Center for Health Care Strategies

New Federal Pharmacy Demonstrations: Key Considerations for Medicaid Decision-Makers

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KEY TAKEAWAYS

- State Medicaid programs are facing sustained pressure from rising drug costs, including high-priced specialty medications and emerging cell and gene therapies, while lacking effective federal mechanisms to constrain price growth.
- New federal drug-pricing demonstrations modeled on Most Favored Nation (MFN) principles create savings opportunities, but they also raise operational, financial, and policy considerations that states should carefully evaluate before deciding whether and how to participate.
- This tipsheet outlines new pharmacy models developed by the Centers for Medicare & Medicaid Services' Innovation Center, highlights key considerations for state decision-makers, and offers a structured framework to assess participation, capacity, and strategic alignment.

State Medicaid programs are facing a period of rapid change in prescription drug pricing and payment. Drug costs have climbed steadily over the past decade — driven by forces that show no signs of slowing, including:

- The arrival of expensive specialty medications, including GLP-1 therapies;
- A growing number of high-cost, and in some cases curative, cell and gene therapies (CGTs); and
- Year-over-year brand-name drug price increases that consistently outpace general inflation.

Unlike most other high-income countries, the United States lacks a reliable federal mechanism to limit how much drug prices can rise each year, and that gap has continued to widen, placing increasing pressure on state Medicaid budgets. CGTs alone — many priced at $1 million or more per treatment — pose fiscal challenges that existing Medicaid pharmacy tools, such as prior authorization and supplemental rebates, were not designed to address. These medications represent significant advances in treatment and meaningfully improve people's lives — but paying for them within current program structures is becoming increasingly difficult.

The federal government is responding with a new drug pricing approach based on Most Favored Nation (MFN) principles, a long-standing feature of international trade. The approach seeks to align U.S. drug prices more closely with those in other high-income countries, rather than relying on back-end rebates to manage costs. While this approach may produce savings for Medicaid programs, it is not a simple fix. Analysts have raised important questions, including whether drug manufacturers could increase prices in other countries rather than lower them in the U.S., whether patient access could be affected, and whether legal challenges could limit implementation.

For state Medicaid leaders, the takeaway is straightforward: there is no easy answer to prescription drug affordability, and any new federal approach requires close consideration before states commit. This tipsheet provides an overview of the Centers for Medicare & Medicaid Services (CMS) Innovation Center's four new pharmacy demonstration models based on MFN pricing. It highlights key design features and outlines considerations to help state leaders assess whether and how to participate in these models.

What is Most Favored Nation Pricing — and Why Does It Matter for States?

Most Favored Nation (MFN) pricing seeks to align U.S. prescription drug prices with those paid in comparable high-income countries. For Medicaid programs, this represents a meaningful change in how drug costs are managed.

- **From rebates to lower prices**. Instead of relying on rebates negotiated after the sale, MFN aims to bring prices down upfront — based on what other countries actually pay.
- **A larger federal role**. CMS would take on more of the price-setting function that states have historically managed through their own supplemental rebate programs.
- **Less state control**. States may get access to lower prices, but likely with less flexibility to manage their own formularies and coverage criteria.

The four Innovation Center pharmacy models in this tip sheet are the primary vehicles for testing whether MFN-based approaches can work in practice across Medicaid and Medicare.

Innovation Center Pharmacy Models and Key Design Features

The CMS models described below reflect a common shift toward new drug-pricing approaches. While each model differs in scope and design, all are intended to lower prescription drug costs for Medicaid and Medicare by aligning U.S. prices with MFN rates — though each applies MFN principles differently. The models fall into two categories: (1) **voluntary models** that state Medicaid agencies can opt into and; (2) **mandatory models** that would primarily affect a portion of Medicaid's dually eligible populations through changes in Medicare drug pricing.

Four Innovation Center Pharmacy Models at a Glance

Model	Type	Primary Goal	How It Works	Who Is Affected
BALANCE	Voluntary	Improve access to GLP-1 therapies while managing long-term costs	CMS negotiates MFN-based GLP-1 prices directly with manufacturers on behalf of participating state Medicaid programs and Medicare Part D plans	Medicaid and Medicare* enrollees who meet overweight/obesity criteria and/or other FDA approved conditions
GENEROUS	Voluntary	Lower drug prices for Medicaid through federal price negotiation	Federal negotiation of MFN-based prices passed through to state Medicaid programs as supplemental rebates	Medicaid enrollees
GLOBE	Mandatory**	Reduce Medicare Part B drug costs through MFN-based pricing	MFN-based pricing applied to Part B drugs in randomly selected geographies representing 25% of Part B enrollees	Medicare enrollees (including those who are dually eligible) in randomly selected geographies
GUARD	Mandatory**	Reduce Medicare Part D drug costs through MFN-based pricing	MFN-based pricing applied to Part D drugs in randomly selected geographies representing 25% of Part D enrollees	Medicare enrollees (including those who are dually eligible) in randomly selected geographies

* The Innovation Center delayed the BALANCE model Medicare launch and will instead extend access through the Medicare GLP-1 Bridge program from July 1, 2026 – December 31, 2027.

** Note on mandatory models: GLOBE and GUARD apply to randomly selected geographies. When announced, states should immediately assess whether their geography has been selected and begin internal planning regardless of preference.

Decision Framework for States

State Medicaid leaders can use the questions below to guide their assessment across four decision areas. Each state may arrive at different answers based on its population, program structure, and budget.

Model	Program Fit	Readiness	Budget Impact	Access
BALANCE [Voluntary]	• Does your state cover GLP-1s for weight loss or other FDA approved indications in Medicaid? • Would broader access fit your chronic disease strategy? • Is there political will at the governor's office or state legislature to expand coverage?	• Can your claims system track GLP-1 utilization at the level CMS requires? • Do your managed care organization (MCO) contracts allow formulary changes? • Do you have care management infrastructure to support consistent prescribing and access across geographies? • Do you have the staff to manage model participation?	• What are you spending on GLP-1s now — and what happens to that number if coverage expands? • What does your actuary say about long-term medical savings from fewer obesity-related complications? • Are you evaluating this as a pharmacy cost or a total cost of care investment?	• Are there rural or underserved populations facing barriers to GLP-1 access beyond cost? • Would federal coverage criteria expand or restrict access compared to what you have now? • Do you have monitoring systems to catch access problems early if they develop? • Does your provider network have the capacity to prescribe fairly — not just in urban centers?
GENEROUS [Voluntary]	• Do you have enough Medicaid drug spend to make federal price negotiation worthwhile? • How does GENEROUS interact with your existing supplemental rebate deals — would it help or get in the way? • Are you willing to trade some formulary control for lower prices?	• Can your data systems track federally negotiated prices alongside existing rebate agreements without creating a reconciliation nightmare? • Are your MCO contracts flexible enough to absorb new federal pricing without triggering renegotiation? • Does your legal team have bandwidth to execute a new federal agreement on a reasonable timeline?	• Are MFN prices lower than your current net costs after supplemental rebates across all drug categories, or just some? • What does participation cost to administer — and does that diminish your savings? • If formulary flexibility is reduced, what does that mean for downstream medical costs?	• Who is impacted if federal negotiation leads to a tighter formulary? • Are there drug categories where reduced state flexibility would disproportionately affect your most vulnerable enrollees? • Would federal coverage criteria expand or restrict access compared to what you have now? • Do you have monitoring systems to catch access problems early if they develop?

Model	Program Fit	Readiness	Budget Impact	Access
GLOBE [Mandatory]	• How large is your dually eligible population and what share use Part B drugs? • Are high-cost Part B drugs, like oncology infusions, a significant driver of your costs for dually eligible enrollees? • If your geography is selected for mandatory participation, how will you manage implementation?	• Do you have data infrastructure to track Part B drug use by dually eligible enrollees at the geographic level CMS requires? • Are your MCOs and Part B providers, such as oncologists and infusion centers, prepared for what MFN-based reimbursement changes would mean for them? • If access problems arise, do you have systems to catch them early and escalate to CMS?	• What are you currently spending on cost-sharing for dually eligible enrollees' Part B drugs? How much of that could change under MFN-based pricing? • If lower reimbursement leads providers to administer certain drugs less frequently, where would enrollees receive treatment instead, and what additional costs could result? • Are you thinking about total cost of care, not just pharmacy expenditures?	• If MFN pricing makes it less viable for oncologists and infusion centers to administer certain Part B drugs, what happens to your dual-eligible cancer patients? • Are rural dually eligible populations especially at risk if provider participation drops?
GUARD [Mandatory]	• What share of your dually eligible population depends on Part D for specialty drug coverage? • If Part D prices change, how does that affect what your state owes for Medicare cost-sharing? • Are there drug categories where lower Part D prices would make the biggest difference for your population?	• Do you have data-sharing agreements with CMS that give you visibility into Part D utilization for your dual-eligible population? • Are your Low-Income Subsidy administration systems set up to handle changes in Part D cost-sharing? • Do you have the infrastructure to communicate changes clearly to dually eligible enrollees, caregivers, and providers?	• What are you currently paying for Medicare cost-sharing for dually eligible enrollee's Part D drugs — and does lower Part D pricing meaningfully reduce that obligation? • Are there scenarios where lower prices reduce clawback payments in ways that produce net savings for Medicaid? • What does it mean for your total Medicaid medical spend if adherence drops because of formulary changes?	• If Part D formularies shift because of pricing changes, what happens to adherence for chronic disease medications that people take daily? • Are your most complex dual eligibles — people with serious mental illness or multiple chronic conditions — adequately protected?

Considerations Across Models

Beyond the model-specific questions above, there are broader operational and strategic issues that apply across all four models. These are the kinds of issues that can make or break a participation decision — and they are best worked through at the state Medicaid agency leadership level, with pharmacy, finance, legal, managed care, and policy staff all at the table.

Operational Factors

- **Participation strategy and timing**. For voluntary models, find out early whether phased or limited participation is an option — or whether participation is all or nothing. For mandatory models, state Medicaid leadership should establish early whether their state's geography has been selected and start planning. States that engage with CMS' Innovation Center early — even just to ask questions — can gain clarity on requirements, raise implementation concerns, and identify opportunities to inform model design before they are finalized.
- **Interaction with managed care and existing programs**. In most states, model implementation will run through managed care organizations (MCOs). That means MCO contracts matter. If they are not set up to accommodate new federal pricing terms or reporting requirements, states will need to amend them, and that takes time. Before state Medicaid leadership commits to anything, they should check whether participation conflicts with their existing supplemental rebate deals, value-based contracts, or PDL structure. States should treat this as a cross-functional decision, with pharmacy, finance, managed care, and legal, and policy staff involved from the outset.
- **Data infrastructure and reporting obligations**. Every one of these models comes with data-reporting requirements — including utilization, outcomes, costs — and the bar may be higher than what current systems can deliver, especially if states are trying to connect pharmacy data to medical claims for their dual-eligible population. If states' data infrastructure is not ready, the administrative burden of participation could diminish a significant portion of any savings.
- **Manufacturer relationships and supplemental rebate implications**. Many states have built strong supplemental rebate agreements over the years and need to think carefully about how model participation might affect those relationships. Manufacturers may see federal MFN-based pricing as a reason to scale back state-level negotiations. States can prepare by understanding which of their current agreements could be affected, and whether any contain provisions that are triggered by changes in federal pricing. In some cases, current net costs after supplemental rebates may be better than what MFN pricing would produce.
- **Capacity and workforce implications**. States must be realistic about whether their teams can take this on. Participating in an Innovation Center model is not a one-time decision — it is an ongoing operational commitment that requires staff time across pharmacy, finance, managed care, and data. For states with limited staff capacity, adding model participation to existing workloads poses implementation and oversight risks. That said, capacity constraints do not necessarily preclude participation. Peer state partnerships, technical assistance, and phased participation strategies can all help distribute and manage the workload.

Strategic Factors

- **Legislative authority and legal considerations**. Depending on state law, Medicaid agencies may need legislative approval, budget appropriation, or formal legal sign-off before the state can participate. States should not assume they have the necessary authority and should confirm any legal or procedural requirements early in the process. The state's legal team should also read the participation agreement carefully, especially anything related to federal preemption of state coverage decisions, what happens if the model is terminated, and what recourse the state has in case of the unexpected. For mandatory models, it is important to understand available options if participation harms program or membership.

- **Political context and stakeholder engagement**. MFN pricing has supporters and opponents across the ideological spectrum, and participation in these models will attract attention. Manufacturers, providers, patient groups, and legislators all have a stake in how these models take shape. States that navigate this dynamic best engage stakeholders early — before a decision is made, not after. That includes MCOs, Part B providers, legislative leadership, and peer states already working through similar questions. This also includes engaging enrollees and their advocates to help design support systems that enable individuals to navigate any disruptions that may arise.

- **Multi-model participation.** Participating in more than one model at the same time might make sense strategically, but it also multiplies the operational burden. Overlapping reporting requirements, potential conflicts across model terms, and the volume of CMS engagement can be challenging to manage, especially for smaller agencies. States should carefully consider sequencing — it may be more efficient to successfully implement one model effectively before taking on another.

- **Total cost of care considerations**. One of the most significant risks for a state in evaluating these models is focusing only on the pharmacy budget. The more important consideration is how participation affects total Medicaid spending, including both pharmacy and medical costs. The value proposition of GLP-1 therapies under BALANCE is that preventing obesity-related complications — including hospitalizations, cardiovascular events, amputations — can generate savings that exceed the cost of the drugs. The same logic applies to cell and gene therapies — an expensive one-time treatment may ultimately save money if it eliminates the need for lifelong disease management. If a state's MCO contracts separate pharmacy and medical budgets, it creates a structural problem that makes it very difficult to capture, or even measure, these savings. Total cost of care must be the framework — not just for these models, but for how Medicaid approaches pharmacy more broadly going forward.

- **Federal policy uncertainty and contingency planning**. These models are demonstrations, not permanent policy. Innovation Center demonstrations can be paused, modified, or cancelled, and the broader political environment around drug pricing can shift quickly. Before committing, states should consider how they would transition out of a model if it ends or changes significantly, especially when participation may create new member expectations around drug coverage. States should also consider establishing clear processes for escalating any access or implementation challenges to CMS.

What if a State Chooses Not to Participate?

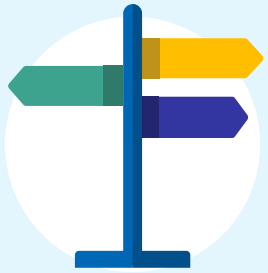
Before deciding whether to participate, states should also consider an equally important question: what happens if they do not participate? The pipeline of expensive therapies heading toward Medicaid is unlikely to slow down. Without new approaches to manage costs, states will continue to rely on tools such as prior authorization and supplemental rebates — mechanisms designed for a very different era of drug pricing.

The participation decision looks very different when states move beyond pharmacy budgets and consider total Medicaid costs. What medical costs might be avoided if enrollees have better access to effective therapies? What happens to a dually eligible cancer patient who loses access to a Part B drug because their oncologist stops administering it under GLOBE? What does the 10-year Medicaid cost look like for an enrollee with obesity who does — or does not — get GLP-1 therapy under BALANCE? Answering these questions requires a different way of thinking about pharmacy than most state programs have historically used.

States that choose not to participate in these models may be less prepared for future federal policy changes, including potential mandatory models, and may lack the relationships, data systems, and internal capacity to respond effectively.

If Full Participation Is Not Feasible: Alternative Pathways

If full participation is not realistic — because of staff capacity, legal constraints, political timing, or budget uncertainty — states have meaningful options:



- **Stay engaged without committing**. States can engage with their CMS regional office, build baseline pharmacy data, and monitor peer state activity. Staying informed keeps options open.
- **Get technical assistance**. Technical assistance and health policy organizations can help states build the internal capacity needed to evaluate and eventually participate in these models without requiring an immediate commitment.
- **Make the most of existing tools**. States can strengthen their supplemental rebate program, push harder on value-based contracting with manufacturers, and tighten their MCO pharmacy contract terms. These approaches may help generate near-term savings and strengthen pharmacy management while states develop longer-term strategies.
- **Use state voices in federal processes**. Comment periods, CMS stakeholder sessions, and advocacy through national health policy organizations give states a way to shape how these models evolve.
- **Start with cell and gene therapy**. If the broader Innovation Center pharmacy models feel too complex, the Innovation Center's Cell and Gene Therapy Access Model may offer a more manageable starting point. It addresses one of the most pressing cost challenges Medicaid programs are facing.

Looking Forward

Federal changes are coming to Medicaid pharmacy management and states will need to determine how to best respond. High-cost drugs will continue to emerge, and fiscal pressure on Medicaid pharmacy programs will continue to grow. The Innovation Center models described in this tipsheet reflect a federal commitment to test new approaches to drug pricing and reimbursement.

Whether or not states participate in these particular models, the operational and policy issues they raise are likely to become increasingly important. Strengthening data infrastructure, getting MCO contracts in order, engaging stakeholders, and developing a pharmacy strategy that is grounded in total cost of care rather than a siloed pharmacy budget lens can help states assess emerging opportunities and challenges as the federal landscape continues to evolve.