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The Policy-Driven PMA Pivot Series

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A compilation of "The Policy-Driven PMA Pivot" series

April 2026

WHITE PAPER

Is "Net First" Pricing an Impending Strategic Imperative or a Policy-Induced Mirage?

Introduction

Market access has become one of the most critical determinants of a successful pharmaceutical launch in the United States. However, developing an effective market access strategy has grown significantly more complex over the past decade. Rising healthcare costs, gaps in coverage from traditional health plans, and margin pressures for manufacturers have accelerated complexity as well as the demand for solutions that best serve patients and support industry-wide innovation.

Historically, the expectation from key value stakeholders was clear – enable rebates across the value chain to unlock access and minimize management. For many years, the GTN bubble grew, perhaps to unsustainable levels on this basis. Could recent market evolution (e.g., policy, alternative channels) potentially signal the end of the "high list, high rebate" era, as stakeholders across the value chain demand lower costs and better value from therapeutics? Alternatively, is this just another fleeting scenario tied to the ever-evolving policy landscape?

Policy Drivers: Recent policy developments are accelerating pressure toward a lower list-price, lower-rebate - "net-first" - pricing model. Policies such as Most-Favored Nations (MFN) pricing—linking U.S. prices to the lowest prices paid in other developed countries—have gained traction under the current administration. In May 2025, an Executive Order introduced MFN pricing principles and emphasized efforts to "remove the middleman" in pharmaceutical pricing. This was followed by letters sent to major pharmaceutical companies in July 2025 reinforcing demands for MFN pricing. In the months that followed, the administration launched TrumpRx, a cash-price aggregation platform, and advanced several CMMI pilot programs (e.g., GLOBE and GUARD) designed to test MFN-aligned pricing models in select government channels.

Further, the Consolidated Appropriations Act of 2026 and a landmark FTC settlement with Express Scripts signal potential reform of the PBM rebate model. The legislation requires 100% rebate pass-through to health plans and promotes a transition toward flat-fee PBM compensation structures to increase pricing transparency. In parallel, the FTC settlement is expected to introduce a standard formulary offering that does not prioritize high list-price, high-rebate therapies.

These recent policy developments compound the drug pricing pressure introduced by the prior administration through the Inflation Reduction Act. Together, these policy shifts are increasing momentum toward a potential "net-first" pricing framework in the U.S. pharmaceutical market.

Alternative Channels: New access models beyond traditional channels—such as Direct-to-Patient (DTP), Direct-to-Employer (DTE), Cost Plus, and Cash Pay—have also emerged in response to shifting market dynamics and are enabling patient access at potentially lower net prices. Historically, PBMs and some health plans favored high list-price, high-rebate structures. In contrast, these alternative channels give patients greater autonomy to compare and select lower-cost options for their therapies. As these models gain traction, they are expanding viable pathways for manufacturers to adopt lower list-price—or "net-first"—pricing strategies that were previously difficult to implement at scale.

This white paper series will explore the factors that may be moving the industry towards a radical shift away from list prices and where a lower list, lower rebate strategy could meaningfully improve access, and as importantly, where it should not be employed. We'll seek to understand if the 'lower list, lower rebate' strategy is a meaningful go-forward approach or just a current pharma pricing trend.

INFLATION REDUCTION ACT IN 2026: STRATEGIC CONSIDERATIONS FOR PHARMA

Since its enactment in 2022 under the prior administration, key drug pricing provisions of the Inflation Reduction Act (IRA) have been fully implemented, including Part D Redesign in 2025 and the first 10 CMS-negotiated maximum fair prices (MFPs) for drugs in initial price applicability year (IPAY) 2026. CMS has also negotiated an additional 15 Part D drugs for IPAY 2027, with an additional 15 drugs, including Part B therapies, selected for negotiation for IPAY 2028. While the practical implications of each of these policies (Part D Redesign, CMS Price Negotiations) by themselves have been discussed by Triangle Insights previously, the interplay between these policies is increasingly important for manufacturers to consider, given new policies implemented by the current administration in recent months. **Since the IRA became fully implemented, Triangle Insights has seen a dichotomy of incentives emerge between the two IRA policies (a signpost for other policies to come later in this series) that serve to place pressure on manufacturers as they determine their pricing and contracting strategies ahead of launch into the Medicare markets and as they competitively contract within the market.**

CMS Price Negotiations – Dichotomy of Incentives with Provider Demand for IPAY 2028

One of the key practical outcomes of IRA was to eliminate the gross-to-net (GTN) differential for the highest-spend pharmaceuticals in Medicare (CMS Price Negotiations), helping CMS reduce reinsurance for specialty drugs, and patients reduce their OOP cost sharing for retail and specialty-lite drugs. This lower-price, lower-rebate contracting approach accomplished that objective in 2026, with the average absolute reduction in price coming in at ~13% below estimated Part D rebates.[1] However, since manufacturers are not obligated to share in statutory Part D Redesign costs (i.e., Manufacturer Discount Program cost-sharing obligations) once negotiated, the impact on their margins is expected to be less than the reported discount for retail and specialty-lite drugs and may even be minimal for specialty drugs – benefiting the bottom line for the negotiated drugs along with patients and CMS.

Competitor manufacturers, however, may require higher rebates to compete with CMS-negotiated drugs as well as higher patient assistance program (PAP) spend to drive conversion to paid scripts, since the CMS-negotiated drugs are guaranteed coverage in Medicare and carry a lower OOP cost for patients at the point of sale (potentially driving volume plays for drugs that previously faced coverage challenges). These risks have only increased in the most recent round of CMS negotiations (IPAY 2027), where the average absolute reduction in price is much higher than that observed in IPAY 2026.[2]

However, the real impact comes at the expense of institutional payers – certainly MCOs, who lose out on valuable rebate dollars, but also providers, who lose out on margin with MFP-based reimbursement in Part B. Importantly, 92% of providers in a recent survey suggest that they may may stop stocking Part B drugs subject to negotiation – underscoring the dichotomy of incentives that has emerged from IRA, with severe implications for Part B drugs selected for IPAY 2028.[8]

Part D Redesign – Dichotomy of Incentives with CMS Price Negotiations

Payer burden from CMS price negotiations compounds with the multitude of requirements from Part D Redesign – an annual cap on patient OOP spending at $2,000, fewer rebates from manufacturers overall, and a higher up-front cost-sharing obligation in catastrophic coverage. At the time, many in the industry anticipated that increased payer cost burden exposure would translate into heightened rebate demands across books of business.

However, recent industry analysis shows that this has not broadly materialized. Rather than uniformly increasing rebates, many payers are pursuing alternative strategies to offset their higher cost exposure – such as by introducing or increasing coinsurance to shift more cost-sharing back to patients, or exiting the Part D market altogether, with the number of PDPs declining by 55% since the passage of the IRA[7]. These trends persist despite substantial increases in up-front direct subsidies from CMS that effectively counterbalance the losses in reinsurance payments to payers.[3] In essence, as Part D plans have seen increasing up-front costs and decreasing back-end support, the new Part D landscape has exceeded their risk tolerance.

Further, the Part D Redesign itself may not actually in practice incentivize the **lower-list, lower-rebate** contracting approaches motivating CMS Price Negotiations. As reported extensively by the team at Drug Channels, once changes in direct and indirect remuneration (DIR; i.e., the share of rebate dollars flowing to Part D plans vs CMS) are factored in, specialty drug manufacturers may be incentivized to implement **higher-list, higher-rebate** pricing strategies.[4] Thus, the dichotomy in incentives persists in the market – while many notable list price reductions for branded drugs have been publicized in the past few years,[5] an order of magnitude greater number have increased their WAC in just the first week of 2026.[6]

Implications of CMS Price Negotiations and Part D Redesign on Competitive Manufacturers

What Triangle Insights is seeing from the interplay between these two policies as they have been fully implemented (Part D Redesign, CMS Price Negotiations) is a signpost of broader challenges facing pharmaceutical manufacturers as they develop their pricing strategies. We routinely receive the following questions from our clients:

- "How do policies like IRA complicate the gross-to-net incentives in the market today?"
- "What interplay in incentives does IRA have with other policies (e.g., MFN, O3BA)?"
- "How should I price my products to be competitive in the context of these policy dynamics (high-list/high-rebate vs low-list/low-rebate)?"

As we continue this white paper series, we'll build upon the dichotomies from this discussion as we consider MFN and DTP/DTE emergence, ultimately building toward a framework for manufacturers to consider as they attempt to tackle these challenges.

Strategic Considerations

1. **MFPs Shaping Indication Price Corridor:** Manufacturers with drugs in therapeutic areas that will have MFPs implemented should be aware of possible reduced pricing potential for pipeline drugs and increased rebate demands for inline drugs

2. **Potential for Increased Patient Cost Burden:** As payers attempt to shift cost-sharing back to patients across channels to compensate for losses in Medicare, early-year abandonment rates may increase for Medicare patients, and additional Commercial copay support may be needed to ensure prescription fulfilment

3. **Deflation of the GTN Bubble:** As CMS Price Negotiations start to deflate the gross-to-net bubble, the bargaining power provided by rebates may be declining for certain drugs (e.g., retail, specialty-lite); manufacturers may need to consider low list/low net strategies, and adjust their copay spend (rather than rebates) in their forecasting to focus more on maximizing volume rather than price

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MOST-FAVORED NATIONS (MFN) POLICIES IN 2026: STRATEGIC CONSIDERATIONS FOR PHARMA

Months of anticipation following the current administration's MFN executive order and letters to 17 top pharmaceutical companies has culminated in the past quarter in three CMS reimbursement models – GLOBE (Part B FFS), GUARD (Part D), and GENEROUS (Medicaid). These current administration policies tackle a much larger cross-section of US drug prices, benchmarking to exchange rate- and purchasing power parity-adjusted prices observed in a basket of economically comparable countries and adding a global pricing comparator to the domestic framework established by IRA under the prior administration. **Though the models are selective in the scope of their impact (GENEROUS is voluntary, while GLOBE and GUARD impact only ~25% of Part B FFS and Part D beneficiaries, respectively), they represent a continuation of the dichotomy we discussed in our most recent piece on IRA – a push for lower drug prices and volume-driven markets even as their initial impact leads to higher rebates, and an increasingly confounding policy environment for manufacturers to launch and contract within.**

GENEROUS – A Potentially Counterintuitive Increase in Spend for Medicaid Payers

The first of the current administration's MFN models to be released, GENEROUS is unique compared to GLOBE and GUARD primarily in two capacities: (1) it is voluntary rather than mandatory, and (2) it is collaborative in access rather than simply being prescriptive in pricing. As manufacturers' drugs are being evaluated for potential pricing reductions under the MFN model, manufacturers are also given the opportunity to negotiate with state Medicaid agencies for access benefits such as PDL placement and reduced utilization management.

These factors should raise a complicating question in the minds of manufacturers (and payers) with meaningful Medicaid volume in their books of business – is there opportunity for manufacturers to increase access and unlock demand as drug prices are reduced? Triangle Insights anticipates that MCO payers (who are subject to state Medicaid agreements with manufacturers under GENEROUS) will be less enthusiastic about potential increases in spend that may result from highly managed drugs in Medicaid today. Expensive medications in therapy areas such as psychiatry often involve complicated prior authorizations and multiple step therapy requirements – improved access to expensive treatment options, even at reduced prices, could still end up costing Medicaid payers more in the long run.

GLOBE, GUARD, and GENEROUS – Dichotomy of Incentives for Pharmaceutical Pricing Strategy

However, while GENEROUS may provide opportunity to increase volume at the expense of price, it (as well as GLOBE and GUARD) still fundamentally operates as a supplemental rebate agreement from manufacturers – increasing gross-to-net (GTN) spread rather than lowering net prices. Since model rebates are paid to CMS rather than exposed to the broader drug channel, little behavioral incentive exists for manufacturers (many of whom have struck confidential deals with the Trump administration) to change their current pricing approaches absent competitive forces (e.g., new transformative drug launches at close-to-net prices).

While the stated objectives of the current administration for GENEROUS (voluntary) and GLOBE and GUARD (minority of beneficiaries impacted) were to lower the price of pharmaceuticals for patients,

the practical reality of designing the models as rebate agreements serves only to increase the GTN spread in the market overall. Triangle Insights anticipates that these competing incentives will come in conflict as transformative therapies come to market:

- "Will lower list prices be favored to align with ex-US markets?"
- "Or, will manufacturers continue to leverage supplemental rebates to follow the incentive structures set by Part D Redesign and at play in the Commercial channel?"

As we continue the white paper series, we'll explore the extent to which rebate incentives, particularly in the Commercial channel, are expected to persist or transform in the coming years – driven by federal rebate reform and the emergence of the direct-to-patient (DTP) channel.

Strategic Considerations

1. Manufacturers must apply to participate in the GENEROUS Model by April 30th, 2026 to offer MFN prices to state Medicaid programs through supplemental rebate agreements (which include the opportunity to negotiate for improved coverage and management)

2. Manufacturers in GLOBE and GUARD will owe the greater of a) the MFN-adjusted weighted-average net price across included countries, and b) the difference between US list price and the lowest MFN-adjusted benchmark price across included countries – careful analysis of which scenario is more favorable (based on the therapeutic area, book of business, and reference countries involved) as well as potential spillover effects (e.g., disclosure of confidential discounts to different reference countries) will be critical

3. Manufacturers will face pressure to avoid "outlier low prices" or delay launch in certain markets – careful analysis of each product's clinical and economic value proposition in each market will be important to consider for specific ex-US launches (or launching ex-US in general)

ALTERNATIVE CHANNELS: NOISE VS. A REAL STRATEGY?

Alternative access models have begun to emerge to challenge the traditional PBM-rebate pricing structure that has historically governed how patients access medications in the US market. Whether in response to the shifting policy landscape or as an independent indicator that the GTN bubble was becoming unsustainable, these models offer increased transparency and more choice in accessibility to therapy. But do they really unlock additional access or represent a shift in how manufacturers should think about gross-to-net? Reading between the lines, are these channels "noise" in an ever-complex market access environment or do they realistically open a new strategic lever for manufacturers?

As previously discussed in this series, there are occasionally dichotomous incentives around pricing created by recent policies in the US (e.g., high list high rebate strategies supported by Part D Redesign while lower list lower rebate strategies are incentivized by CMS Negotiations and MFN models). While the dichotomy around pricing strategy remains, these alternative channels potentially enable manufacturers to meaningfully execute on 'lower list, lower rebate' strategies that previously faced barriers given the importance of the PBM relationship within the value chain.

This paper will explore three alternative channels and the potential considerations to evaluate before pursuing each: Cost Plus Models, Direct-to-Patient (DTP) Models, and Direct-to-Employer (DTE) Models.

Cost Plus

The concept of Cost Plus Pharmacies emerged (e.g., Mark Cuban Cost Plus Drug Company) prior to many of the policies reflected in our white paper series to-date, reflecting the challenges emerging with drug pricing and the implications for many patients (i.e., high OOP based on list pricing when paying with insurance). Cost Plus models focus on transparent pricing using a cost plus set fee model that is available to the consumer. While this model has improved access to therapy for many patients with high-deductible plans or uninsured patients, there has been limited traction in the branded drug market, leaving the newest therapeutic innovation available through standard channels and subject to the GTN bubble. In a "net first" world, there may be more incentive for manufacturers to engage with Cost Plus Pharmacy models to offer their products to patients at the same price they are contracting with insurers.

Cash Pay and DTP

While cash pay is not a new concept within the pharmaceutical industry (patients have long been able to acquire certain therapies – those that are deemed lifestyle or non-covered – at cash prices), there has been an increasing focus and utility of the cash pay channel in the past 12 months. The market was likely primed for increasing cash pay options given growing GTNs, evolving pharmacy models, and the rise of punitive plan tools such as accumulators and maximizers. The cash pay and DTP emergence was further fueled by recent policy and executive orders (e.g., MFN pricing, TrumpRx, Letters to Large Pharma).

DTP models represent a broad umbrella of prescribing and distribution approaches that ultimately enable a patient to pay cash for their prescription therapy without submitting a claim to their insurance. Additionally, DTP often, but not always, involves integrations that have empowered patients to own their healthcare decisions (e.g., consumer-like telehealth platforms).

With the increase in DTP demand, the capabilities (e.g., prescribing & telehealth, pharmacy, cash transactions) to efficiently execute these models have rapidly expanded. Some pharmaceutical companies have built internal capabilities to facilitate components of DTP access. Even the government has become involved, launching TrumpRx, a federal aggregator of "MFN" drug prices that often links patients to either coupons or cash pay sites for their prescription therapies.

A key component to explore when evaluating cash pay / DTP feasibility will be the underlying population readiness to engage in these channels and the implications for volume/price trade-offs. Further, there may be downstream implications on reducing volume through traditional insured channels in favor of DTP (e.g., PBM/plan push back on lack of visibility, limited member continuity, and reduction in rebates as manufacturers shift resources to build DTP infrastructure). As it stands today, the DTP channel may be most feasible for a targeted set of product archetypes or an alternative strategy that is triggered later in the product lifecycle.

Direct-to-Employer

A more novel access model has recently emerged, led by some of the obesity therapy manufacturers, to offer Direct-to-Employer platforms. For this innovative access channel, manufacturers partner and contract directly with employers to bypass the PBM model altogether. The intent of these models is to reduce costs and drive price transparency for the employer, particularly in higher cost or highly prevalent categories.

These models could enable more predictable pharmaceutical spend for employers in certain categories and avoid the temporal component associated with rebates that are passed through by the PBM in the traditional model. Similar to DTP, this model has substantial nuance in how it can be deployed and there are still outstanding questions that remain as this model emerges. For example, how will member cost-sharing influence deductibles? And what are the downstream implications on the PBM-Employer relationship?

Alternative Channel Considerations and Implications

Despite the fervor surrounding alternative or innovative access strategies, it remains to be seen if these models offer a real strategic path to decrease US prices by removing intermediary rebates or ultimately serve as increasing complexity and noise in the marketplace. For example, as you evaluate the therapies that have been offered as DTP or cash prices to-date, they are overwhelmingly therapies that fit into a few product archetypes:

1. Medications without meaningful insurance coverage (e.g., obesity and fertility medications)

2. Medications towards the end of the product life cycle offered via cash pricing as a life-cycle management or share preservation option

3. Medications with existing high GTN spread where the product can be offered at the current net price as a cash price to patients with little additional concession

At this point, it will be important for manufacturers to critically evaluate if and when alternative channel strategies are worth the investment. Further, manufacturers may have to be willing to place bets on more novel pricing strategies (i.e., lower list, lower rebate) to optimize use of alternative channels to drive patient access.

For example, manufacturers must meaningfully consider the cost and volume trade-off that arises when pursuing these alternative access avenues for products that do not fit into the above archetypes (e.g., launch brands, limited GTN erosion). Reasonable cash prices for the manufacturer may still result in higher OOP exposure than most patients are accustomed to, reducing demand. Further, DTE arrangements could have negative implications on PBM-Manufacturer relationships and contracting if these arrangements and platforms expand into a meaningful share of the PBM business.

While these channels do create meaningful additional avenues to unlock patient access, we at Triangle Insights Group believe these channels must eventually be combined with continued meaningful pricing and PBM reform to truly drive change in the marketplace and genuinely unlock 'low list, lower rebate' pricing strategies. Until those market factors align, these additional channels are likely to remain as alternatives for specific product archetypes.

In the absence of major market reforms (e.g., PBM reform), we could also envision these channels serving to further fragment the US market. For example, manufacturers may start to consider multiple channels throughout the lifecycle of a therapeutic to manage GTN or coverage depending on their relevant patient population(s).

We'll be watching for market signs that suggest these access channels (DTP, DTE) unlock meaningful strategic value across more product archetypes but in the meantime, these channels may be self-limiting to a smaller set of product categories.

In summary, for manufacturers exploring alternative channels, it will be critical to evaluate the product and market characteristics to determine if these channels unlock access or create complexity. Manufacturers should have solid expectations of anticipated coverage and GTN over the product life cycle to determine if (and when) new-to-market brands should invest in these alternative channels and which channel will be most meaningful. Connect with Triangle Insights Group to define realistic, strategic, and actionable access channel strategies.

Strategic Considerations

1. As manufacturers consider investing in alternative channels for new product launches, they should carefully consider the cost and volume tradeoffs that may result.

2. The implications on stakeholders across the value chain should be carefully integrated into alternative channel planning (e.g., PBM/plan pushback, potential lack of impact on deductible for patients when pursuing DTE)

3. Careful review of the underlying product, market, and patient characteristics to determine readiness for engagement with alternative channels.

4. Execution considerations should be tailored to the product and patient population to bring an alternative channel strategy to the market (careful consideration of required tech platforms, partnerships, integrations with existing infrastructure, and data demands)

REBATE REFORM

The combined forces of federal legislation (impacting all PBMs by requiring 100% rebate pass-through and flat-fee compensation structures), and the settlement outcomes of the FTC's suit with Express Scripts, one of the largest PBMs (requiring a standard formulary offering that does not prioritize high list-price, high-rebate therapies) are some of the newest developments accelerating the pressure toward a "net-first" pricing framework, at least as far as PBMs are concerned.

Should these forces play out as intended, PBMs—particularly CVS Caremark, Express Scripts, and OptumRx—could lose significant revenue from hidden fees, rebates, and spread pricing. On the other hand, while the hope is that independent pharmacies, patients, and employers could benefit from increased price transparency, the end of spread pricing, and lowered out-of-pocket drug costs, the reality could be that employers will have to raise premiums in a net-first model to compensate for lower patient cost-sharing, overall plan spend may increase due to reduced patient abandonment, and pharmacies' total reimbursement and margin may decrease.

Consolidated Appropriations Act (H.R. 7148, signed into law on February 3, 2026)

Reining in drug costs has long been a bipartisan priority for lawmakers. PBMs in particular have been a focus of attention for reasons ranging from their business practices, market consolidation, and lack of transparency; all of which factor into concerns about the role that PBMs have played in increasing drug prices. In February of 2026, Congress enacted several PBM-related provisions in the Consolidated Appropriations Act of 2026, which includes provisions that will delink PBM compensation from the price of a drug or rebate arrangements. It also requires PBMs to pass through 100 percent of rebates to employer health plans, and increases oversight of PBM services through transparency and data reporting requirements.

Triangle Insights anticipates that actions to increase PBM transparency and moving to a net-first pricing environment will not necessarily translate into lower costs for employers and patients. Narrowing gross to net requires bargaining power, and the reforms as currently contemplated, while they do potentially weaken the bargaining power of the PBMs, may give more power to the drug manufacturers , rather than patients and employers (who, for example, may see higher premiums and higher plan spend, respectively).

As an illustration, imagine a hypothetical drug with a $500 monthly WAC. If, in the current model, there is a 20% ($100) rebate, and patient coinsurance is 20% ($100), then the net cost to the PBM for this drug is $300 per month. In a net-first model, that same drug would be priced at $400 per month, and patient coinsurance of 20% ($80) would put the net cost to the PBM at $320 – an increased liability to the PBM which will likely result in new fee structures.

FTC settlement with Express Scripts

The FTC's landmark settlement with Express Scripts is a direct challenge to the foundational economics of PBMs. While the settlement specifically applies to Express Scripts, it signals a broader shift toward net-first pricing and away from the opaque rebate- and spread-driven models that have long dominated the market. The settlement calls for a "Standard Offering" to plan sponsors that includes requiring that out-of-pocket costs are based on a drug's net cost, and access to an insulin savings program. This "Standard Offering" would be an option available to all plan sponsors.

Though considered a landmark settlement, PBMs have seen these shifts coming. Many have already

begun adjusting their models; to wit, the Evernorth (Cigna's health services division) Rebate-Free Pharmacy Benefit model. Many core components of the FTC settlement shared design elements consistent with this new benefit design.

Triangle Insights anticipates that while the outcomes of the settlement can help shield patients and plans from the excesses of the gross-to-net bubble, the "Standard Offering" contemplated by the settlement is not universal, and the "Meeting Competition" clause of the settlement (Section XI) could provide a path for Express Scripts to make minimal changes to its overall business practices. As the "standard offering" is simply an option sponsors can request, Express Scripts could find innovative ways to convince sponsors to continue with their existing formulary design (perhaps by incentivizing benefits consultants/brokers to keep the status quo). Further, the settlement still leaves opportunity for inflated pricing: it does not address the value PBMs can gain by holding onto rebate dollars over time before passing them back to clients; nor does it address that other stakeholders in the supply chain, such as wholesalers, will try to maintain current revenue streams (potentially by taking a larger percentage of the drug's price), and that patients may be facing premium increases if plan spend increases.

It remains to be seen whether the "Standard Offering" will become the norm. If it gains broad market acceptance, a meaningful change in PBM contracting dynamics, rebate strategies, and pricing models could result. However, if most plan sponsors opt for alternative arrangements, reform may be limited, and most (if not all) traditional PBM practices could persist. Thus the settlement's ultimate impact on a manufacturer's pricing and rebate strategy will largely depend on whether sponsors migrate to the Standard Offering, and the outcome of any additional settlements reached with the other large PBMs.

For pharmaceutical manufacturers, this is not a PBM problem to watch from the sidelines. It will require manufacturers to reassess their pricing and contracting strategies, understand the impacts on channel strategy, and ultimately determine how to compete for access while keeping an eye on where the squeeze will come next. The FTC's action, combined with mounting legislative pressure and public scrutiny, is forcing a redefinition of how value is created, measured, and monetized across the drug distribution ecosystem.

Strategic Considerations

1. PBMs are likely to adapt their business models in a number of ways to a net-first world; manufacturers should prepare individual products and the portfolio at large for how different scenarios may unfold, and be aware of other avenues PBMs may use to extract economic value from their customers beyond GTN

2. At the product level, manufacturers should adapt their contracting and pricing strategies to a net-first pricing framework, as well as consider other levers their products will need in order to compete in a net-first environment

3. Manufacturers should also determine how their overall channel and distribution strategies might need to be adjusted under a net-first framework

4. Manufacturers need to determine if they should change their focus or strategy with respect to self-insured employers, who may either switch to the redesigned PBM model or maintain bespoke formularies and benefit designs

5. Beyond PBM reform, manufacturers will need to keep an eye on where the next drug pricing and access reforms) will come from, and how to respond

COMPOUNDING EFFECTS OF POLICY ON MANUFACTURERS/PRICING + ACCESS LANDSCAPE

While this series has examined the impact of individual policy changes, assessing them in isolation provides only a partial view. In practice, manufacturers will contend with the compounded effect of these policies, as their interdependencies and reinforcing dynamics collectively redefine the pricing and access landscape. The combined effects of the IRA, MFN, FTC actions, PBM reform, and related policies are expected to drive several structural shifts. Most notably, they may contribute to a bifurcation in pricing models – accelerating a transition toward "lower-list, lower-rebate" frameworks for some product archetypes, while reinforcing the persistence of "high-list + rebate" models for others. This dynamic is explored further through two illustrative analogues later in this paper: GLP-1s in cardiovascular-renal-metabolic conditions, and CD20-directed therapies in autoimmune CNS disease. Beyond pricing, these intersecting policies introduce a set of multiplicative pressures, including heightened constraints on manufacturer economics and value expectations, as well as an imperative to evolve channel and access strategies.

With respect to constraints on manufacturers, the IRA-driven redesign of the Part D benefit has materially increased plan liability, contributing to an exodus of payers from the Part D market. This shift is likely to introduce new affordability challenges for patients, as product-specific access becomes more fragmented and less predictable for Medicare beneficiaries. At the same time, the effect of increased financial exposure from the IRA is compounded by MFN-driven price transparency and further heightens payer sensitivity to higher prices. Together, these dynamics raise the bar for manufacturers to demonstrate value through more rigorous clinical evidence, clearer differentiation, more robust real-world evidence strategies, and, in some cases, innovative portfolio-based contracting approaches, particularly in competitive markets with low-cost generics or entrenched brands. In effect, manufacturers will need to be prepared to operate with reduced pricing flexibility and rising evidence expectations, necessitating tighter coordination between access and medical/HEOR functions, along with more dynamic and continuous price sensitivity assessment as the landscape continues to evolve.

Concurrently, disruption of the traditional PBM model for certain product archetypes is driving margin compression and prompting a fundamental reset of pricing and access strategies. As PBM reform intersects with the rise of HDHPs/HSAs1 and increased momentum toward direct-to-consumer distribution spurred by MFN transparency and emerging direct distribution models (e.g., Cost-Plus, TrumpRx), new stakeholders, including patients and employers, are taking on a more prominent role in decision-making. In this evolving landscape, manufacturers will need to shift from a primary focus on PBMs and rebate optimization toward a more holistic channel strategy, including investment in direct-to-consumer and direct-to-employer capabilities, reimagined patient support and hub models, and a more deliberate evaluation of which products may benefit from direct distribution as a margin defense strategy.

Ultimately, navigating this increasingly complex policy environment will require a product- and archetype-specific approach, as well as a partners capable of helping patients navigate alternative channels. Key considerations, including benefit design, channel and book-of-business mix, therapeutic areas and indications of focus, and competitive intensity, will inform the most effective path forward for pharmaceutical manufacturers. The following sections begin to outline archetype-based

strategic imperatives in more detail, reflecting the types of strategic questions and analyses Triangle addresses in close partnership with clients.

Compounding Policy Effects on Price and Access: Archetype Case Studies

To emphasize the interplay of these policies and understand the impact on pricing and access strategy, consider two product archetypes: a product appropriate for a "lower-list, lower-rebate" ("net first") strategy vs a more traditional "higher-list + rebate" strategy.

Example characteristics of a product that may be more likely to implement a "lower-list, lower-rebate" pricing strategy include products with [1] significant potential market share in government channels (particularly Medicare/Medicaid), [2] access restrictions that may encourage distribution through alternative access models, [3] a large patient population with [4] appetite for purchasing through alternative channels (particularly for "lifestyle," acute/on-demand, or retail-priced products for younger adults), and [5] a GTN that limits patient willingness to pay.

These factors (outlined in Figure 1) and their aggregate impact can be seen in the evolution of the pricing model for GLP-1 therapies, such as semaglutide (Wegovy, Ozempic, Rybelsus) and tirzepatide (Zepbound, Mounjaro). Upon expansion from type 2 diabetes into obesity, coverage became extremely restricted under many plans and channels to control costs as patient demand surged, with an untapped market in Medicare due to statutory exclusion of obesity medications. GLP-1 drugs were thus primed for distribution through alternative models to initially optimize patient access, and to later on limit the potential impact of restrictions in Medicare/Medicaid. Alternative models (e.g., direct-to-patient, direct-to-employer) will also continue to encourage lower list prices for a "lifestyle" medication with population-level demand and potential health benefits (e.g., secondary to significant weight-loss). At the same time, policies such as MFN and IRA dovetail with "lower-list, lower-rebate" pricing and direct-to-stakeholder approaches for GLP-1s. MFN GENEROUS may expand access to GLP-1s in Medicaid (lower prices may come with reduced utilization management for participating state Medicaid plans, and their MCO-managed counterparts in those states, as part of GENEROUS model negotiations). Medicare price negotiations under IRA underscore the value of GLP-1s to the channel as well as a price benchmark for other payer channels, reducing patient OOP costs as a result in a patient population that historically has shown less appetite to pursue alternative channels. Altogether, GLP-1 drugs represent a clear example of a class evolving to a "lower-list, lower-rebate" strategy across the five example characteristics in Figure 1.

In contrast, key features of a product archetype more likely to retain traditional "higher-list+ rebate" pricing include [1] a primarily commercially insured patient population with [2] favorable access, [3] a more indication-specific than population-level addressable market with [4] less appetite to purchase through alternative channels (particularly for chronic, disease-specific, and specialty-priced products for older adults), and [5] a GTN that doesn't materially impact patient willingness to pay.

These factors (outlined in Figure 1) are hypothesized through CD20-directed cytolytic antibodies for the treatment of multiple sclerosis (MS). Approximately 75% of MS patients are commercially insured3, translating to minimal spend from the Medicare/Medicaid channels (and thus a more limited impact of IRA/MFN on pricing decision-making).

	"Lower-List, Lower-Rebate" Archetype: GLP-1 Targeted Obesity Therapies	"Higher-List + Rebate" Archetype: CD20-Directed MS Therapies
Channel Mix	Significant share of Medicare/Medicaid spend; more likely to be impacted by IRA/MFN	Primarily commercially-insured patients; less likely to be impacted by IRA/MFN
Quality of Access (Current/Historical)	Restricted coverage (both by payer and statute)	Favorable coverage and management
Population Health Potential	Broad/population-level health benefit anticipated from reduction in obesity	Relatively older adult prevalent population > less likely to pursue
Appetite for Alternative Channels	Relatively younger adult prevalent population > more likely to pursue	Relatively older adult prevalent population > less likely to pursue
GTN Impact on Patient Willingness to Pay	High (retail pricing supports "net-first" strategy)	Low (patients unlikely to pay OOP for specialty drugs)

Figure 1: Comparison of Key Factors for "Lower-List, Lower-Rebate" and "Higher-List + Rebate" Product Archetypes

CD20-directed antibody therapies have shown strong clinical differentiation and value with significantly reduced relapse rates compared to other MS treatment classes4 (e.g., pyrimidine synthesis inhibitors), resulting in favorable payer access. While MS represents a significant healthcare burden unto itself, its treatment does not bring the population-level cross-indication benefits of GLP-1 therapy. Further, channeling MS treatments through alternative distribution models would be more dependent upon patients north of middle age that may be less primed to pursue such models than younger patients.

Lastly, the pricing dynamic of MS therapies vs GLP-1 therapies (specialty vs retail) remains important to consider – movement to a "net first" pricing strategy for MS brands would do little to increase patient willingness to pay in either traditional or alternative channels. Altogether, these factors support maintenance of traditional "higher-list + rebate" pricing strategies, with CD20-directed antibody therapies for MS offering a hypothesized archetype to contrast with GLP-1 therapies.

Strategic Considerations

As manufacturers launch new therapies into an ever-evolving pricing and access landscape, Triangle Insights encourages manufacturers to consider the following when evaluating potential pricing and access strategy:

1. What share of Medicare/Medicaid spend is allocated to this indication and class of drugs? To what extent is the patient population insured through commercial versus public channels?

2. To what extent have competitor drugs been targeted by (or responded to) major drug pricing policy reforms such as IRA and MFN?

3. What evidence may payers require to support favorable access as payers face greater cost exposure and liability from policy changes?

4. What volume benefit might be gained through use of alternative rather than traditional access models? Do the population and drivers to pursue alternative channels align with your product?

5. Does a reduced GTN materially affect the patient value proposition / willingness to pursue and pay for your therapy (e.g., opening up access for new demographics or use cases)?

While GLP-1 and CD20 targeted therapies represent contrasting examples across the factors outlined in Figure 1, and the questions highlighted above, it is anticipated that most manufacturers considering a "net first" pricing strategy will encounter products that share a mix of factors. Reach out to Triangle Insights Group today to discuss how to optimize your pricing decision-making amid the shifting pricing and access landscape.

Reach out to Triangle Insights Group today

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