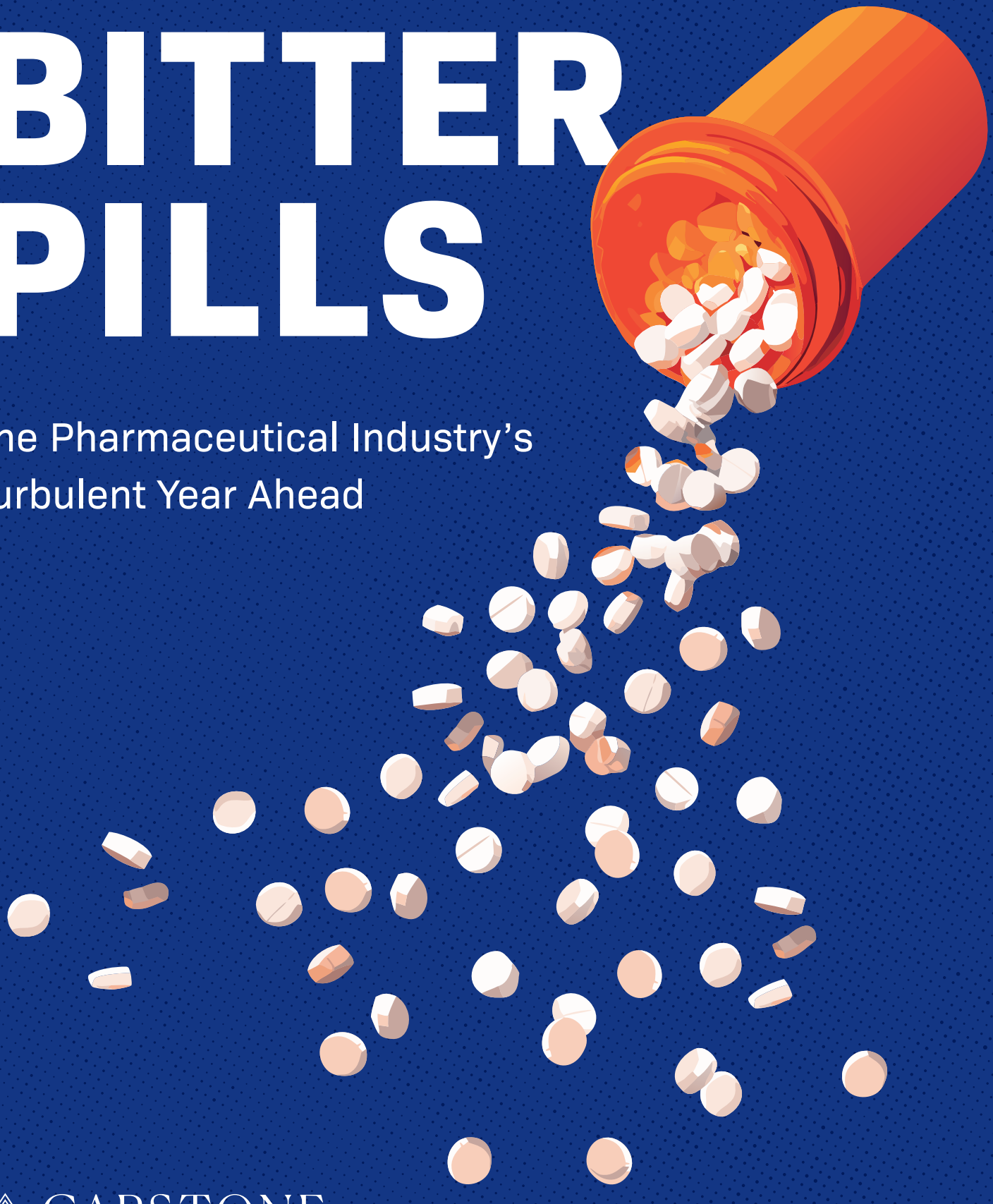
Pharma Policy 2026 Preview

BITTER PILLS

The Pharmaceutical Industry's Turbulent Year Ahead



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Pharma Policy 2026 Preview:

THE BOTTOM LINE

Capstone believes 2026 will mark a fundamental power shift in pharma economics. Policy interventions are redistributing value across the supply chain as pharmacies and wholesalers bear margin compression and drugmakers seek leverage through Most Favored Nation (MFN) frameworks. Execution risk is high as untested systems, pending litigation, and regulatory uncertainty determine whether the transition unfolds gracefully or chaotically.

Outlook at a Glance

- IMPLEMENTATION OF THE INFLATION REDUCTION ACT IMPOSES MARGIN HEADWINDS ON THE PHARMA VALUE CHAIN
- REGULATORY INSTABILITY AND GEOPOLITICAL TENSIONS CREATE EXECUTION RISK FOR BIOTECH
- MOST FAVORED NATION DEALS PROVIDE TARIFF RELIEF, BUT REVENUE THREAT TO PHARMA DEPENDS ON IMPLEMENTATION SCOPE
- GRAB BAG: OTHER AREAS TO WATCH IN 2026 AND BEYOND

Implementation of the Inflation Reduction Act Imposes Margin Headwinds on the Pharma Value Chain

COUNTING DOWN TO MEDICARE TRANSACTION FACILITATORS: CHAOS IS A RISK FOR INDEPENDENT PHARMACIES

The first IRA-negotiated drug pricing discounts (maximum fair prices, or MFPs) take effect January 1st. To implement the discounts while preserving manufacturers' Wholesale Acquisition Costs (WACs), the Centers for Medicare & Medicaid Services (CMS) is using external vendors called Medicare Transaction Facilitators (MTFs) to route chargeback payments from drugmakers to pharmacies.

Under this system, manufacturers are fully responsible for ensuring refunds reach pharmacies, even if the MTF misroutes funds. Pharmacies must finance the payment difference for up to 14 days, creating cash-flow strain that will be particularly acute for independent pharmacies.

The MTF system's complexity serves a purpose. Preserving WACs protects manufacturer revenues while preventing margin compression for pharmacies and wholesalers who rely on gross-to-net spreads. However, if the system proves dysfunctional, Capstone believes legislative intervention could eliminate chargebacks and mandate outright WAC reductions instead, a simpler approach that would drive severe margin compression across the supply chain. While Capstone views this as an edge risk, it remains a meaningful tail scenario if operational chaos demands emergency action.

IN A NEGATIVE FOR CVS, THE 340B REBATE PILOT PROGRAM WILL TRANSFORM HIGH-MARGIN BUSINESS MODEL

Contract pharmacies face potentially significant losses from the 340B rebate pilot program launching in January 2026. Currently, pharmacies generate substantial fees by capturing part of the spread between 340B-discounted acquisition costs and reimbursement rates. The pilot eliminates this mechanism entirely. Contract pharmacies will purchase IRA-negotiated drugs at full price, and covered entities will file for rebates directly with manufacturers, cutting contract pharmacies out of the transaction.

The pilot is mandatory for covered entities and voluntary for manufacturers. All eligible drugmakers chose to participate. Covered entities have raised concerns about increased administrative burden, extended rebate-collection cycles, and the potential for manufacturer disputes over unpaid rebates. Drugmakers contend that the model addresses concerns about duplicate discounts.

On December 1st, the American Hospital Association (AHA) filed suit against the Department of Health and Human Services (HHS) to block the pilot program, alleging violations of the Administrative Procedure Act. The court has not yet ruled. Capstone views the lawsuit outcome as a significant 2026 wild card with material implications for drugmakers, contract pharmacies, and covered entities.

LOWER WHOLESALE ACQUISITION COSTS REDUCE SPREAD-BASED PROFITS FOR PHARMACIES AND WHOLESALERS

In response to recent legislation penalizing high gross prices, manufacturers are voluntarily lowering WACs, narrowing the gap between gross and net prices. This behavior has accelerated following the passage of the IRA and other inflation-linked rebate programs. Over the next two months, manufacturers reportedly plan to reduce list prices for at least 13 branded drugs, and Capstone expects more drugmakers to follow suit.

This trend puts pressure on downstream participants in the pharmaceutical supply chain. Pharmacies and wholesalers typically contract based on gross pricing benchmarks or retain a portion of the gross-to-net spread. Capstone believes that as manufacturers continue to tighten this spread, participants will see corresponding erosion in gross profit.

Pharmacies, such as CVS Health Corp. (CVS), Walmart Inc. (WMT), and Cigna Group (CI), and wholesalers, including Cencora Inc. (COR), Cardinal Health Inc. (CAH), and McKesson Corp. (MCK), face mounting pressure from three converging dynamics.

First, the MTF chargeback system launching January 1st requires pharmacies to float the difference between WAC and negotiated MFPs for up to 14 days, straining working capital. It also may lead them to steer away from IRA-negotiated drugs, creating volume risk for affected manufacturers, including Johnson & Johnson (JNJ), Bristol-Myers Squibb Co. (BMY), Novartis AG (NVS), and AstraZeneca PLC (AZN). While larger chains have greater financial capacity to absorb delayed reimbursements than independent pharmacies, operational complexity is significant, and the system's ultimate efficacy remains unknown.

Second, the 340B rebate pilot program, beginning January 2026, eliminates high-margin contract pharmacy operations entirely by requiring covered entities to purchase at full price and seek manufacturer rebates directly. Already, Walgreens has stopped processing 340B claims for pilot drugs ahead of the deadline. The AHA lawsuit seeking to block the pilot is a major 2026 wild card. If the pilot proceeds, pharmacy margins face meaningful headwinds, while drugmakers benefit incrementally from added friction to providing 340B rebates and enhanced oversight over duplicate discounting.

Third, manufacturers are voluntarily lowering WACs. As gross-to-net spreads tighten, supply chain participants relying on spread-based contracts will experience a corresponding erosion of gross profit. An edge risk is that dysfunctional MTF operations may prompt further legislative intervention, requiring outright WAC reductions rather than chargebacks, which would drive severe margin compression by further collapsing spreads across the entire supply chain.

Winners	Drugmakers
Losers	Pharmacies, including CVS Health Corp. (CVS), Walmart Inc. (WMT), and Cigna Group (CI), and wholesalers, such as Cencora Inc. (COR), Cardinal Health Inc. (CAH), and McKesson Corp. (MCK)

Most Favored Nation Deals Provide Tariff Relief, but Revenue Threat to Pharma Depends on Scope

CMS WILL USE CMMI DEMONSTRATIONS TO IMPLEMENT MFN PRICING

On December 19th, CMS announced a notice of proposed rulemaking for Global Benchmark for Efficient Drug Pricing Model (GLOBE) and Guarding US Medicare Against Rising Drug Costs Model (GUARD). These mandatory CMMI demonstrations will implement MFN pricing in Medicare Parts B and D, respectively. The demonstrations will apply to a randomly selected subset of 25% of the Medicare population. Capstone believes that, if implemented, these models would materially reduce manufacturers' revenues, as Medicare net prices substantially exceed international prices.

Surprisingly, there appears to be no carveout for companies that struck MFN deals with the White House, and it appears to apply to nearly all currently marketed single-source (branded) drugs (rather than only newly launched drugs) above the spending thresholds. While CMMI has broad authority to conduct demonstrations under Section 1115A, a mandatory demonstration of this scale may exceed the intended statutory authority. We expect an immediate legal challenge from the pharma industry.

It is unclear why the administration would pursue these models now. Pharma has been cooperative with Trump's voluntary MFN framework, with the expectation that compliance would prevent precisely this sort of mandatory intervention. By initiating these demonstrations, the administration is abandoning a functional collaborative approach for a legally vulnerable, more punitive alternative.

CMS will also use a demonstration to implement MFN in Medicaid. The GENEROUS model enables MFN pricing in Medicaid. As we predicted, GENEROUS is a voluntary demonstration that allows pharmaceutical manufacturers to provide supplemental rebates to Medicaid to lower prices. The use of supplemental rebates means that these discounts are excluded from Best Price calculations, preventing additional gross-to-net losses in other channels.

TARIFF THREATS REMAIN AN OVERHANG FOR PHARMA STOCKS

Threats of tariffs on pharmaceutical products were a persistent headwind to drugmakers in 2025. Over the course of the year, it became clear that President Trump intended them as leverage to advance his broader pharmaceutical agenda. His aim was to secure more voluntary agreements to expand domestic manufacturing and ensure pricing parity between the US and non-US markets. The tariffs have not yet taken effect, but we believe the administration will continue to use trade policy to incentivize domestic manufacturing and MFN pricing.

MOST FAVORED NATION DEALS PROVIDE A PATH TO EXEMPTION

Lower drug prices have remained a policy priority of both Trump administrations. In July 2025, the president wrote directly to pharma CEOs, exhorting them to adopt a voluntary MFN framework. Relative to the risk of noncompliance—especially after Trump invoked the threat of retaliatory tariffs—Capstone considers the MFN framework to be quite manageable for drugmakers, and we believe that companies should play ball.

The administration has since struck MFN deals with 14 companies. While the contours of each deal are generally consistent with the framework outlined in the CEO letters, the deals with Eli Lilly & Co. (LLY) and Novo Nordisk A/S (NVO) introduced a highly impactful new provision: CMS has committed to covering the companies' GLP-1 products under Medicare Part D.

Coverage may begin as early as April 1, 2026, through a pilot program, potentially a voluntary demonstration through the Center for Medicare and Medicaid Innovation (CMMI). It is unclear how this demonstration would compel Part D plan sponsors and other stakeholders—which operate through a series of private contracts—to cover these drugs, especially given concerns over high usage increased plan liability for drug spending.

MEDICARE DRUG PRICE NEGOTIATION PROGRAM RAISES QUESTIONS ON MFN-MFP INTERACTION

On November 25th, CMS published MFPs negotiated under the IRA's Medicare Drug Negotiation Program for 15 drugs covered under Medicare Part D, including Novo Nordisk's Wegovy.

As an IRA-negotiated product, Part D plan sponsors will be required to cover Wegovy. However, this requirement does not override the statutory exclusion on covering drugs used for weight loss.

Beyond 2026, it is unclear how the two prices (MFP and MFN) will interact when both are in effect in 2027, especially as the negotiated MFP for a 30-day supply of semaglutide is higher ($274) than the MFN price for Medicare ($245), although the ultimate cost will vary based on dose. While CMS issued a brief statement suggesting that MFN prices would supersede those negotiated under the IRA, it remains unclear how the voluntary MFN arrangement would trump the statutory MFP.

The GLOBE/GUARD models, if implemented, would substantially lower revenues for drugmakers selling through Medicare. Our preliminary view is that, surprisingly, the demonstrations do not provide carveouts for companies that struck MFN deals. While we expect a strong legal challenge against the demonstration, implementation would be a significant headwind for pharma in 2026 and beyond.

Beyond the risk of GLOBE/GUARD, we believe the MFN frameworks are generally manageable for pharma. The Lilly and Novo Nordisk deals are uniquely favorable, offering (1) substantial new Part D market opportunities, (2) expedited approvals, and (3) a three-year tariff reprieve. For Lilly and Novo Nordisk, the net financial impact in 2026 and beyond will depend on the extent of coverage offered by Part D plan sponsors, and whether increased volume offsets the voluntary pricing concessions made to gain access to this substantial new patient population. Capstone believes that there may be a delay before the positive financial impact of higher volumes offsets the revenue pressure of lower prices.

GLP-1 coverage timing and mechanics remain uncertain. Mid-year implementation would likely require Part D plans to resubmit already-finalized 2026 bids, and it's unclear how CMMI could compel private plan participation. Should coverage proceed in 2026, we believe the impact would be negative for Part D sponsors as increased utilization likely outweighs savings from lower MFN prices across the rest of LLY and NVO's portfolios, especially under the Part D redesign that increases plan cost-sharing. We believe this negative impact may be temporary, as plans can adjust bids accordingly in 2027 and beyond to accommodate the increased utilization.

Winners	GLP-1 manufacturers Eli Lilly & Co. (LLY) and Novo Nordisk S/A (NVO), benefiting from new markets to offset voluntary price reductions.
Losers	Drugmakers (if GLOBE/GUARD go into effect) Part D plan sponsors, including Humana Inc. (HUM), CVS Health Corp. (CVS), UnitedHealth Group Inc. (UNH), and Centene Corp. (CNC), who face increased utilization if they cover GLP-1s for obesity.

Regulatory Instability and Geopolitical Tensions Create Execution Risk for Biotech

FDA POLICY CHANGES

The US Food and Drug Administration (FDA) has adopted an innovation-friendly posture, taking steps to disrupt established processes, expedite drug approvals, and ease regulatory burden. In 2026, we believe drugmakers would benefit from additional measures that streamline review or clarify approval standards. However, staff churn risks reducing the agency's efficacy. Greater leadership stability in 2026 would benefit biopharma, providing greater assurance that the "rules today" will indeed be the "rules tomorrow." At the staff level, it is not yet clear if turnover is slowing administrative operations, such as drug review timelines.

BIOSECURE ACT AND US-CHINA BIOTECH TENSIONS

The BIOSECURE Act creates manageable transition risk for biotechs exposed to Chinese Contract Development and Manufacturing Organizations (CDMOs). While the restrictions would disproportionately impact small- and mid-cap biotechs that rely on low-cost, high-quality Chinese CDMOs, we believe the generous implementation timeline provides ample opportunity for at-risk companies to shift operations to domestic or ex-China partners before the 2033 deadline.

We believe BIOSECURE favorably positions ex-China CDMOs such as Charles River Laboratories International Inc. (CRL), Fortrea Holdings Inc. (FTRE), and Lonza Group AG (LONN on the Swiss exchange) to capture market share as at-risk drugmakers pivot away from Chinese exposure in the supply chain. The prominent and popular Chinese CDMO WuXi AppTec Co. Ltd. (2359 on the Hong Kong exchange) is not currently designated as a Biotech Company of Concern (BCC), but that may change in Q1 2026. Listing WuXi as a BCC would eliminate a major revenue driver for the company, as US revenue accounted for 64% of WuXi AppTec's total 2024 sales, despite the risk of BIOSECURE.

CAPSTONE EXPECTS NATIONAL INSTITUTES OF HEALTH FUNDING TO REMAIN STABLE

As Capstone predicted, Congress rejected the Trump administration's attempts to drastically reduce the National Institutes of Health's (NIH) budget in 2025.

We consider it unlikely that Congress will make meaningful cuts to NIH funding in 2026. Not only does Congress broadly support the NIH's critical role in basic scientific research, but it also respects the economic impact of NIH funding. Major academic health centers are among the largest regional employers in many states, including the key swing states of Pennsylvania and North Carolina. Additionally, we find it unlikely that the administration will pursue, or succeed in enacting, further reductions in the indirect costs associated with NIH grants.

Winners	Ex-China CDMOs, such as Charles River Laboratories International Inc. (CRL), Fortrea Holdings Inc. (FTRE), and Lonza Group AG (LONN on the Swiss exchange)
Losers	Clinical-stage biotech companies, Chinese CDMOs, including WuXi AppTec Co. Ltd. (2359 on the Hong Kong exchange)

Grab Bag: Other Areas to Watch in 2026 and Beyond

INCLUDING THE MFP IN ASP CALCULATIONS MAY DESTABILIZE COMMERCIAL REIMBURSEMENT BENCHMARKS

Manufacturers must include IRA-negotiated MFPs in Average Sales Price (ASP) calculations, immediately lowering reported ASP for negotiated drugs. This creates two direct impacts once Part B MFPs become effective in 2028: (1) lower revenue for Part B manufacturers, and (2) margin compression for physicians and providers who earn the same percentage spread on a lower ASP base. We expect pressure on manufacturers of IRA-selected Part B drugs once they are announced by February 1st.

The disruption extends beyond Medicare. Commercial and Medicare Advantage plans rely on ASP as the primary pricing benchmark in reimbursement contracts. With CMS publishing only MFP rather than ASP in quarterly pricing files starting in 2026, payors lose their standard benchmark, creating three potential outcomes for commercial contracting:

- Commercial payors default to MFP as a new benchmark. Capstone believes this will be negative for Part B manufacturers, while providers see lower gross profit (but stable margins).
- Commercial payors freeze contracts at the last published ASP. Capstone believes this is unlikely but neutral for manufacturers and providers in the short term.
- Market shifts to alternative pricing benchmark (e.g., Average Wholesale Price). Capstone believes this outcome would be favorable for all stakeholders. However, it would require significant coordination. Progress towards such a solution is an area to watch in 2026.

Congressional intervention represents a wild card. Representative Greg Murphy's (R-NC) Protecting Patient Access to Cancer and Complex Therapies Act would maintain physician reimbursement at ASP+6%, rather than shifting to MFP+6%. The bill has gained limited traction to date, but we are continuing to monitor it in case it gains traction.

Winners	None
Losers	Part B Manufacturers selected for IPAY 2028 Providers with significant Part B drug exposure

PBM REFORM LIKELY MODEST DESPITE CONSTANT LAWMAKER SCRUTINY

Congressional reform remains a perennial threat to the operations of Pharmacy Benefit Managers (PBMs). Their perceived role as middlemen, concerns over business practices and consolidation, and strong lobbying efforts from hospitals and pharmaceutical companies eager to shift blame for high drug costs ensure constant attention from lawmakers and regulators.

Bipartisan PBM reform bills (Pharmacists Fight

Back Act and PBM Price Transparency and Accountability Act) introduced towards the end of 2025, while unlikely to pass, set baseline expectations for 2026 efforts. Capstone believes that, while incremental reforms are plausible, drastic federal overhauls remain unlikely. We expect the most likely reforms will focus on transparency requirements. More aggressive structural changes face significant political and practical hurdles.

PBMs are adept at navigating policy headwinds. Sustained regulatory pressure has pushed PBM operations towards greater transparency and alternative pricing models, as they seek to demonstrate enough self-reform to avoid a legislative crackdown and keep earnings drivers one step ahead of potential regulation.

PBMs offering more transparent pricing models have gained market share, pushing larger PBMs to respond in kind. Cost-plus arrangements, such as Mark Cuban's Cost Plus Drugs, have gained traction by offering more transparent generic pricing rather than spread-based economics. Traditional PBMs, meanwhile, have launched early iterations of pass-through pricing options for employers, though uptake remains limited.

Winners	None
Losers	PBMs, such as UnitedHealth Group Inc. (UNH), Cigna Group (CI), CVS Health Corp. (CVS)

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