



NATIONAL
ASSOCIATION
OF SPECIALTY
PHARMACY

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Submitted electronically via www.regulations.gov

The Honorable Dr. Mehmet Oz
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-5546-P (GUARD Model)
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-5546-P - Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model

Dear Dr. Oz:

The National Association of Specialty Pharmacy (NASP) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule for the Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model (90 FR 60346). NASP represents the specialty pharmacy industry, including pharmacies, manufacturers, distributors, some PBMs, GPOs, patient advocacy organizations, and technology companies that collectively serve Medicare beneficiaries with the most complex, chronic, and life-sustaining conditions in America. NASP represents specialty pharmacies that provide comprehensive patient care services for individuals with complex, chronic and rare medical conditions requiring high-touch specialty medications covered under Medicare Part D.

While NASP shares CMS's goal of controlling Medicare Part D drug spending and improving affordability for beneficiaries, we have concerns about the GUARD Model's potential unintended consequences for the specialty pharmacy channel, patient access to essential medications, and continuity of care. Our comments focus on how the proposed international reference pricing methodology and rebate calculation structure may disrupt the specialty drug distribution system, eliminate critical patient support services, and ultimately harm the Medicare beneficiaries the model is intended to help.

NASP's feedback on the GUARD model seeks to address the following key issues:

- **Direct and Indirect Remuneration (DIR) Fee Calculation:** Including DIR in the Medicare Net Price calculation could perpetuate pharmacy financial instability and create perverse incentives for Part D plans to increase DIR fees on specialty pharmacies.
- **No Direct Out-of-Pocket Savings:** Despite generating an estimated \$15 billion in savings, the GUARD Model provides no direct out-of-pocket relief to Medicare Part D enrollees who face affordability challenges
- **Supply Chain and Distribution Disruption:** Financial pressures may force manufacturers to consolidate networks, restrict specialty pharmacy access, or shift to direct-to-consumer models that bypass clinical support infrastructure.
- **Geographic Randomization Operational Complexity:** The use of randomly selected ZIP Code Tabulation Areas creates administrative burden and possible confusion for specialty pharmacies serving patients across multiple geographic areas.
- **Lack of Clarity on Selected Drugs for Model:** Uncertainty about which manufacturers and drugs will be exempt from the model as proposed for stakeholder comment makes it near impossible for stakeholders to fully assess the model's true scope and impact as intended under the Administrative Procedures Act.

Background: The Critical Role of Specialty Pharmacy in Medicare Part D

Specialty pharmacies serve as essential access points for Medicare beneficiaries with complex, life-threatening, rare disease, and chronic conditions requiring specialty medications. These include such conditions as cancer, multiple sclerosis, rheumatoid arthritis, inflammatory bowel disease, organ transplant, HIV/AIDS, hepatitis C, cystic fibrosis, and many rare and orphan diseases. Specialty pharmacies provide comprehensive clinical services that extend far beyond drug dispensing, including:

- Medication management and adherence monitoring to optimize clinical outcomes and prevent costly hospitalizations;
- Patient education and training on proper administration techniques for complex injectable and infusible therapies;
- Side effect management and clinical monitoring including coordination with prescribers and laboratory services;
- Prior authorization and insurance navigation to facilitate timely therapy initiation;
- Financial assistance coordination including alternative funding sources;
- 24/7 patient access to accredited specialty pharmacists for urgent medication-related questions.

Specialty pharmacy services are particularly critical for Medicare beneficiaries, who often have multiple comorbidities, complex medication regimens, and heightened affordability concerns. Research demonstrates that specialty pharmacy clinical interventions improve medication adherence, reduce emergency department visits and hospitalizations, and enhance patient quality of life.

The proposed GUARD Model, as explained thus far, raises concerns for NASP that specialty pharmacies may be forced to reduce clinical services, limit patient therapy access, or restrict participation in Medicare Part D networks without protections.

I. Direct and Indirect Remuneration (DIR) Fee Calculation Concerns

CMS proposes to calculate the Medicare Net Price for GUARD Model drugs as Wholesale Acquisition Cost (WAC) minus Part D direct and indirect remuneration (DIR) fees minus manufacturer payments under the Part D Manufacturer Discount Program (Federal Register, 90 FR 60386). While CMS states this approach ensures manufacturers receive credit for rebates and discounts provided to Part D plans, the inclusion of DIR in this calculation creates significant unintended consequences for specialty pharmacies.

DIR fees represent post-point-of-sale adjustments that Part D plans and pharmacy benefit managers (PBMs) retroactively assess against pharmacies weeks or months after a prescription is dispensed. These fees had previously grown substantially in recent years before requirements that all fees and concessions be assessed at the point of sale under Part D; however, it is unclear to NASP whether and how DIR fees could be reapplied to pharmacies under the terms of the model. DIR fees have always been unpredictable, opaque, and unrelated to specialty pharmacy performance, creating significant cash flow challenges and margin compression.

A. GUARD Model May Incentivize Plans to Increase DIR Fees

The proposed GUARD rebate calculation methodology creates a potential incentive structure that may harm specialty pharmacies. If manufacturers respond to GUARD rebate obligations by reducing rebates paid to Part D plans and PBMs—a widely anticipated response—plans could seek to maintain their revenue by increasing DIR fees assessed against pharmacies. This dynamic would shift the economic burden of the GUARD Model from manufacturers to pharmacies without benefiting patients.

The inclusion of DIR in the Medicare Net Price calculation exacerbates this problem by making DIR a component of the manufacturer's rebate liability. This structure could incentivize Part D plans to maximize DIR fees to reduce manufacturers' GUARD rebate obligations, threatening to make specialty pharmacies a pressure relief valve for the entire payment model.

B. Recommendations

NASP strongly recommends that CMS exclude DIR from the Medicare Net Price calculation for GUARD Model rebates. Instead, CMS should calculate Medicare Net Price using only WAC minus manufacturer discounts and rebates that flow directly to the federal government or Part D plans.

II. No Direct Out of Pocket Savings for Beneficiaries

Medicare Part D beneficiaries with complex, chronic conditions often face significant out-of-pocket costs for specialty medications, even with Part D coverage.

CMS acknowledges in the proposed rule that manufacturers facing new GUARD rebate obligations may respond by reducing or eliminating patient assistance programs (Federal Register, 90 FR 60398). This is not speculation—it is the inevitable economic response when manufacturers face increased financial obligations without corresponding revenue increases. Manufacturers will likely view patient assistance programs as discretionary expenses that can be cut to offset GUARD rebate liabilities.

A. Zero Direct Beneficiary Savings Compounds the Problem

We are concerned that while the GUARD Model is anticipated to achieve billions in savings, those savings are expected to only flow to the federal government, with no expected direct out-of-pocket relief for Medicare Part D enrollees (Federal Register, 90 FR 60407). Unlike the Medicare Part D benefit redesign implemented through the Inflation Reduction Act, which includes a \$2,000 out-of-pocket cap, the GUARD Model will not modify beneficiary cost-sharing structures.

Medicare beneficiaries are likely to not receive direct benefit from the GUARD Model savings. The result threatens:

- Increased prescription abandonment as patients cannot afford their medications despite reduced GUARD pricing on selected drugs.
- Worse health outcomes if patients begin to ration medications or discontinue therapy.
- Increased downstream acute care costs including emergency department visits and hospitalizations.
- Greater burden on hospital charity care and social services as patients seek alternative assistance.

Specialty pharmacies witness these dynamics daily. Patients with cancer, multiple sclerosis, rheumatoid arthritis, inflammatory bowel disease, and other serious conditions already struggle with affording their drugs.

B. Recommendations

NASP strongly urges CMS to reconsider the design of the GUARD Model to deliver direct patient savings, not just federal budget savings. Specifically, CMS should:

- **Redirect a substantial portion of GUARD rebate savings** to reduce patient cost-sharing.
- **Create a beneficiary assistance fund** using GUARD rebate revenues to provide supplemental financial assistance for Medicare beneficiaries taking GUARD Model drugs.
- **Require Part D plans to pass savings through to patients** via lower premiums or reduced cost-sharing tiers for GUARD Model drugs.

III. Supply Chain and Distribution Disruption Threatens Patient Access

A. Specialty Drug Distribution and Manufacturer Networks

Some specialty medications are distributed through manufacturer networks due to clinical complexity, special handling requirements, and regulatory Risk Evaluation and Mitigation Strategies (REMS) programs. Independent or other specialty pharmacies are selected for these medications, providing not only medication distribution but also critical clinical management and patient support services.

The specialty pharmacy distribution model is characterized by:

- **Manufacturer-pharmacy partnerships** with service agreements.
- **Clinical infrastructure investments** including specialized storage, handling, and administration support.
- **REMS program administration** ensuring safe and appropriate use.
- **Patient support services** to support patient adherence and management of the medication in consultation with health providers.

B. GUARD Financial Pressures Could Disrupt Distribution Networks

CMS acknowledges that manufacturers facing GUARD rebate obligations may respond by "changing distribution channels" and "restricting access" (Federal Register, 90 FR 60398). NASP is deeply concerned that manufacturers could attempt to reduce costs by:

- **Consolidating distribution networks** to fewer specialty pharmacies, reducing patient choice and access.

Such a change would have severe consequences for Medicare beneficiaries who depend on specialty pharmacy services.

C. Impact on 340B Contract Pharmacy Arrangements

The proposed rule does not include a 340B program exclusion for the GUARD Model (in contrast to the proposed GLOBE Model for Part B drugs). This creates additional financial exposure for manufacturers whose GUARD Model drugs are dispensed through 340B contract pharmacy arrangements, likely accelerating the already troubling trend of some manufacturers trying to restrict 340B contract pharmacy access.

Many specialty pharmacies operate as 340B contract pharmacies serving safety-net populations. If manufacturers view 340B contract pharmacy dispensing as increasing their combined 340B plus GUARD rebate exposure, we are concerned they may further restrict or terminate these arrangements, directly limiting affordable drug access for vulnerable Medicare beneficiaries served by safety-net providers.

D. Recommendations

- **NASP urges CMS to encourage continuity of the specialty pharmacy distribution channel, recognizing medications with REMS programs or other clinical management requirements that necessitate specialty pharmacy involvement.**
- **CMS should likewise monitor specialty pharmacy network adequacy** for GUARD Model drugs to ensure that accredited specialty pharmacies in addition to PBM- or plan sponsor-affiliated specialty pharmacies are in network for the dispensing of those Part D drugs requiring clinical support services to support patients on specialty drugs.
- **CMS should add 340B exclusion to GUARD consistent with the GLOBE Model.**

IV. Geographic Randomization Creates Operational Complexity

CMS proposes to implement the GUARD Model in randomly selected ZIP Code Tabulation Areas representing approximately 25% of Medicare Part D beneficiaries, with the remaining 75% serving as a comparison group (Federal Register, 90 FR 60370). While CMS states this approach facilitates evaluation, it creates significant operational challenges for specialty pharmacies.

A. Operational Burden for Multi-Site Specialty Pharmacies

Many specialty pharmacies operate across multiple states and serve patients in hundreds or thousands of ZIP codes. The proposed geographic randomization means that specialty pharmacies would need to:

- Track eligibility status for each patient based on residential ZIP code.
- Manage differential pricing for the same medication depending on patient location.
- Adjust inventory management systems to account for zip code-based reimbursement variations.

- Modify billing systems to apply GUARD Model pricing rules only for patients in selected geographic areas.
- Train pharmacy staff to navigate complex eligibility rules that vary by patient location.

This administrative complexity is particularly burdensome for specialty pharmacies, which already manage complex prior authorization requirements, REMS programs, and patient assistance coordination for each prescription.

B. Patient Confusion and Access Concerns

The geographic randomization approach also creates patient confusion and access concerns. Medicare beneficiaries with identical clinical needs and Part D coverage will face different pricing and access conditions based solely on their residential ZIP code. This is particularly problematic for specialty medications where:

- Patients may relocate during treatment (e.g., for family caregiving or medical care access).
- Retired beneficiaries maintain residences in multiple states.

C. National Drug Pricing Market Realities

Drug pricing operates in a national market. Manufacturers set WAC, Average Sales Price (ASP), and contracting terms nationally, not by ZIP code. Part D plan formularies and benefit designs are uniform within plan offerings. Pharmacy acquisition costs do not vary by patient residential location.

The geographic randomization approach attempts to impose localized variation on a fundamentally national market, and NASP is concerned this will create significant operational friction without clear benefits. For example, could the variation in contract costs affect plan bids and ultimately beneficiary premiums? How will Medicare Part D ensure there are safeguards so some plans and some beneficiaries are not disproportionately impacted?

V. Lack of Transparency Regarding Manufacturer Exemptions

A. Reported White House Manufacturer Agreements

Multiple stakeholder reports indicate that certain pharmaceutical manufacturers have entered into separate drug pricing agreements with the White House and may be exempt from GUARD and GLOBE Model participation. Up to 14 manufacturers have reportedly signed "Most Favored Nation" pricing deals as of February 2026 and may be excluded from these mandatory payment models.

B. Impact on Model Scope and Specialty Pharmacy Planning

The uncertainty regarding manufacturer exemptions makes it impossible for specialty pharmacies to accurately assess the GUARD Model's true scope and to prepare accordingly. To provide full and accurate feedback, NASP and its specialty pharmacy members need to understand:

- Which specific manufacturers and drugs are subject to GUARD rebates?
- What specific drugs and percentage of a manufacturer's portfolio will be affected?

Without this transparency, specialty pharmacies cannot accurately forecast revenue impacts and adjust operations accordingly and assess whether model participation creates competitive advantages or disadvantages.

C. Arbitrary and Anti-Competitive Concerns

The reported exemption of certain manufacturers through separate White House agreements raises concerns about consistency, transparency and competitive neutrality in the application of the GUARD Model. This is particularly concerning given that:

- Smaller specialty and rare disease manufacturers may lack political access to negotiate exemptions.
- Innovative companies developing novel therapies face GUARD rebate exposure while established manufacturers may be exempt.
- Medication access and continuity of care could be a concern if Part D plans change their formularies and opt not to cover drugs based on concerns over financial implications to the plan.
- If certain manufacturers and their drugs are exempt while others face significant rebate obligations, this creates differential market pressures that could affect manufacturer willingness to maintain specialty pharmacy distribution partnerships.

D. Recommendations

NASP strongly opposes finalizing the GUARD Model without full transparency on manufacturer exemptions. How exemptions affect the spending threshold calculations and the list of drugs subject to GUARD will be important information for pharmacies to understand. **CMS should extend the comment period for 60 days after providing complete transparency on exemptions, allowing stakeholders to submit informed comments on the model's actual scope and impact.**

VI. Minimum Spend Threshold and Therapeutic Category Concerns

A. Spending Threshold Methodology

CMS proposes to include sole-source drugs and sole-source biological products with annual application-level total gross covered prescription drug costs of at least \$69 million (adjusted annually for inflation) in the GUARD Model (Federal Register, 90 FR 60354). NASP requests clarification on whether this threshold appropriately captures low-volume, high-cost drugs typical in specialty disease care.

Many specialty medications for rare and orphan diseases, for example have:

- Low patient volumes (sometimes fewer than 1,000 patients nationally)
- Very high per-patient costs (often exceeding \$100,000-\$500,000 annually)
- Application-level spending that may fall below the \$69 million threshold despite representing critical therapies for vulnerable populations

B. Therapeutic Category Selection

CMS proposes 17 USP therapeutic categories for GUARD Model inclusion (Federal Register, 90 FR 60352). While NASP appreciates CMS's focus on categories with documented affordability challenges and high Part D spending, we note that the proposed categories are somewhat arbitrary and create competitive distortions.

Specialty pharmacies often specialize in specific therapeutic areas or disease states. The inclusion or exclusion of particular categories will have differential impacts across the specialty pharmacy sector, potentially creating financial sustainability challenges for specialty pharmacies.

VII. Interaction with Other Medicare Programs and Policies

A. Medicare Drug Price Negotiation Program (MFP)

The proposed rule indicates that drugs with a Maximum Fair Price (MFP) in effect under the Medicare Drug Price Negotiation Program are excluded from the GUARD Model (Federal Register, 90 FR 60348). However, CMS has not adequately addressed the interaction between GUARD and MFP during the negotiation period before an MFP takes effect, including:

- Whether drugs remain subject to GUARD during the 1.5-2 year MFP negotiation period
- How rebates are reconciled when drugs transition from GUARD to MFP mid-model.
- How inflation rebate baselines are adjusted for drugs moving between programs

Specialty pharmacies dispense many drugs selected for MFP negotiation and need clarity on how to forecast costs, manage inventory, and plan operations when drugs may be subject to multiple different pricing mechanisms over a five-year period.

B. Part D Redesign and Benefit Structure

The GUARD Model will be implemented concurrently with the Inflation Reduction Act's Part D benefit redesign, which includes:

- \$2,000 out-of-pocket spending cap for beneficiaries
- Modified manufacturer discount program requirements
- Changes to catastrophic coverage cost-sharing
- New Part D plan liability structures

CMS should clarify how the GUARD Model interacts with these benefit changes and whether GUARD rebate calculations appropriately account for the modified Part D program structure beginning in 2025.

VIII. Monitoring, Evaluation, and Unintended Consequences

A. Proposed Evaluation Approach

CMS proposes to evaluate the GUARD Model's impact on Medicare net spending, quality of care, and beneficiary access (Federal Register, 90 FR 60406). NASP strongly supports rigorous evaluation but urges CMS to expand evaluation metrics to include specialty pharmacy-specific impacts.

B. Recommended Monitoring Metrics

NASP recommends CMS establish comprehensive monitoring with quarterly public reporting on:

Patient Access Metrics:

- Prescription abandonment rates for GUARD Model drugs
- Continued coverage of GUARD Model drugs (maintaining Part D drugs on plan formularies)
- Prior authorization denial and appeal rates
- Specialty pharmacy network adequacy and participation rates
- Patient-reported access problems and delays in therapy initiation
- Geographic variation in medication availability

C. Suspension Authority

NASP strongly recommends CMS establish model suspension or modification if:

- Prescription abandonment rates increase by more than 10% for GUARD Model drugs compared to baseline;
- DIR fees increase by more than 5% year-over-year for GUARD Model drugs;
- Specialty Pharmacy market decreases by more than 15% in any therapeutic category;
- Manufacturer patient assistance programs are eliminated for more than 25% of GUARD Model drugs;
- Patient access metrics demonstrate harm exceeding CMS-defined thresholds

Without clear guardrails and responsive modification authority, the GUARD Model risks causing substantial harm to Medicare beneficiaries before CMS can implement corrective actions.

D. Real-Time Monitoring and Rapid Response

Given the critical nature of specialty medications for patients with serious and chronic conditions, CMS must implement real-time monitoring rather than relying solely on retrospective evaluation. Specialty pharmacies experience patient access problems, manufacturer program eliminations, and reimbursement disruptions immediately when they occur—waiting for annual evaluation reports is insufficient to protect beneficiaries.

NASP recommends CMS establish:

- Quarterly stakeholder convenings with specialty pharmacies, patient advocates, manufacturers, and Part D plans to identify emerging problems
- Rapid response authority to issue temporary modifications or waivers addressing acute access issues.
- Stakeholder reporting mechanisms for specialty pharmacies to report patient access problems, distribution disruptions, or financial sustainability concerns.

Conclusion

The National Association of Specialty Pharmacy appreciates CMS's focus on addressing Medicare Part D drug spending and improving affordability for beneficiaries. However, we are concerned that the proposed GUARD Model creates substantial risks for the specialty pharmacy channel and the vulnerable Medicare beneficiaries who depend on specialty pharmacy services.

NASP looks forward to continued engagement with CMS on the GUARD Model and stands

ready to provide additional input, data, and expertise as the agency refines this policy.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Sheila Arquette", followed by a large, stylized flourish or loop.

Sheila Arquette, R.Ph.

President & CEO