Weekly Checkup

2026 Key Areas of Interest – Drug Pricing

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In 2026, health policy has the potential to be even more tumultuous than in 2025. While the health insurance forecast seems stable (even if the end results are shrouded), the drug pricing debate recently became more convoluted with the end-of-2025 rash of model announcements and "deals" between the White House and industry. Several important debates and distinct authorities are converging in ways that are likely to force government and industry action, rather than another cycle of short-term solutions and incremental regulatory tweaks. Although most health care policy challenges emerge as political priorities based on contemporary circumstances rather than careful planning, below are some key areas to watch in the pharmaceutical pricing landscape.

Part D "Negotiated Price" Implementation and Potential MFN Realization

Beginning January 1, 2026, the Centers for Medicare and Medicaid Services' (CMS) first set of Inflation Reduction Act "negotiated prices" (Maximum Fair Prices) for 10 Part D drugs moved from policy design to operational reality, requiring implementation across plans, pharmacies, and manufacturer chargeback/discount mechanics, while potentially prompting tighter utilization management or contracting shifts as manufacturers adapt to a new government-set price in a traditionally competitive market. In parallel, the administration's most-favored-nation (MFN) push continues to signal an additional pathway that relies on "voluntary" manufacturer arrangements for government and private programs alike to adopt MFN price targets. Watch to see if MFN constructs can scale beyond discrete deals, how they interact (or conflict) with other statutory purchasing/negotiation frameworks, and whether the combined posture materially changes launch, access, or net-pricing strategies across public and commercial markets.

CMMI Model Implementation

The Center for Medicare and Medicaid Innovation (CMMI) will take on a new importance in 2026. Widely criticized as a circumspect method for implementing new policy in Medicare and Medicaid, newly announced CMMI models set up an important implementation watchlist for 2026 – both because of their operational complexity and because CMS projects multi-billion-dollar budget effects. Global Benchmark for Efficient Drug Pricing (GLOBE) is a proposed mandatory Part B model that would use international pricing benchmarks to modify inflation-rebate calculations for selected separately payable Part B drugs, launching October 1, 2026, in geographic areas covering about 25 percent of Medicare beneficiaries. CMS estimates $11.9 billion in Medicare Part B net spending savings over the model period. The new Guarding U.S. Medicare Against Rising Drug Costs (GUARD) is the Part D counterpart: a proposed mandatory model starting January 1, 2027 (with 2026 devoted to finalization and build-out), that similarly benchmarks prices internationally and applies to about 25 percent of Part D enrollees. CMS projects GUARD would reduce Medicare spending by $14.1 billion (2028–2033).

The Better Approaches to Lifestyle and Nutrition for Comprehensive hEalth (BALANCE) is structurally different – and potentially high-magnitude depending on uptake – because it directly targets GLP-1 access and pricing. CMS would negotiate guaranteed net prices and standardized coverage terms, launching in Medicaid as early as May 2026 and in Medicare Part D in January 2027, with a July 2026 Medicare bridge demonstration outside the Part D risk corridor and $50/month beneficiary cost-sharing for eligible users.

Combine all these new announcements with the previously touted models (ACCESS, GENEROUS, MAHA ELEVATE) and CMMI could be an incredibly consequential avenue to implement what should probably be done legislatively – or at least through uniform notice-and-comment rulemaking. Across 2026, watch for final rule risk (including litigation), data integrity and transparency for international benchmarks, rebate invoicing and reconciliation mechanics, and how these models interact with Part D bidding, premiums, and manufacturer behavior.

PBMs, 340B, and the Drug Distribution Stack

Pharmacy benefit manager (PBM) policy is increasingly treated as a core affordability lever, with momentum split between federal legislation aimed at rebate levels,spread pricing, and pharmacy access practices, and state-level reforms that are becoming more aggressive. In parallel, the enforcement and litigation backdrop is intensifying. The Federal Trade Commission's PBM focus has kept the rebate model on the policy agenda, even as process and governance issues affect the cadence of that fight. The 340B conflict remains the other fault line, with ongoing disputes over contract pharmacy access, manufacturer distribution restrictions, and the scope of state 340B laws, producing a

patchwork of court decisions and continued uncertainty for covered entities and manufacturers. Watch for whether Congress can consolidate competing PBM reform concepts into an actionable package, whether enforcement meaningfully changes rebate and formulary incentives, and whether the courts (or the Health Resources and Services Administration) deliver clearer rules of the road for 340B contract pharmacy and data/audit expectations.

FDA "Speed" Initiatives Versus Predictability, Evidence Standards, and Postmarket Credibility

In 2026, the central Food and Drug Administration (FDA) tension will be accelerating timelines without sacrificing the predictability that sponsors (and patients) rely on – clear evidentiary standards, consistent endpoint expectations, and credible postmarket enforcement. That balancing act is getting sharper as long-standing expedited pathways (fast track, breakthrough therapy, accelerated approval, and priority review) are increasingly complemented by newer "speed" efforts, including the Commissioner's National Priority Voucher pilot. The operational question is not just whether FDA can move quickly, but whether it does so in a way that is repeatable and defensible – particularly when applications are complex, data packages are immature, or manufacturing issues introduce quality risk. Watch for how FDA pairs speed with guardrails: more explicit expectations for "right-first-time" submissions, clearer thresholds for when expedited clocks can be extended or paused, and a firmer postmarket posture – especially in accelerated approval, where FDA has emphasized confirmatory trial requirements and the conditions under which approvals can be reconsidered. The key signal will be whether expedited decisions remain exceptional case studies – or become a broader operating model that reshapes sponsor behavior and investor expectations across the development pipeline.