Issue Brief

FEDERAL ISSUE BRIEF

Analysis provided for MHA by Larry Goldberg, Goldberg Consulting

December 22, 2025

Proposed Drug GUARD Model Rule

The Centers for Medicare and Medicaid Services (CMS) have issued a proposed rule for the establishment of a Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model to test a new rebate formula for Medicare Part D drugs, which includes outpatient prescription drugs typically dispensed at retail, mail order, home infusion, and long-term care pharmacies. The GUARD Model would factor in existing Medicare Part D manufacturer rebates and discounts, and CMS would leverage its authority to test a change in the calculation of inflation rebates in Medicare Part D that accounts for how much certain drugs cost in economically similar countries.

The intent of the proposed GUARD Model is to test drugs using international drug pricing information to identify a benchmark that reflects prices paid in a set of economically comparable countries, which CMS expects would reduce program expenditures for Medicare Part D while preserving or enhancing beneficiaries' quality of care.

The GUARD Model would begin January 1, 2027, and operate for five years with rebate invoicing and payment continuing until 2033. The model would encompass 25 percent of Part D enrollees and would only apply to beneficiaries that live in randomly selected geographic areas of the country.

The ***Inflation Reduction Act of 2022*** (IRA), made several additions and amendments to the Act that affected the structure of the defined standard Part D drug benefit. Currently, the Part D defined standard benefit consists of three phases that enrollees go through depending on their use and cost of drugs: the deductible phase, the initial coverage phase, and the catastrophic coverage phase. Plans are responsible for setting the specific deductible, up to a maximum of $615 in 2026. In the 2026 defined standard benefit, enrollees are responsible for 25 percent of drug costs until their true out-of-pocket (TrOOP) spending reaches $2,100,

A copy of the display version of the proposal is available at: https://public-inspection.federalregister.gov/2025-23705.pdf. A 60-day comment period ending February 23 is provided.

Comments

Although the proposal does not contain a table of contents, page numbers in red text are included.

Summary of Major Provisions (Page 9)

The proposed model includes the following major provisions:

The GUARD Model would include a subset of Part D rebatable drugs that are included in the Part D Inflation Rebate Program. Specifically, the GUARD Model would include sole source drugs and sole-source biological products that are in the following specific therapeutic categories: Analgesics; Anticonvulsants; Antidepressants; Antimigraine Agents; Antineoplastics; Antipsychotics; Antivirals; Bipolar Agents; Blood

Glucose Regulators; Cardiovascular Agents; Central Nervous System Agents; Gastrointestinal Agents; Genetic or Enzyme or Protein Disorder: Replacement or Modifiers or Treatment; Immunological Agents; Metabolic Bone Disease Agents; Ophthalmic Agents; and Respiratory Tract/Pulmonary Agents.

The GUARD Model would exclude: (1) generics and biosimilar biological products; (2) sole source drugs or sole-source biological products with annual application-level total gross covered drug costs below the GUARD minimum spend threshold; and (3) drugs that are subject to a negotiated MFP, during the price applicability period. (Page 10)

CMS proposes to test two approaches to calculating the GUARD Model international benchmark: the default international benchmark (also referred to as Method I) and the updated international benchmark (also referred to as Method II).

The GUARD Model would require manufacturers to pay a GUARD Model rebate payment if the Medicare net price is greater than the GUARD Model applicable international benchmark for a GUARD Model drug. The Medicare net price would be calculated by subtracting manufacturer rebates (obtained from Direct and Indirect Remuneration (DIR)) and discounts (under the Manufacturer Discount Program) from the WAC of the GUARD Model drug.

Summary of Costs and Benefits (Page 13)

Provisions	Brief Description	Financial Impact
All of the GUARD Model provisions presented in this proposed rule.	As defined in detail throughout this proposed rule, the GUARD Model tests, for a specific subset of Part D rebatable drugs and biologic products, specific geographic locations, and specific Medicare Part D beneficiaries, the effects of replacing the Part D inflation rebate calculation with an alternative rebate calculation that takes into account international prices in economically comparable countries. CMS aims to understand whether the alternative payment calculation tested under the GUARD Model will reduce Medicare spending while preserving or enhancing beneficiary quality of care.	Over the 2028-2033 period, the GUARD Model is expected, in aggregate, to reduce Medicare spending by $14.1 billion. This sum would be deposited into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.

Detailed Description of Provisions in the Proposed Guard Model (Page 34)

The GUARD Model drugs would consist of a subset of Part D rebatable drugs. CMS believes that focusing the GUARD Model test on a subset of the Part D rebatable drugs, rather than all Part D rebatable drugs, would allow CMS to understand the GUARD Model's impacts with a smaller set of drugs. (Page 40)

CMS believes that the focus of the GUARD Model on sole-source drugs and sole-source biological products mitigates the potential confounding factors that would arise if the full set of Part D rebatable drugs were included in the GUARD Model test.

CMS proposes to exclude from the GUARD Model, generics and biosimilar biological products. At § 514.5 CMS proposes "generic" to mean, for the United States, a drug approved and marketed under an Abbreviated New Drug Application (ANDA) under section 505(j) of the FD&C Act; and "biosimilar biological product" to mean, for the United States, a biological product approved and licensed under a BLA under section 351(k) of the PHS Act. Given that the only generics that are Part D rebatable are sole-source generics, another way of stating the exclusion is that sole-source generics and any (sole or multi-source) biosimilar biological products are excluded from the GUARD Model. (Page 49)

CMS proposes at § 514.120(c) that the second exclusion would be based on whether a sole-source drug or biological product's application-level total gross covered prescription drug costs are below the GUARD Model minimum spend threshold.

CMS says it believes applying a threshold of $69 million that is adjusted for inflation annually thereafter means that manufacturers of GUARD Model drugs would have significant revenue from the Medicare Program and thus would likely remain in the Medicare program during the GUARD Model test. (Page 52)

CMS says the GUARD Model should be tested with approximately 25 percent of Medicare beneficiaries. (Page 62)

CMS proposes in § 514.130(b) that 30 calendar days prior to the start of the model, CMS would identify a beneficiary as a GUARD Model beneficiary. (Page 63)

If this proposed rule is finalized, the GUARD Model geographic areas would be identified in a table that lists the model test areas, total number of Medicare beneficiaries at the time of analysis, and any other relevant information no later than 60 calendar days in advance of the beginning of the GUARD Model performance period. (Page 64)

At § 514.110(a), CMS proposes that manufacturers would be the participants of the GUARD Model. CMS proposes at § 514.5 that "manufacturer" would have the same meaning as that term is defined and used in § 428.20 and section 1927(k)(5) of the Act. (Page 66)

CMS proposes that model participation would be mandatory for all manufacturers that receive a Part D inflation rebate report. (Page 68)

Set of Reference Countries for the GUARD Model Identified Using the Proposed Methodology (Page 82)

The material beginning on page 82 describes the counties that CMS would weigh against US Drug prices.

CMS proposes a 2 percent increase in the GUARD Model default international benchmark amount to account for potential differences between the U.S. market and markets in the reference countries that would not be addressed otherwise, meaning that the GUARD Model default international benchmark would represent 102 percent of the original value after adjustment. (Page 133)

Further, CMS proposes a 5 percent increase in the GUARD Model updated international benchmark amount to account for potential differences between the U.S. market and markets in the reference countries that would not be addressed otherwise; this means that the GUARD Model updated international benchmark would represent 105 percent of the original value after adjustment. (Page 133)

Determination of the GUARD Model Rebate Payment Amount (Page 138)

In this Section of this proposed rule, CMS describes its proposal for the alternative calculation of the rebate amount described in section 1860D-14B(b) of the Act to yield the GUARD Rebate Payment amount, including the steps to calculate the performance year Medicare net price and the per unit GUARD Model rebate, as well as determining whether the per unit GUARD Model rebate exceeds the per unit Part D inflation rebate amount.

Enforcement of Manufacturer Payment of Rebate (§ 514.650) (Page 179)

CMS proposes that manufacturers of a GUARD Model drug that have failed to timely pay the Total Incremental GUARD Model rebate amount as described in proposed § 514.510(c)(2) may be subject to a Civil Money Penalty (CMP).

Final Thoughts

Several items become apparent. First and foremost is that this proposal is intended to save Medicare some $14 billion over 10-years.

Second the proposal is both redundant in many explanations and extremely detailed, such that it is difficult to summarize. The only way to truly grasp the mechanisms being employed is to carefully read the entire rule.

Third, the proposal has a short time frame for implementation. It is intended to be operational by January 1, 2027.

Finally, as CMS notes, the cost of drugs has been increasing at an unsustainable rate. Further, the question is why and why do other countries have lower costs for the same item as one in the U.S? Perhaps this proposal may help mitigate the differences.