



The professional society for health economics and outcomes research

Improving healthcare decisions

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February 23, 2026

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File Code CMS-5546-P

ISPOR – The Professional Society for Health Economics and Outcomes Research - is pleased to respond on behalf of its membership to your consultation entitled “Guarding U.S. Medicare against Rising Drug Costs Model (GUARD) (CMS-5546-P).”

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ISPOR is a scientific and educational society with many of its members engaged in evaluating health technologies, including pharmaceuticals, medical devices, public health measures, and other interventions. We have a large membership living and working in 110 countries globally, across a range of disciplines, including health economics, epidemiology, public health, pharmaceutical administration, psychology, statistics, medicine, and more, from a variety of stakeholder perspectives, such as the life sciences industry, academia, research organizations, payers, patient groups, government, and health technology assessment bodies. The research and educational offerings presented at our conferences and in our journals are relevant to many of the issues and questions raised in this request for information.

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The response to this consultation was led by the ISPOR Health Policy Initiatives Team. Comments were solicited from the ISPOR Health Science Policy Council, ISPOR Corporate Partners, ISPOR Health Policy Community of Interest and the ISPOR Health Policy Working Group. The attached document provides a summary based on their comments. We hope they prove useful.

ISPOR would be happy to answer any questions about our response, or to participate in any follow-up consultations on the relevant topics mentioned within the proposed models.

Sincerely,

Robert Abbott
Chief Executive Officer
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ISPOR Commentary on the Proposed GLOBE and GUARD Models

We appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed GUARD and GLOBE payment models. CMS's interest in addressing high prescription drug spending and advancing long-term system sustainability is both timely and important.

ISPOR's vision is a world in which healthcare is accessible, effective, efficient, and affordable for all. With respect to drug pricing, we therefore believe it is important that prices reflect value to the patient – without constraining innovation in drug discovery and development. Our comments that follow are informed by this belief and reflect input from our global community of experts in health economics, outcomes research, and payer decision making.

Integration of Value Assessment

For more than 30 years, ISPOR has advanced rigorous, transparent, and evidence-based approaches to assessing the clinical and economic value of healthcare interventions [1,2,3]. These frameworks are grounded in explicit consideration of desired patient outcomes, societal preferences, opportunity costs, and context-specific willingness to pay.

The proposed GLOBE and GUARD models rely primarily on international reference pricing mechanisms and formula-based constraints. By linking U.S. payment levels to prices established in other countries, such approaches may implicitly import other jurisdictions' value assessments, social value judgements, and willingness to pay. These conditions reflect health system priorities and budgetary planning that are specific to those countries and may not align with U.S. clinical, societal, or economic contexts.

ISPOR has long emphasized that sustainable payment reform should be grounded in transparent, evidence-based assessments and clearly articulated value frameworks [4]. Consistent with this position, payment policies are most sustainable when aligned with rigorous evaluations of clinical and economic value. We therefore encourage CMS to consider how structured value assessment methodologies can be explicitly integrated into these or future payment models to ensure alignment with domestic patient needs and health system priorities. Explicit incorporation of structured value assessment would enhance transparency, reinforce domestic accountability, and help ensure that payment determinations reflect U.S.-specific evidence and societal preferences.

Impact on patient affordability

Stakeholders expressed concerns that the proposed models may not significantly reduce Medicare beneficiary out-of-pocket costs, as patient cost-sharing in many cases remains tied to list prices rather than net prices. Without additional reforms to benefit design, administrative

reimbursement adjustments alone are unlikely to translate into predictable or sustained reductions in beneficiary financial burden.

From a social welfare perspective, the effectiveness of any pricing reform should ultimately be evaluated by its impact on patients. If payment changes at the system level do not result in lower out-of-pocket obligations, improvements in affordability may be limited. Persistent cost exposure can contribute to low adherence to treatments and adverse health outcomes. Improving affordability remains a central objective of drug pricing reform and a priority reflected in ISPOR's Strategic Plan 2030 [5].

We encourage CMS to ensure that any final model is structured in a manner that demonstrably benefits beneficiaries and clearly demonstrates savings directly to American patients.

Methodological transparency and data considerations

Stakeholders highlighted the need for clearer documentation of the data sources, processing methods, assumptions, and adjustment mechanisms used to determine payment amounts. Transparency and reproducibility are essential for stakeholder confidence [6,7,8]. Concerns were also raised regarding the use of proprietary or third-party data such as clear safeguards, validation procedures, and documentation should be established prior to implementation.

Predictability and system stability.

Abrupt payment changes may influence provider behavior, site-of-care decisions, and manufacturer planning. To mitigate disruption, ISPOR recommends publishing detailed methodological specifications, conducting prospective modeling, and implementing monitoring systems to track effects of the policies on access, quality, and care settings.

Stakeholders also raised concerns regarding the downstream operational implications for providers, particularly in “buy and bill” settings where acquisition costs, reimbursement timing, and inventory management are tightly coupled. If CMS adopts reference-based pricing that diverges significantly from provider acquisition costs, clinics and infusion centers may face reimbursement shortfalls, cashflow constraints, or stocking challenges. These risks are especially pronounced in physician office oncology, rheumatology, and rare disease infusion settings, where inventory is high cost, perishable, and clinically essential. This could result in delays in patient access or disincentivize providers from administering effected drugs.

Exploring value-aligned approaches

ISPOR's longstanding position is that payment policies are most effective when explicitly aligned with structured assessments of clinical and economic value. In addition to the models under consideration, members noted that value-based pricing arrangements and value-based insurance design represent policy approaches that more directly link reimbursement to patient

outcomes and demonstrate therapeutic benefit [9].

Such frameworks are designed to align payment with value in a transparent and evidence-driven manner. As CMS evaluates pathways to improve affordability and sustainability, approaches that explicitly incorporate value assessment methodologies may offer a more direct mechanism for ensuring that payment reflects health outcomes while preserving incentives for innovation.

Implications for future innovation

Significant reductions in expected revenue may influence investment in research and development. The literature in economics consistently demonstrates a relationship between expected returns and innovative output. While cost containment is an important objective of public policy, payment reforms should carefully consider potential long-term effects on the pace, direction, and risks on medical innovation [10,11].

Pricing approaches that do not explicitly incorporate structured assessments of clinical and economic value may unintentionally reduce incentives to invest in high-impact or scientifically uncertain areas of research. Sustainable reform requires a balanced approach, improving affordability while maintaining the conditions necessary to support continued medical innovation.

Any drug pricing framework should be grounded in transparent methodology, explicit value assessment, and clear alignment between payment and demonstrated patient benefit. Policies that reflect these principles will be better positioned to achieve affordability while maintaining access and long-term system sustainability.

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