1. Overview and Purpose

Agency: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).
Title: *Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model*.
CFR Affected: 42 CFR Part 514.
Type: Proposed rule implementing a new Medicare payment model under section 1115A of the Social Security Act.
Goal: Test an alternative payment method for calculating inflation rebates for certain Medicare Part D prescription drugs in order to **reduce costs for the Medicare program and beneficiaries**, while preserving or enhancing quality of care. Public Inspection Federal Register+1
The proposed GUARD Model stems from long-standing concern about the high and rising cost of prescription drugs in the United States, which has placed financial strain on Medicare beneficiaries and the Medicare program. U.S. drug prices significantly exceed those in economically comparable countries, contributing to increased premiums, out-of-pocket costs, and financial hardship for patients, especially older adults and people with chronic conditions. Public Inspection Federal Register

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2. Background and Context

Medicare Part D and Drug Pricing

Medicare Part D provides outpatient prescription drug coverage through private plans approved by Medicare. Unlike Part B, where some pricing mechanisms (including inflation rebates) have been in effect for certain drugs, Part D historically has lacked a robust federal mechanism to directly control net drug costs, relying instead on plan-level negotiations with manufacturers. As a result, Part D drug spending has grown substantially over time, leading to higher premiums and increased beneficiary cost-sharing. Public Inspection Federal Register
The GUARD Model is proposed as part of CMS's Innovation Center authority under **section 1115A of the Social Security Act**, which allows CMS to test innovative payment and service delivery models designed to reduce expenditures while maintaining or improving quality. This authority has been used in the past for other payment innovations across Medicare. Public Inspection Federal Register

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3. Key Features of the GUARD Model

Model Design and Scope

A. Rebate Calculation Based on International Prices

Under the proposed model, CMS would test a **new method for calculating inflation rebates** for a subset of Part D drugs and biological products based on **international price benchmarks** — that is, price levels in other economically similar countries. The purpose is to align what Medicare pays (net of rebates) more closely with global pricing, thereby reducing costs. Centers for Medicare & Medicaid Services

- **Manufacturer Rebates:** If a participating drug's price in the U.S. exceeds the international benchmark, manufacturers would be liable for additional rebates to Medicare.
- This methodology changes how inflation rebates are computed for the drugs covered under the model. Centers for Medicare & Medicaid Services

B. Geographic Randomization and Phased Testing

- The GUARD Model would be implemented in **randomly selected geographic areas** across the U.S. rather than nationwide at once.

- It would initially cover a defined portion (e.g., 25%) of Medicare Part D enrollees, allowing CMS to study impacts and refine calculations.
- The model's **performance period is proposed to run for five years** (January 1, 2027, through December 31, 2031), with rebate reconciliation and invoicing extending to 2033. Centers for Medicare & Medicaid Services

C. Interaction with Existing Structures

- The GUARD Model would **factor in existing Part D manufacturer rebates and discounts**, ensuring adjustments build on the current Part D payment system rather than replace it entirely.
- Drugs subject to the model would be a subset of Part D drugs and not necessarily all Part D medications.
- Drugs already covered under other negotiation programs (e.g., Medicare price negotiations under the Inflation Reduction Act) may be excluded so as not to duplicate rebate requirements. Axios

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4. Intended Outcomes and Policy Rationale

A. Cost Reduction for Medicare and Beneficiaries

The central aim of the GUARD Model is to **reduce overall Medicare Part D spending and beneficiary out-of-pocket costs**, particularly where U.S. prices significantly exceed international benchmarks. Lower net prices (via rebates) could lead to reduced premiums, lower coinsurance, and potentially fewer skipped medications due to cost barriers. Centers for Medicare & Medicaid Services

B. Sustainability and Quality

CMS proposes that tying rebate formulas to international pricing will **enhance the sustainability** of the Medicare Part D program without adversely affecting quality of care. The model is designed to **preserve or improve health outcomes** for beneficiaries by maintaining access to necessary drugs even as prices are moderated. Centers for Medicare & Medicaid Services

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5. Implementation and Regulatory Process

Comment Period

CMS is accepting public comments on the proposed rule for 60 days after publication in the Federal Register, which is scheduled for **December 23, 2025**. Stakeholders including beneficiaries, manufacturers, Part D plans, health economists, and patient advocacy groups can provide input. Public Inspection Federal Register

Evaluation and Reporting

As a test model under section 1115A, CMS will evaluate variables such as:

- Impact on Medicare drug spending and premium trends
- Beneficiary out-of-pocket costs
- Drug utilization patterns
- Quality of care and access outcomes
- Net financial effects on manufacturers and Part D plans

Model evaluations typically include **interim and final reports** to CMS leadership and may inform future broader policy decisions if successful. Centers for Medicare & Medicaid Services

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6. Regulatory and Economic Significance

Economic Impact

The GUARD Model is designated an **economically significant regulatory action**, suggesting that its implementation could have substantial fiscal effects on Medicare spending, drug pricing dynamics, and the broader prescription drug market. It received review under Executive Order 12866 as such. RegInfo

Innovation in Medicare Payment Policy

This model represents a noteworthy expansion of CMS's use of international price benchmarks to address high drug costs — an approach previously reflected in other pilot programs (e.g., the GLOBE Model for Part B drugs). It underscores a broader policy trend toward **value-based and internationally informed payment models** in federal health programs. American Hospital Association

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7. Potential Implications and Stakeholder Considerations

- **Manufacturers** may face new rebate liabilities if U.S. prices exceed international benchmarks for covered drugs.
- **Part D plans** will need to integrate model requirements into their pricing and rebate workflows.
- **Beneficiaries** may see indirect benefits through lower premiums or reduced cost sharing, but effects will vary by drug and market.
- **Healthcare economists and policy analysts** may debate model design choices, including selection of international comparators and measurement of quality outcomes. Centers for Medicare & Medicaid Services

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Conclusion

The **GUARD Model proposed rule** introduces an innovative test of international benchmark–based rebates for Medicare Part D drugs. Its primary objective is to **curb rising drug costs** for the Medicare program and enrollees while preserving access and quality of care. CMS's proposal reflects broader efforts to enhance affordability and sustainability in federal health benefit programs, and engaging stakeholders through the public comment process will shape its final design and potential rollout. Public Inspection Federal Register