Issue Brief

FEDERAL ISSUE BRIEF

Analysis provided for MHA by Larry Goldberg, Goldberg Consulting

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Global Benchmark for Efficient Drug Pricing (GLOBE) Model

The Centers for Medicare and Medicaid Services (CMS) have issued a proposed rule for the establishment of a mandatory GLOBE Model, including the general framework for implementing and evaluating the GLOBE Model and model-specific parameters, requirements, and definitions.

"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."

A copy of the display version of the proposal is available at: https://public-inspection.federalregister.gov/2025-23702.pdf. A 60-day comment period ending February 23 is provided.

Comments

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.

This is another complex and untried payment system. The proposal lays out the framework for those that would be required to participate, but does not, in this rule, identify specific locations or suppliers.

CMS estimates 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. The bottom line is savings to Medicare. In the regulatory analysis section, CMS provides the following table which is easier to understand.

Estimated Impacts To Medicare (Page 205)

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

Questions? Contact Andrew Wheeler, MHA's Vice President of Federal Finance, at 573-893-3700 | ext. 136 or awheeler@MoHospitals.org

4712 Country Club Drive, Jefferson City, Mo. 65109
P.O. Box 60, Jefferson City, Mo. 65102
573-893-3700 | MoHospitals.org

Further, CMS says that "the GLOBE Model would result in overall cost savings in Medicare Part B FFS net spending of approximately $2.3 billion."

As usual, there is no table of contents. We are supplying numbers in red.

Proposed Defined Population and Intervention

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. (Page 5)

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)." (Page 5)

Provisions of the Proposed Regulations (Page 26)

Proposed GLOBE Model Drugs (Page 29)

CMS would identify the GLOBE Model drugs for an applicable calendar quarter by applying the following 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 United States Pharmacopeia (USP) Drug Classification (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. (Page 34)

Proposed Exclusion of Certain Part B Rebatable Drugs (Page 40)

CMS proposes 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.

Considerations Related to Cell and Gene Therapies and Plasma-Derived Products (Page 47)

CMS says it is 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. CMS seeks comments.

Proposed Defined Population (Page 49)

CMS proposes 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.

Prior to the model start, CMS would randomly identify the model geographic areas (based on ZIP Code Tabulation Areas). CMS proposes that, prior to the 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 is updated with the GLOBE Model Eligible Beneficiary List information.

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.

Proposed Scale for Inclusion of GLOBE Model Beneficiaries (Page 54)

CMS proposes to select geographic regions to represent 25 percent of Medicare FFS beneficiaries.

Proposed Mandatory Participation of Manufacturers of GLOBE Model Drugs (Page 55)

CMS proposes that model participation would be mandatory for all manufacturers of GLOBE Model drugs that are furnished to a GLOBE Model beneficiary during the GLOBE Model performance period.

Proposed Criteria and Process for Identifying the Set of Reference Countries (Page 80)

CMS 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.

Comment

The proposal identifies several sets of counties for possible inclusion in the model, but does not specify any particular group.

Proposed Data and Methodology for Identifying the GDP (PPP) Adjuster (Page 90)

Prior to the model start and 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.

Proposed Methodology for Identifying the Per Unit GLOBE Model Benchmark Amount for an Applicable Calendar Quarter (Page 108)

In this section, CMS proposes the methodology CMS would use to determine the per unit GLOBE Model benchmark amount for a GLOBE Model drug for an applicable calendar quarter.

CMS proposes 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.

Final Comments

Not being a manufacturer of drugs, makes it difficult to understand all the processes involved in the proposal. Further, without real specific numbers and factors it is difficult to follow the illustrative examples.

This proposal is just about 6 months away from implementation. Yet, it contains many requests for comments on CMS choices. One must wonder how this program will be able to meet its July 1 effective date.

Further, considering this is a proposed rule with a 60-day comment period, further clouds CMS' ambitious time frame.

To say the least this is another example of a model program that most may not truly understand its implications. To this reader, the model seems convoluted, but one element is clear—to significantly reduce Medicare overall spending.