE Model benchmark nor a per unit Method II GLOBE Model benchmark is available, CMS identifies that the per unit GLOBE Model benchmark for the GLOBE Model drug for the applicable calendar quarter is not available.

(c) *Calculation of the per unit GLOBE Model benchmark amount. F*or each applicable calendar quarter, for a GLOBE Model drug, when a per unit GLOBE Model benchmark is available as set forth in paragraph (b), CMS calculates the per unit GLOBE Model benchmark amount as follows:

(1) CMS multiplies the per unit GLOBE Model benchmark by the applicable threshold percentage as set forth in 42 CFR 513.400(d).

(2) CMS calculates add-on percentage amount which is the dollar value of the add-on percentage included in the Medicare Part B payment limit for the HCPCS Level II code for the GLOBE Model drug as specified under section 1847A(b) of the Act for the applicable calendar quarter. In general, the Medicare Part B payment limit is equal to the specified amount (as defined at 42 CFR 427.302(b).

(3) CMS sums the amounts calculated in paragraphs (c)(1) and (c)(2) of this section.

(4) CMS rounds the amount calculated in paragraph (c)(3) of this section to the third decimal place and identifies this amount as the per unit GLOBE Model benchmark amount.

(d) *Applicable threshold percentage.* When the per unit GLOBE Model benchmark is based on the per unit Method I GLOBE Model benchmark, the applicable threshold percentage is 102 percent. When the per unit GLOBE Model benchmark is based on the per unit Method II GLOBE Model benchmark, the applicable threshold percentage is 105 percent.

§ 513.410 Identification of the per unit Method I GLOBE Model benchmark.

For each GLOBE Model drug, CMS identifies the per unit Method I GLOBE Model benchmark by identifying the lowest per unit GDP (PPP) adjusted country-level price using available international drug pricing information from available data sources, in accordance with 42 CFR 513.310, as determined by CMS, and the methodology described in this section.

(a) *Per unit country-level price.* CMS identifies the per unit country-level price for each country specified in 42 CFR 513.310(b), as available, using the following steps:

(1) *Identify available international drug pricing data.* By country, using the data source selected in accordance with 42 CFR 513.310(c)(2), CMS identifies available international drug pricing data for the GLOBE Model drug, for the applicable ASP calendar quarter for the first applicable calendar quarter that the drug is a GLOBE Model drug, by aligning the GLOBE Model drug's HCPCS Level II code long description (including scientific or nonproprietary name, dosage form, route of administration (if applicable), and other details within the billing and payment code long description, as applicable) with the data sources' standardized method for identifying scientific names or nonproprietary names, dosage form, and route of administration (if applicable), as applicable. CMS extracts available drug pricing data for the countries specified in 42 CFR 513.310(b) from the selected international drug pricing information data sources that, as determined by CMS—

(i) Represent the price of a U.S. originator drug or international originator drug (as applicable for data for a country);

(ii) Have complete package size information;

(iii) Represent scientific or nonproprietary name and dosage form and include route of administration (if applicable), that could be described by the GLOBE Model drug's HCPCS Level II code descriptor; and

(iv) Have strength data.

(2) *Apply data checks.* As determined by CMS, CMS applies the following steps as applicable:

(i) Identify and discard extracted data as follows:

(A) When international drug pricing information with sales and volume data are available, CMS excludes international drug pricing data without both sales and volume data that are greater than zero.

(B) [Reserved.]

(ii) When the product information (for example, product strength or package size) is inconsistent or not verifiable with available product information such as product labeling or product approval information for the GLOBE Model drug's HCPCS Level II code descriptor.

(3) *Convert volume data to unit of measurement delineated in the HCPCS Level II Code descriptor.* CMS converts the volume data to the unit of measurement delineated in the GLOBE Model drug's HCPCS Code Level II descriptor, as applicable.

(i) CMS adjusts the volume data, as applicable, before converting the volume data unit of measurement delineated in the GLOBE Model drug's HCPCS Level II code descriptor when the data source shows the package size or a presentation level (dosage form or route of administration (if applicable)) that is inconsistent with the manufacturer's information about that product for the GLOBE Model drug's HCPCS Level II code descriptor, as determined by CMS.

(ii) CMS limits the number of HCPCS billing units when—

(A) The available information (such as package labeling) indicates a limited quantity of drug is to be used from the presentation level; and

(B) The HCPCS dosage is per dose.

(4) *Calculate the per unit country-level price for the GLOBE Model drug by country.* Using the international drug pricing information extracted and adjusted in accordance with paragraphs (3)(i) and (3)(ii) of this section, respectively, CMS calculates the per unit country-level price for the international drug by country for each country specified in 42 CFR 513.310(b) for which international drug pricing information is available, using the calculation that is applicable.

(i) If an international drug pricing information data source with sales and volume data is used, the applicable calculation is as follows:

(A) CMS removes pricing information at the dosage form and strength level for a country that falls below 5 percent of the average price in the U.S. as set forth in paragraph (d) of this section.

(B) Using remaining data, CMS sums the adjusted volume data (as specified in paragraph (3) of this section) for the presentation levels of the applicable international analog (as specified in 42 CFR 513.600).

(C) Using remaining data, CMS sums the total sales for the presentation levels for the applicable international analog (as specified in 42 CFR 513.600) (that remain after performing the data checks).

(D) CMS divides the sum determined in paragraph (a)(4)(i)(C) of this section by the sum determined in paragraph (a)(4)(i)(B) of this section, resulting in an average price per unit, where the unit is the same unit delineated in the HCPCS Level II code descriptor.

(ii) If an international drug pricing information data source with ex-manufacturer or list prices is used, the applicable calculation is as follows:

(A) For each extracted ex-manufacturer or list price, CMS

calculates the number of HCPCS billing units in the presentation level by dividing the quantity of drug in the presentation level by the quantity of drug represented in the HCPCS dosage from the HCPCS Level II code descriptor.

(B) CMS divides the ex-manufacturer or list price, as applicable, by the number of HCPCS billing units in the presentation level (as calculated in paragraph (a)(4)(ii)(A) of this section), resulting in a price per unit where the unit is the same unit delineated in the HCPCS Level II code descriptor.

(C) CMS removes pricing information at the dosage form and strength level for a country that falls below 5 percent of the average price in the U.S. as set forth in paragraph (d) of this section.

(D) CMS calculates the sum of the price per (as calculated in paragraph (a)(4)(ii) (B) of this section) for each ex-manufacturer or list price that was identified as available as set forth in paragraph (a)(1) of this section and not removed as set forth in paragraph (a)(4)(ii)(B) of this section.

(E) CMS divides the sum calculated in paragraph (a)(4)(ii)(D) of this section by the number of ex-manufacturer or list prices that were identified as available as set forth in paragraph (a)(1) of this section and not removed as set forth in paragraph (a)(4)(ii)(C) of this section, resulting in an average price per unit where the unit is the same unit delineated in the HCPCS Level II code descriptor.

(iii) CMS performs the applicable calculation for each country specified in 42 CFR 513.310(b) for which international drug pricing information is available in the selected data source.

(b) *Per unit GDP (PPP) adjusted country-level price for the GLOBE Model drug by country.* CMS applies the applicable GDP (PPP) adjuster for the applicable ASP calendar quarter as identified 42 CFR 513.430 to each per unit country-level price identified as set forth in paragraph (a)(4) of this section to calculate the per unit GDP (PPP) adjusted country-level price by multiplying each per unit country-level price by the applicable GDP (PPP) adjuster for such country and rounds the result at the fifth decimal place.

(c) *Per unit Method I GLOBE Model benchmark.* (1) CMS identifies the lowest per unit GDP (PPP) adjusted country-level price for the international drug calculated in paragraph (b) of this section to the third decimal place and identifies the result as the per unit Method I GLOBE Model benchmark.

(2) For each Part B rebatable drug that becomes a GLOBE Model drug during the model performance period, CMS identifies the per unit Method I GLOBE Model benchmark for the first applicable calendar quarter for which the drug is a GLOBE Model drug and this benchmark remains in place for each applicable calendar quarter thereafter until the end of the model performance period.

(d) *Average U.S. price.* (1) Subject to paragraph (d)(2), when there is international pricing information available as set forth in 42 CFR 513.410(a), CMS identifies the average U.S. drug price using the same pricing information from the selected data source used for the reference country for the applicable ASP calendar quarter.

(2) If the selected data source for the reference country does not contain available U.S. pricing information, to identify the average U.S. price CMS uses the most recently published Medicare Part B payment limit minus the add-on amount for the HCPCS Level II code for the GLOBE Model drug for the calendar quarter before the applicable ASP calendar quarter.

§ 513.420 Identification of the per unit Method II GLOBE Model benchmark.

For each applicable calendar quarter, when there is an applicable submission as set forth in 42 CFR 513.610(a) for a GLOBE Model drug, CMS identifies the per unit Method II GLOBE Model benchmark using available manufacturer-submitted international drug net pricing data for the applicable ASP calendar quarter, as identified by CMS in accordance with 42 CFR 513.20, and the methodology described in this section.

(a) *Identify available across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit in U.S. dollars.* For the GLOBE Model drug, within each applicable submission for the applicable calendar quarter, CMS identifies the across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit where, using the basic data elements, the scientific or nonproprietary name, dosage form, route of administration (if applicable), and other details within the billing and payment code long description, as applicable, align with the HCPCS Level II code long descriptor for the GLOBE Model drug.

(b) *Identify the per unit Method II GLOBE Model benchmark based on number of manufacturer submissions.* Subject to paragraph (c) of this section, CMS identifies the per unit Method II GLOBE Model benchmark using the applicable steps as follows:

(1) *When there is one manufacturer submission.* CMS identifies the across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit data element as the per unit Method II GLOBE Model benchmark for the applicable calendar quarter.

(2) *When there is more than one manufacturer submission.* CMS calculates a volume-weighted average using data across all of the applicable submissions using the following steps:

(i) Separately, for each applicable submission, CMS multiplies the across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit by the sum of the volume in billing units.

(ii) CMS sums the amounts calculated in paragraph (b)(2)(i) of this section.

(iii) CMS calculates the total volume by summing the billing units across all applicable submissions.

(iv) CMS divides the sum calculated in paragraph (b)(2)(ii) by the total volume calculated in paragraph (b)(2)(iii) of this section.

(v) The resulting volume-weighted average is rounded at the third decimal place and is identified as the per unit Method II GLOBE Model benchmark for the applicable calendar quarter.

(c) *Unavailable net pricing data.* When a manufacturer submission for an applicable calendar quarter as set forth in § 513.20 is either not accepted by CMS as set forth in § 513.610 or was not submitted by all manufacturers of the GLOBE Model drug, CMS identifies that the per unit Method II GLOBE Model benchmark is unavailable for such applicable calendar quarter.

§ 513.430 Calculation of the GDP (PPP) adjuster.

(a) *GDP (PPP) adjuster formula.* Subject to paragraphs (b), (c), and (d) of this section, for a country, CMS calculates the GDP (PPP) adjuster by dividing the U.S. GDP (PPP) per capita by the country's GDP (PPP) per capita and rounds the result at the third decimal place.

(b) *Data used.* Subject to the limitations specified in paragraphs (c) and (d) of this section, the GDP (PPP) per capita for a country is the most recent estimate of GDP per capita based on purchasing power parity for that country available in the CIA World Factbook at the start of the applicable ASP calendar quarter, as determined by CMS.

(c) *Limitations.* (1) The country's GDP (PPP) per capita and U.S. GDP (PPP) per capita must be for the same year.

(2) The GDP (PPP) per capita used must be for the same year as the data used to calculate the unadjusted per unit country-level price, if available, or the most recent earlier year available.

(d) *Maximum ratio.* In cases where the resulting ratio is less than 1.000, the GDP (PPP) adjuster is set to 1.000.

Subpart F—Determination of the total GLOBE Model Rebate Amount for GLOBE Model Drugs

§ 513.500 Calculation of the total GLOBE Model rebate amount and incremental GLOBE Model rebate amount due.

(a) *Total GLOBE Model rebate amount.* The total GLOBE Model rebate amount for a GLOBE Model drug for an applicable calendar quarter is equal to the product of the per unit GLOBE Model rebate amount of such drug, as determined under § 513.520(a), and the total number of GLOBE Model billing units, as identified by CMS as set forth in § 513.520.

(b) *Incremental GLOBE Model rebate amount.* The incremental GLOBE Model rebate amount for a GLOBE Model drug for an applicable calendar quarter is equal to the product of the incremental per unit GLOBE Model rebate amount of such drug, as determined under § 513.510(b), and the total number of GLOBE Model billing units, as identified by CMS as set forth in § 513.520.

(c) *Apportionment of the incremental GLOBE Model rebate amount.* When there is more than one manufacturer for a GLOBE Model drug for an applicable calendar quarter, CMS uses the proportion of manufacturer-reported ASP units as calculated by CMS in accordance with 42 CFR 427.301(b) or (c) and reported by CMS in the Rebate Reports specified in 42 CFR 427.501 for a manufacturer to apportion the incremental GLOBE Model rebate amount to such manufacturer.

(d) *Reducing the incremental GLOBE Model rebate amount for GLOBE Model drugs currently in shortage.* (1) For an applicable calendar quarter when the total rebate amount determined under 42 CFR 427.301(a) is reduced as specified in 42 CFR 427.401, the incremental GLOBE Model rebate amount calculated in paragraph (c) of this section, if any is owed, is reduced using the following formula:

Equation 1 to Paragraph (c)(1)

Reduced incremental GLOBE Model rebate amount = the incremental GLOBE Model rebate amount multiplied by (1 *minus* ''applicable percent reduction'' determined under 42 CFR 427.401(b)(2) multiplied by (''percentage of time drug was currently in shortage during the applicable calendar quarter'' as determined in accordance with 42 CFR 427.401(b)(3)) added to the incremental GLOBE Model rebate amount multiplied by (1 *minus* ''percentage of time drug was currently in shortage during the applicable calendar quarter'' as determined in accordance with 42 CFR 427.401(b)(3)).

(2) CMS applies a reduction of the incremental GLOBE Model rebate amount determined in paragraph (d)(1) of this section to all the NDCs under the relevant billing and payment code as specified in 42 CFR 427.401(c).

(e) *Reducing the incremental GLOBE Model rebate amount for GLOBE Model biosimilar biological products when there is a severe supply chain disruption.* When CMS reduces the total rebate amount determined under 42 CFR 427.301(a), if any is owed, for a Part B rebatable biosimilar biological product that is a GLOBE Model drug for an applicable quarter, CMS reduces the incremental GLOBE Model rebate amount determined in paragraph (c) of this section for such GLOBE Model drug, if any is owed, using the same percentage reduction that CMS applied under 42 CFR 427.402 for such GLOBE Model drug for the applicable calendar quarter.

(f) *Other considerations for calculating the total GLOBE Model rebate amount and the incremental GLOBE Model rebate amount.* The amounts calculated in paragraphs (a) through (e) of this section are rounded to the third decimal place.

§ 513.510 Calculation of the per unit GLOBE Model rebate amount and incremental per unit GLOBE Model rebate amount.

(a) *Calculate the per unit GLOBE Model rebate amount.* (1) Subject to paragraph (a)(2) of this section, to calculate the per unit GLOBE Model rebate amount for a GLOBE Model drug for an applicable calendar quarter, CMS identifies the greater of the amounts specified in paragraphs (a)(1)(i) and (ii) of this section and rounds that amount to the second decimal place.

(i) The difference between the specified amount (as determined under 42 CFR 427.302(b)) and the per unit GLOBE Model benchmark amount (as determined under 42 CFR 513.400(b)); or

(ii) The difference between the specified amount (as determined under 42 CFR 427.302(b)) and the inflation-adjusted payment amount (as determined under 42 CFR 427.302(g)).

(2) Limitations.

(i) When the per unit GLOBE Model benchmark amount is not available as determined by CMS as set forth in 42 CFR 513.400(b)(3), CMS identifies the per unit GLOBE Model rebate amount by calculating the difference between the specified amount (as determined under 42 CFR 427.302(b)) and the inflation-adjusted payment amount (as determined under 42 CFR 427.302(g)).

(ii) The per unit GLOBE Model rebate amount is set at $0 when the amount identified as set forth in paragraph (a) of this section is less than $0.

(b) *Calculate the incremental per unit GLOBE Model rebate amount.* (1) Subject to paragraph (b)(2) of this section, for a GLOBE drug for an applicable calendar quarter, CMS calculates the incremental per unit GLOBE Model rebate amount by subtracting the per unit Part B rebate amount calculated as set forth in 42 CFR 427.302(a) from the amount calculated as set forth in paragraph (a) of this section. The result is the incremental per unit GLOBE Model rebate amount for the GLOBE drug for an applicable calendar quarter.

(2) *Limitation.* The incremental per unit GLOBE Model rebate amount is set to $0 when the amount calculated in paragraph (b)(1) of this section is less than $0.

§ 513.520 Identification of the total number of GLOBE Model billing units.

(a) *General.* (1) CMS identifies the total number of billing units as set forth in 42 CFR 427.303, as determined by CMS, before identifying GLOBE Model billing units.

(b) *Identify GLOBE Model billing units.* For an applicable calendar quarter for each GLOBE Model drug, from the total number of billing units that CMS identified in accordance with 42 CFR 427.303(b), CMS identifies billing units where, on the date of service, the beneficiary was identified by CMS as a GLOBE Model eligible beneficiary and for which Medicare Part B FFS made separate payment.

(c) *Identify the total number of GLOBE Model billing units.* The sum of the billing units identified as set forth in paragraph (a) of this section equal the total number of GLOBE Model billing units for the GLOBE Model drug for the rebate quarter.

§ 513.530 Manufacturer payment responsibilities.

(a) *General.* For the purposes of the GLOBE Model, a manufacturer is defined in accordance with 42 CFR 427.20, in that the manufacturer has the meaning set forth in section 1847A(c)(6)(A) of the Act for a GLOBE Model drug as set forth in § 513.130.

(b) *Multiple manufacturers linked to a single HCPCS Level II code.* CMS apportions the total GLOBE Model rebate liability proportionally, based on each manufacturer's reported share of Medicare Part B units in that rebate quarter in accordance with § 513.500(c).

Subpart G—Manufacturer-Submitted International Net Pricing Information

§ 513.600 Definitions.

As used in this subpart, the following definitions apply:

Authorized representative means an individual, designated by a manufacturer, as responsible for submitting international drug net pricing data, and who is also responsible for managing all communications related to such submission on behalf of the manufacturer. The authorized representative must also be legally authorized to bind the manufacturer to the terms and conditions contained within the data agreement.

Applicable international analog means a non-US analog whose scientific or nonproprietary name, dosage form, and route of administration (if applicable) align with a GLOBE Model drug and that are sold in one or more reference countries during the applicable ASP calendar quarter, excluding those identified in their respective country as a generic or biosimilar biological product according to the country's own regulations.

Average net-to-gross ratio means for a reference country, the total net sales of the set of applicable international analogs in the reference country divided by the total gross sales of the same set of drugs in the same reference country.

Gross sales amount means for each sale the manufacturer made in that reference country to a purchaser, the amount of money owed to a manufacturer by the purchasers, before subtracting any discounts, rebates, or price concessions.

Non-U.S. country regulatory approval status means information relevant for CMS to determine whether each applicable international drug's regulatory approval status (according to the applicable reference country's regulatory framework) is an international generic (international non-originator drug), international biosimilar biological product (international non-originator drug), international originator drug, or other.

Net price level, with respect to sales of applicable international analogs, means all sales of the applicable international analogs in a reference country at the same price net of price concessions during the applicable ASP calendar quarter.

Net sales amount means for each sale the manufacturer made in that reference country to a purchaser, the amount of money owed by the purchaser exclusive of any price concessions. Each net sales amount has a corresponding sales volume in HCPCS billing units.

Price concession means the sum of the value of the following types of transactions and items whether at the time of sale or afterwards:

(1) Volume discounts: ''Volume discounts'' are also known as quantity discounts or bulk discounts where the price per unit is reduced when purchased in larger quantities.

(2) Prompt pay discounts: The term ''prompt pay discounts'', also known as early payment discounts, means any reduction in the total value of units purchased routinely offered to a purchaser when a payment is made within a specified timeframe and consistent with customary business practices for payment.

(3) Cash discounts: The term ''cash discounts'' refers to reductions on the price per unit when payment is made in cash. This may be facilitated through discount cards, coupons, or other agreements.

(4) Free goods include samples or other benefits provided to purchasers or patients that are contingent on any purchase requirement.

(5) Chargebacks: This term refers to retrospective payments made from manufacturers to purchasers.

(6) Rebates: This term refers to reimbursements made by a manufacturer to a wholesaler or other purchaser, for the difference between the price the wholesaler or other purchaser initially paid for the product and the lower price at which the wholesaler or other purchaser sold the product.

(7) Other price concessions that lower the amount realized by the manufacturer.

Purchaser means the entities or organizations acquiring the drug product for subsequent sale within the pharmaceutical supply chain or for administration or dispensing to a human. It may include, among others, wholesalers, distributors, hospitals, pharmacies, and other healthcare providers and practitioners.

Volume-weighted net price means exclusive of any price concessions, the volume-weighted reference country average net price in U.S. dollars where the weights are volumes in HCPCS billing units.

§ 513.610 Submission and acceptance of international net pricing information.

(a) *General.*

(1) *Timing of submission.* The submission must be received by CMS no later than 30 calendar days after the end of the applicable ASP calendar quarter for which the manufacturer is making the submission.

(2) *Scope of submission.* Manufacturers may make a submission for one or more GLOBE Model drug(s). For each GLOBE Model drug, the submission must include all applicable international analogs with sales in the reference countries identified in § 513.310 that occur during the applicable ASP calendar quarter for which they are making the submission. Manufacturers must ensure that any allocation and calculations are done in a manner consistent with the generally acceptable accounting principles (GAAP), international financial reporting standards (IFRS), or other internationally recognized accounting approaches.

(3) *Verification of manufacturer submissions.* CMS conducts a review of all submissions for completeness and validity, upon which CMS may request additional data or information before finalizing its review and making a determination of acceptability.

(i) *Completeness.* To be verified for completeness, the submission must include all basic data elements, including presentation level information, as described in paragraph (b) of this section and all net pricing data elements as described in paragraph (c) of this section, as well as fulfill the following requirements:

(A) Proper and full execution of the data agreement.

(B) Proper and full attestation by the manufacturer's authorized representative as described in paragraph (e) of this section.

(C) The submission was done using the proper portal and all security requirements within.

(D) The submission was executed in the manner and form required by CMS.

(E) The submission includes supporting documentation that explains how each of the elements of the submission were compiled or calculated and any reasonable assumptions that were applied.

(ii) *Validity.* CMS—

(A) Verifies the submitted international sales data and calculated pricing values are greater than zero and adhere to the data format requirements;

(B) Utilizes all available data sources and information to assess the extent to which the submission reflects international drug net pricing in the reference countries; and

(C) May choose to request additional supporting information or data or both from manufacturers before completing assessment of validity of the submission.

(*1*) Submission of additional supporting information or data or both is limited to no more than 5 days from

the agency's request for additional supporting information or data or both.

(*2*) [Reserved].

(4) *Applicable submission.* CMS will determine that a submission is an applicable submission only if the submission is both complete, has all the basic data elements under paragraph (b) of this section, has all of the net pricing data elements for one of the two options under paragraph (c) of this section, and is valid as determined by CMS in order for CMS to determine that it is an applicable submission.

(b) *Basic data elements required.*

(1) A submission must include all the following basic data elements, including presentation level information:

(i) GLOBE Model drug brand name, nonproprietary name, and HCPCS Level II code.

(ii) For every reference country where at least one applicable international analog was sold during the applicable ASP calendar quarter—

(A) Reference country name;

(B) For every applicable international analog sold in that country—

(*1*) Scientific or nonproprietary name;

(*2*) Brand name, all international drug names;

(*3*) Names of manufacturers, marketers, or licensees;

(*4*) Non-U.S. country regulatory approval status (international originator drug or international non-originator drug);

(*5*) Dosage form and route of administration (if applicable);

(*6*) Strength;

(*7*) Volume per item (for example, 10 ml in one vial);

(*8*) Package type (for example, syringe, vial, ampule, etc.);

(*9*) Number of items per package (for example, 10 vials in a package);

(*10*) HCPCS dosage (CMS published data which are the quantity of drug represented in one HCPCS billing unit); and

(*11*) Number of HCPCS billing units.

(*i*) HCPCS billings unit are calculated by dividing the quantity of drug in the package by the HCPCS dosage.

(*ii*) [Reserved.]

(2) If for any of the basic data elements, third-party individuals and organizations were relied upon to gather, analyze, or submit data, this must be specified for each element and the third-party individual or organization identified.

(c) *Net pricing data elements required.*

(1) A submission must exclude both the following:

(i) Sales for any international biosimilar biological products and international generic products and only have sales data for international originator drugs.

(ii) International drug price data without both sales and volume data greater than zero.

(2) A submission must include net pricing elements in complete fulfillment of one of the following net pricing data submission options:

(i) *Streamlined option.*

(A) For every reference country where at least one applicable international analog was sold during the applicable ASP calendar quarter corresponding to the submission—

(*1*) For every sale involving an applicable international analog aggregated at the net price level—

(*i*) Gross sales amount in the reference country currency and U.S. dollars rounded to 5 decimal places;

(*ii*) Net sales amount in the reference country currency and U.S. dollars rounded to 5 decimal places; and

(*iii*) Sales volume—in HCPCS billing units.

(*2*) Average net-to-gross ratio rounded to 5 decimal places for each reference country;

(*3*) The exchange rate for currency conversion from the local currency of the reference country to U.S. dollars for the applicable ASP calendar quarter corresponding to the submission—

(*i*) Comes from one of these exchange rate data sources and is rounded to 3 decimal places: World Bank Atlas, IMF exchange rates data, Federal Reserve Bank foreign exchange rates, or exchange rates from country-specific sources;

(*ii*) If the exchange rate data source uses an exchange rate frequency of less than annual, then the exchange rate is an average of exchange rates of the chosen frequency for the applicable ASP calendar quarter during which international sales occurred; and

(*iii*) The manufacturer applies the same exchange rate calculated in paragraph (c)(1)(i)(A)(*3*)(*ii*) of this section to all net pricing data in a reference country for the applicable ASP calendar quarter.

(iv) The manufacturer reports which exchange rate was used.

(*4*) Volume-weighted net price in U.S. dollars rounded to 5 decimal places for each reference country; and

(*5*) GDP (PPP) adjustment published by CMS at the beginning of each applicable calendar quarter.

(B) Across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit in U.S. dollars rounded to 3 decimal places across all the reference countries.

(ii) *Limited option.*

(A) For every reference country where at least one applicable international analog was sold during the applicable ASP calendar quarter corresponding to the submission—

(*1*) Total gross sales amount for each reference country in the reference country currency and U.S. dollars rounded to 5 decimal places;

(*2*) Total net sales amount for each reference country in the reference country currency and U.S. dollars rounded to 5 decimal places;

(*3*) Average net-to-gross ratio for each reference country;

(*4*) The exchange rate for currency conversion from the local currency of the reference country to U.S. dollars for the applicable ASP calendar quarter corresponding to the submission—

(i) Comes from one of these exchange rate data sources and is rounded to 3 decimal places: World Bank Atlas, IMF exchange rates data, Federal Reserve Bank foreign exchange rates, or exchange rates from country-specific sources;

(ii) If the exchange rate data source uses an exchange rate frequency of less than annual, then the exchange rate is an average of exchange rates of the chosen frequency for the applicable ASP calendar quarter during which international sales occurred; and

(iii) The manufacturer applies the same exchange rates calculated in paragraph (c)(1)(ii)(A)(*3*)(*ii*) of this section to all net pricing data in a reference country for the applicable ASP calendar quarter.

(iv) The manufacturer reports which exchange rate was used.

(5) Total sales volume—in HCPCS billing units—meaning the corresponding volume for the total net sales amount from paragraph (c)(1)(ii)(A)(*1*) of this section;

(6) Volume-weighted net price in U.S. dollars rounded to 5 decimal places for each reference country; and

(7) GDP (PPP) adjustment published by CMS at the beginning of each applicable calendar quarter.

(B) Across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit in U.S. dollars rounded to 3 decimal places.

(d) *Data integrity and quality assurance.* (1) *Corrections and restatements.* Submitting manufacturers may provide corrections and restatements of applicable submissions, provided such corrections and restatements are made in accordance with the requirements in paragraphs (a) through (c) of this section and are submitted within 30 calendar days of the submission deadline, or if responding to a CMS request, within 5 business days of such request.

(1) *Attestation requirements.* (i) Each submission must include an attestation by the authorized representative certifying the completeness and accuracy of the data submission on behalf of the manufacturer and any third-party entities relied upon for gathering, analyzing, or submitting the net pricing data elements.

(ii) The attestation requires the authorized representative to do all of the following:

(A) Provide contact information.

(B) Attest that the—

(*1*) Submission is accurate and complete to the best of the manufacturer's knowledge;

(*2*) Submission is prepared in full compliance with all requirements of this section; and

(*3*) Authorized representative has the authority to make such attestation on behalf of the manufacturer.

(e) *Confidentiality and data protections.* CMS maintains the confidentiality of information submitted under this section to the extent permitted by law and in accordance with applicable privacy and security requirements. Under an effectuated GLOBE Model data agreement, CMS would 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 § 513.210 and § 513.500 (Computation of GLOBE Model beneficiary coinsurance percentage, adjusted Medicare payment for GLOBE, and GLOBE Model rebate).

(f) *Submission platform and security requirements.* (1) The authorized representative must do all of the following:

(i) Gain access to the Health Plan Management System (HPMS).

(ii) Comply with all encryption and submission requirements established by CMS.

(iii) Submit using the appropriate system and in the manner and form as determined by CMS.

(2) CMS may designate a different CMS system for submission, if necessary.

§ 513.620 GLOBE Model data agreement.

(a) General.

(1) *Voluntary submission.* Manufacturers may elect to voluntarily submit manufacturer's international drug net pricing data, henceforth the submission, to CMS in accordance with the data requirements of paragraphs (b) in this section.

(2) *Use of the applicable submission.* CMS uses applicable submissions, determined in accordance to paragraph (b) in this section and § 513.610(b) and (c), to determine the per unit Method II GLOBE Model benchmark per § 513.420 for the applicable ASP calendar quarter corresponding to the submission.

(3) *Requirements for a voluntary submission option of net pricing data elements.* If a manufacturer elects to voluntarily submit manufacturer's international drug net pricing data, manufacturers—

(i) Select one submission option for net pricing data elements for all applicable international analogs to a GLOBE Model drug; and

(ii) Except where paragraph (a)(3)(iii) of this section applies, a manufacturer continues to submit manufacturer's voluntary international drug net pricing data for the duration of the GLOBE model so long as sales of applicable international analogs have occurred in the reference countries identified in 42 CFR 513.310(b) for the applicable ASP calendar quarter.

(iii) If a manufacturer chooses to no longer submit voluntary international net pricing data after the data agreement per paragraph (b) of this section is effective and CMS has determined sales of the applicable international analogs have occurred in the reference countries identified in 42 CFR 513.310(b) for the applicable ASP calendar quarter, CMS may terminate the data agreement. In accordance with paragraph (b) of this section, the manufacturer may also elect to terminate the data agreement.

(B) [Reserved.]

(b) *Data requirements.*

(1) *Data agreement.* Prior to the submission, the manufacturer must execute a data agreement with CMS that establishes the terms, conditions, and requirements related to the international drug net pricing data under this section. Once the data agreement is effective, it remains applicable for the duration of the GLOBE Model unless either the manufacturer or CMS terminates the agreement.

(2) [Reserved.]

Subpart H—Reports of Rebate Amounts, Reconciliation, Suggestion of Error, and Payments

§ 513.700 Definitions.

[Reserved]

§ 513.710 GLOBE Model Rebate Reports and reconciliation—Incremental Approach

(a) *General.* This section applies to GLOBE Model drugs, for all applicable calendar quarters during the model performance years.

(b) GLOBE Model *Preliminary Rebate Report.* CMS provides a GLOBE Model Preliminary Rebate report to each manufacturer of a GLOBE Model drug at least 1 month prior to the issuance of the GLOBE Model Rebate Report as set forth in paragraph (c) of this section for an applicable calendar quarter.

(1) The GLOBE Model Preliminary Rebate Report for each GLOBE Model drug includes the following information:

(i) The NDC(s) and billing and payment codes identified for the GLOBE Model drug as determined by CMS.

(ii) The total number of GLOBE Model billing units as set forth under 42 CFR 513.520.

(iii) The total number of billing units as determined under 42 CFR 427.303.

(iv) The per unit Method I GLOBE Model benchmark as identified under 42 CFR 513.410.

(v) The per unit Method II GLOBE Model benchmark, if available, as identified under 42 CFR 513.420.

(vi) The per unit GLOBE Model benchmark amount as set forth in 42 CFR 513.400.

(vii) The per unit GLOBE Model rebate amount as set forth in 42 CFR 513.520.

(viii) The incremental per unit GLOBE Model rebate amount as set forth in 42 CFR 513.520.

(ix) The applicable calendar quarter specified amount as determined under 42 CFR 427.302(b).

(x) The amount, if any, by which the specified amount as determined under 42 CFR 427.302(b) exceeds the inflation-adjusted payment amount as determined under 42 CFR 427.302(g) for the Part B rebatable drug for the applicable calendar quarter as set forth in 42 CFR 427.302.

(xi) The total GLOBE Model rebate amount as set forth in 42 CFR 513.500.

(xii) The incremental GLOBE Model rebate amount due as determined in 42 CFR 513.500(b).

(xiii) Any applied reductions as determined under 42 CFR 513 subpart F.

(xiv) The proportion of manufacturer-reported ASP units, if applicable.

(xv) The reduced incremental GLOBE Model rebate amount, if applicable.

(c) *GLOBE Model Rebate Report.* CMS provides a GLOBE Model Rebate Report to each manufacturer of a GLOBE Model drug no later than 8 months after the end of each applicable calendar quarter during a performance year.

(1) The GLOBE Model Rebate Report includes the information specified in paragraph (b) of this section, with the inclusion of any revisions to such information resulting from CMS' review of a Suggestion of Error as set forth in 42 CFR 513.730, if applicable, and any

CMS-determined recalculations from paragraph (d)(2) of this section.

(2) The GLOBE Model Rebate Report is the invoice of a manufacturer's total rebate amount due as determined under 42 CFR 513.510, if any, for a GLOBE Model drug for an applicable calendar quarter.

(3) The manufacturer's total rebate amount due is reported as a dollar amount rounded to the nearest cent.

(d) *Reconciliation of the incremental GLOBE Model rebate amount.* CMS performs reconciliation of the incremental GLOBE Model rebate amount provided in a GLOBE Model Rebate Report specified in paragraph (c) of this section for an applicable calendar quarter during a model performance year in the following circumstances:

(1) *Regular reconciliation.* CMS performs one regular reconciliation of the incremental GLOBE Model rebate amount within 12 months of the date of receipt of the GLOBE Model Rebate Report for each applicable calendar quarter to include revisions to the information used to calculate the rebate amount set forth in paragraph (c)(1) of this section.

(i) *Preliminary reconciliation.* At least 1 month prior to the issuance of a report with the reconciled incremental GLOBE Model rebate amount for an applicable calendar quarter as set forth under paragraph (d)(1)(ii) of this section, CMS conducts a preliminary reconciliation of the incremental GLOBE Model rebate amount for an applicable calendar quarter based on the information set forth in this paragraph (b)(1)(i) through (xiii) of this section and provide the information via a Preliminary GLOBE Model Reconciliation Rebate Report set forth in paragraphs (b)(1) and paragraphs (d)(1)(i)(A) through (K) of this section to the manufacturer of a GLOBE Model drug for the applicable calendar quarter, if applicable:

(A) Updated total number of GLOBE Model billing units attributed to GLOBE Model beneficiaries, as determined under 42 CFR 513.520.

(B) Updated per unit Method I GLOBE Model benchmark amount as determined under 42 CFR 513.410 if any inputs are restated within the reconciliation run-out period.

(C) Updated per unit Method II GLOBE Model benchmark amount, if any, as determined under 42 CFR 513.420 if any inputs are restated within the reconciliation run-out period.

(D) Updated per unit GLOBE Model rebate amount, if any, as set forth in 42 CFR 513.510 if any inputs are restated within the reconciliation run-out period.

(E) Applicable calendar quarter specified amount as determined under 42 CFR 427.302(b), if any inputs are restated within the reconciliation run-out period.

(F) The amount by which the specified amount as determined under 42 CFR 427.302(b) exceeds the inflation-adjusted payment amount as determined under 42 CFR 427.302(g), if any inputs are restated in the reconciliation run-out period.

(G) Reconciled total GLOBE Model rebate amount as set forth in 42 CFR 513.500, if any inputs are restated within the reconciliation run-out period.

(H) Reconciled incremental GLOBE Model rebate amount due as set forth in 42 CFR 513.500(b), if any inputs are restated within the reconciliation run-out period.

(I) Reconciled reduced incremental GLOBE Model rebate amount, if applicable.

(J) The difference between the incremental GLOBE rebate amount due as specified on the GLOBE Model Rebate Report set forth in paragraph (c) of this section and the reconciled incremental GLOBE Model rebate amount as set forth in paragraph (d)(1)(i)(I) of this section.

(ii) *GLOBE Model Reconciliation Rebate Report.* With the inclusion of any additional revisions to such information resulting from CMS' review of a Suggestion of Error as set forth in 42 CFR 513.720, if applicable, a report with the reconciled incremental GLOBE Model rebate amount is provided to each manufacturer of a GLOBE Model drug within 12 months after the issuance of the GLOBE Model Rebate Report described in paragraph (c) of this section.

(2) *CMS identification of error and manufacturer misreporting.* CMS may recalculate an incremental GLOBE Model rebate amount and provide the manufacturer of a Part B rebatable drug a GLOBE Model Reconciliation Rebate Report when—

(i) CMS identifies an agency error in the information specified in paragraphs (c) and (d)(1) of this section, including reporting system or coding errors, not later than 3 years from the date of receipt by a manufacturer of a reconciled incremental GLOBE Model rebate amount for the applicable calendar quarter; or

(ii) CMS determines at any time that the information used by CMS to calculate the incremental GLOBE Model rebate amount was inaccurate due to manufacturer misreporting.

(3) *Impact of reconciliation on the incremental GLOBE Model rebate amount.* A reconciliation as set forth in this paragraph (d) could result in an increase, decrease, or no change to the total GLOBE Model rebate amount, as determined under 42 CFR 513.500, owed by a manufacturer for the applicable calendar quarter for the GLOBE Model drug compared to the amount described in the GLOBE Model Rebate Report described in paragraph (c) of this section or an amount described in a previous reconciliation.

(i) A GLOBE Model Reconciliation Rebate Report that is an increase to the incremental GLOBE Model rebate amount is the invoice for such additional amount due on the manufacturer's incremental GLOBE Model amount as determined under 42 CFR 513.500 for a GLOBE Model drug for an applicable calendar quarter.

(ii) [Reserved]

§ 513.720 Suggestion of error.

(a) *General.* The manufacturer of a GLOBE Model drug may submit a Suggestion of Error about the information in their GLOBE Model Preliminary Rebate Reports and the report detailing the preliminary reconciliation of the incremental GLOBE Model rebate amount to CMS, for its discretionary consideration, if the manufacturer believes that there is a mathematical error or errors to be corrected before the GLOBE Model Rebate Report, or a subsequent reconciliation of the incremental GLOBE Model rebate amount, as applicable, is finalized.

(1) Administrative and judicial review is precluded consistent with section 1847A(i)(8) and section 1115A(d)(2) of the Act.

(b) *Process of submission.* Subject to the scope and timing requirements specified in paragraphs (a) and (c) of this section, manufacturers may submit the Suggestion of Error and provide supporting documentation (if applicable) as directed by CMS.

(c) *Timing.* A manufacturer must submit its Suggestion of Error for the applicable calendar quarter within 10 calendar days from the date of receipt of a GLOBE Model Preliminary Rebate Report or a preliminary reconciliation of a total GLOBE Model rebate amount using the method and process established by CMS in paragraph (b) of this section.

(d) *Notice.* (1) CMS includes any revisions to the calculation of the total GLOBE Model rebate amount, if determined necessary by CMS based on the Suggestion of Error submitted under this section prior to issuance of the GLOBE Model Rebate Report as set forth in 42 CFR 513.720 as well as any report

of a reconciled GLOBE Model rebate amount or rebate amount as set forth in 42 CFR 513.720.

(2) CMS notifies the manufacturer whether CMS revised its calculation of the GLOBE Model rebate amount based on the Suggestion of Error.

§ 513.730 Manufacturer access to GLOBE Model rebate reports.

(a) *General.* CMS establishes a method and process for a manufacturer of a GLOBE Model drug to do all of the following:

(1) Access the manufacturer's rebate reports as set forth in 42 CFR 513.710, including any report of reconciled rebate amount.

(2) Submit a suggestion of error as set forth in 42 CFR 513.720.

(3) Pay an incremental GLOBE Model rebate amount due.

§ 513.740 Deadline and process for payment of rebate amount.

(a) *Rebate amounts owed by a manufacturer.* For an incremental GLOBE Model rebate amount owed by a manufacturer, payment is due no later than 11:59 p.m. Pacific Time (PT) on the 30th calendar day after the date of receipt of information regarding the rebate amount on—

(1) A GLOBE Model Rebate Report as set forth in 42 CFR 513.710; or

(2) A report of a reconciled incremental GLOBE Model rebate amount as set forth in 42 CFR 513.710(d).

(b) *Failure to pay an incremental GLOBE Model rebate amount.* Failure to pay an incremental GLOBE Model rebate amount due timely and in full may result in an enforcement action as described in subpart I of this part.

(c) *Refund to the manufacturer.* If a reconciled incremental GLOBE Model rebate amount for an applicable calendar quarter as set forth in 42 CFR 513.710(d) is less than what the manufacturer paid for that applicable calendar quarter, CMS will initiate the process to provide a refund equal to the excess amount paid within 60 days of the date of receipt of the report with such reconciled incremental GLOBE Model rebate amount.

Subpart I—Enforcement of Manufacturer Payment of GLOBE Model Rebate Amounts

§ 513.800 Civil money penalty notice and appeals procedures.

(a) *General.* Under section 1847A(i)(7) of the Act and section 1128A of the Act as applicable, CMS may impose a civil money penalty on a manufacturer that fails to pay the incremental GLOBE model rebate amount as set forth in 42 CFR 513.500 by the payment deadline as set forth in 42 CFR 513.740(a) for such GLOBE Model drug for such applicable calendar quarter.

(b) *Determination of the civil money penalty amount.* CMS may impose a civil money penalty for each failure by a manufacturer to pay the incremental GLOBE Model rebate amount; the civil money penalty amount is an adjusted GLOBE Model rebate amount equal to 125 percent of the incremental GLOBE Model rebate amount determined in 42 CFR 513.500.

(1) The civil money penalty is in addition to the incremental GLOBE Model rebate amount due.

(2) If a reconciled rebate amount as set forth in 42 CFR 513.720 results in an increase to the incremental GLOBE model rebate amount due, a separate civil money penalty may be imposed for the failure by a manufacturer to provide a total GLOBE Model rebate amount for the applicable calendar quarter for the increase to the incremental GLOBE rebate amount due.

(c) *Notice of imposition of civil money penalties.* If CMS makes a determination to impose a civil money penalty described in paragraph (b) of this section, CMS will send a written notice of its decision to impose a civil money penalty that includes the following:

(1) A description of the basis for the determination.

(2) The basis for the penalty.

(3) The amount of the penalty.

(4) The date the penalty is due.

(5) The manufacturer's right to a hearing as specified in paragraph (e) of this section.

(6) Information about where to file the request for a hearing.

(d) *Collection.*

(1) Subject to paragraph (d)(2) of this section, a manufacturer must pay the civil money penalty in full within 60 calendar days after the date of the notice of imposition of a civil money penalty from CMS under paragraph (c) of this section.

(2) In the event a manufacturer requests a hearing, in accordance with 42 CFR part 423 subpart T, the manufacturer must pay the amount in full within 60 calendar days after the date of a final decision by the Departmental Appeal Board, to uphold, in whole or in part, the civil money penalty.

(3) If the 60th calendar day described in paragraphs (d)(1) and (2) of this section is a weekend or a Federal holiday, then the timeframe is extended until the end of the next business day.

(e) *Appeal procedures for civil money penalties.* Section 1128A(c)(2) of the Act provides that CMS may not collect a civil money penalty until the affected party has had notice and the opportunity for a hearing.

(1) Manufacturers may appeal the following determinations:

(i) A CMS determination that the incremental GLOBE Model rebate amount due was not paid by the applicable payment deadline as set forth in 42 CFR 513.740.

(ii) The calculation of the amount of the civil money penalty.

(2) If CMS decides to impose a civil money penalty, CMS will provide the manufacturer with a notice in accordance with the process set forth in paragraph (c) of this section.

(3) A manufacturer has a right to a hearing following a decision by CMS to impose a civil money penalty following the administrative appeal process and procedures established in 1128A of the Act.

(f) *Bankruptcy.* In the event that a manufacturer declares bankruptcy, as described in Title 11 of the United States Code, and as a result of the bankruptcy, fails to provide either the total GLOBE Model rebate amount owed or the total sum of civil money penalties imposed, the Government reserves the right to file a proof of claim with the bankruptcy court to recover the unpaid amount of the rebates and civil money penalties owed by the manufacturer.

Subpart J—Quality Strategy, Beneficiary Protections, and Compliance Activities

§ 513.900 Quality measures.

(a) *General.* Quality measures do not adjust GLOBE Model rebates, GLOBE Model beneficiary coinsurance percentages, or Medicare payments for GLOBE Model drugs and are used for monitoring purposes.

(b) *Collection of quality measures.* (1) CMS uses existing data sources to the extent available.

(2) If CMS determines it is necessary, new surveys to a sample of manufacturers, providers and suppliers, and beneficiaries who receive a GLOBE Model drug may be conducted. A sample of non-GLOBE Model beneficiaries may also be surveyed.

§ 513.910 Beneficiary protections.

In a form and manner specified by CMS, CMS will establish procedures for collecting complaints from beneficiaries and providers about difficulties obtaining specific drugs during the GLOBE Model performance period.

Subpart K—Waivers

§ 513.1000 Waivers of Medicare program requirements for purposes of testing the GLOBE Model.

CMS waives the Medicare program requirements in the following provisions that are necessary solely for purposes of testing the GLOBE Model:

(a) Section 1847A(i)(3) of the Act and §§ 427.302 and 427.301 of this chapter as related to calculation of rebate amounts as necessary to permit testing of an alternative rebate calculation and coinsurance adjustment for certain units of GLOBE Model drugs.

(b) Section 1847A(i)(1) of the Act as related to the invoicing timing requirements as necessary to permit testing of an alternative invoicing procedure for GLOBE Model rebate amounts.

(c) Sections 1833(a)(1), 1833(a)(1)(S), 1833(a)(1)(EE), and 1833(t) of the Act and §§ 410.152(m), 419.41(e), 489.30(b)(1), and 489.30(b)(6) of this chapter related to beneficiary coinsurance and the Medicare payment portion of the allowed payment amount as necessary to permit testing of an alternative beneficiary coinsurance adjustment and adjusted payment to providers of certain units of GLOBE Model drugs.

Robert F. Kennedy, Jr.

Secretary, Department of Health and Human Services.

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