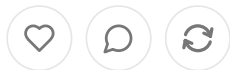


What the Six Hundred Billion Dollar MFN Headline Misses: The Best Price Carveout, the IQVIA Net Price Hole, and the CMMI BALANCE Workaround That Makes Trump's Drug Pricing Framework Run

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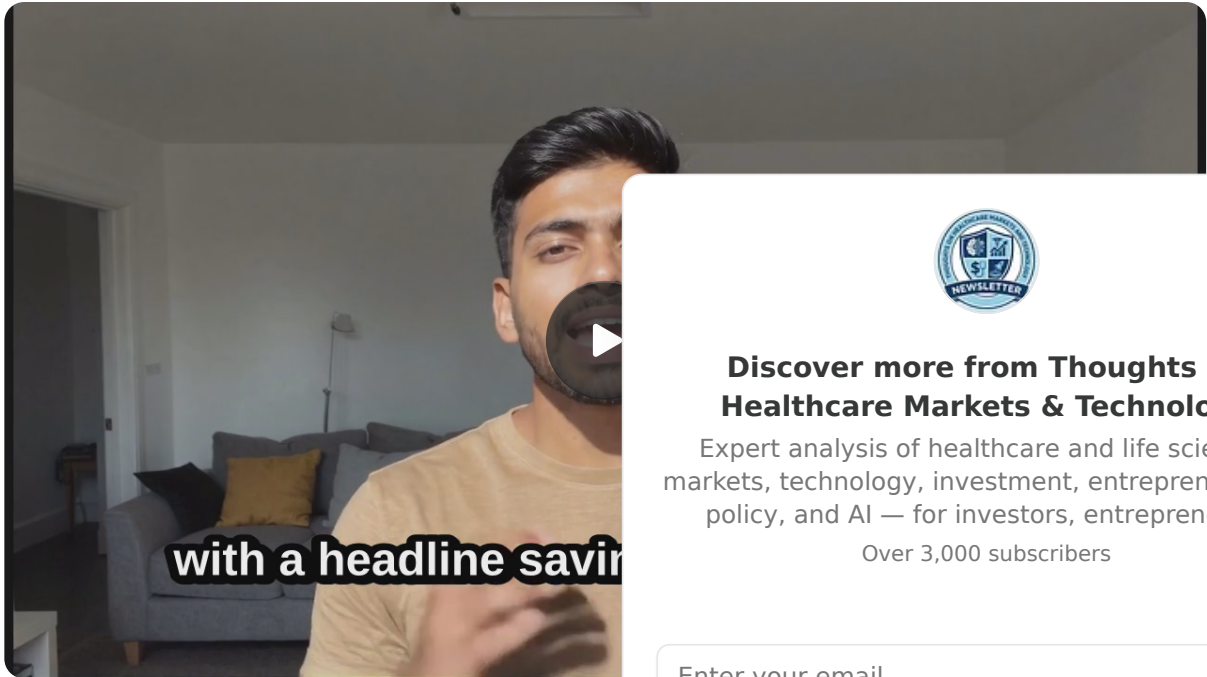
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Part I: What the Six Hundred Billion Dollar MFN Headline Misses: The Best Price Carveout, the IQVIA Net Price Hole, and the CMMI BALANCE Workaround That Makes Trump's Drug Pricing Framework Run

The CEA's six hundred billion dollars drug savings projection is built on data the report's own footnotes say don't measure net prices. The policy is net-price-based. The data are gross-price-based...

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Part II: What the Six Hundred Billion Dollar MFN Headline Misses: The Best Price Carveout, the IQVIA

Net Price Hole, and the CMMI BALANCE Workaround That Makes Trump's Drug Pricing Framework Run

The Counsel of Economic Advisor's six hundred billion dollars drug savings projection is built on data the report's own footnotes say don't measure net prices. The policy is net-price-based. The data are gross-price-based...

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Abstract

The Council of Economic Advisers dropped a Most-Favored-Nation drug pricing analysis on May 5, 2026, with a sticker number of nearly six hundred billion dollars in projected domestic savings over ten years. The press cycle went exactly where it always goes. Medicare GLP-1 access. Fertility coupons. The seventeen voluntary manufacturer deals. The political contrast with Biden-era IRA. None of this is the actual story. Read the report once for the headline. Read it twice for the architecture.

Three findings worth carrying through:

- The voluntary manufacturer agreements work only because the entire MFN rebate flow gets routed through Medicaid supplemental rebates, which 42 U.S.C. 1396r-8(c)(1)(C) already excludes from Best Price calculation. The November 6, 2025 GENEROUS Model is the regulatory machine that operationalizes this. Without that statutory shield, every MFN rebate would trigger a Best Price reset that cascades through 340B liability. The shield is the reason seventeen pharma CEOs signed up without legislation. It is also one administrative reinterpretation away from collapse, which the AHA v. Kennedy 340B litigation makes painfully obvious.
- The 529 billion dollar prospective MFN savings number is built on top of IQVIA MIDAS data that the report itself, in footnote 26, says does not reflect net prices realized by manufacturers. The whole policy is defined as net-price-based. The data underneath are gross-price-based. The 30 percent price convergence assumption (footnote 28) is essentially a midpoint guess. Tomas Philipson, who chaired CEA in Trump's first term, published a June 2025 paper finding U.S. public payer prescription prices are 18 percent lower than peer nations when

measured properly across the full prescription distribution. He is about to be uncomfortable for somebody.

- The Medicare GLP-1 Bridge demo starting July 1, 2026 is not the durable mechanism. It is a six-month payment plumbing exercise. The actual mechanism is the BALANCE Model, a Section 1115A demonstration running 2027 to 2031 that pulls GLP-1s into Part D for participating plans, with eligibility, cost sharing, and access criteria negotiated directly between CMMI and manufacturers. BALANCE only goes live if 80 percent of Part D sponsors opt in, which makes “voluntary” effectively mandatory at scale. The whole construct is using demonstration authority to work around the Part D weight-loss exclusion in statute, the same pattern attentive readers already saw with ACO LEAD and the ACCESS Model.

Together these three pieces are the framework. The press release is the marketing. There is a real essay sitting underneath, with real implications for hospitals, manufacturers, PBMs, plans, and anyone trying to build a company in this space.

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Section One. The Headline Versus the Architecture

The Council of Economic Advisers report released on May 5, 2026 is twelve pages of marketing wrapped around four pages of policy mechanics. The marketing got covered. The mechanics did not. Most of the press cycle latched onto the six hundred billion dollar topline, the ninety percent of GLP-1 list price reduction on TrumpRx, the political contrast with the Inflation Reduction Act, and the seventeen voluntary

manufacturer deals representing 86 percent of the branded drug market. All of which is true and none of which explains how the framework actually functions or why it could fall apart.

The report has a structure worth reading carefully. It splits MFN into two regimes. Existing drugs get routed through state Medicaid via supplemental rebates, projected to save 64.3 billion dollars over ten years. New drugs (the prospective MFN piece) get a commitment from manufacturers to launch at prices comparable to a defined basket of reference countries, projected to save 529 billion dollars over ten years. TrumpRx.gov is the direct-to-consumer interface, which is where the GLP-1 and fertility numbers live. The Medicare GLP-1 Bridge plus the BALANCE Model expand Medicare anti-obesity coverage. The trade policy machinery is supposed to extract reciprocal price increases from foreign payers, which is why the U.S. and U.K. pharmaceutical pricing arrangement is folded into the analysis as the proof point.

Read past the structure and three things become visible. First, the entire voluntary architecture rests on a single piece of statutory plumbing buried in Medicaid law, and seventeen pharma companies are counting on that plumbing not getting touched. Second, the most aggressive savings number in the report is built on data the report's own footnotes admit does not measure net prices, even though the policy is defined entirely in net-price terms. Third, the GLP-1 Medicare expansion that gets framed as a coverage win is operationally a CMMI demonstration that is working around statute the same way three other demonstrations have done in the past two years.

None of this is hidden. It is all in the document. It just does not fit the headline. What follows works through each piece in turn, then connects them to the trade policy lever and to the operational implications for everybody building, investing, or operating around the U.S. drug pricing stack.

Section Two. The Best Price Carveout, or How GENEROUS Quietly Does the Real Work

To see why seventeen pharma companies signed voluntary MFN agreements without anyone subpoenaing them, the right place to start is the Medicaid Drug Rebate Program. Every manufacturer that wants Medicaid coverage of its drugs has to participate in the MDRP, and every covered outpatient drug under the MDRP gets rebated to state Medicaid programs. The basic rebate for a brand-name drug is the greater of 23.1 percent of Average Manufacturer Price or the difference between AMP and Medicaid Best Price. That second clause is the trap. Best Price is defined

statutorily as the lowest price the manufacturer offers to any wholesaler, retailer, provider, HMO, nonprofit, or government entity in the United States, with a handful of carved-out programs (VA, 340B, DoD, PHS, IHS).

If a manufacturer offers a steep discount to anyone in the United States, that discount typically resets Best Price downward, which in turn increases the basic Medicaid rebate, which in turn flows through to state Medicaid programs as a higher rebate, which manufacturers eat as a hit to net revenue. This is why pharma has spent decades structuring rebates through PBMs, formularies, and managed care to avoid Best Price contamination. The system is intentionally booby-trapped against ad-hoc concessions.

Layered on top is 340B. Manufacturers that participate in MDRP must also sell outpatient drugs to 340B-covered safety-net providers (FQHCs, DSH hospitals, critical access hospitals, Ryan White clinics, children's hospitals, and so on) at the 340B ceiling price, which is calculated as a function of AMP and the unit rebate amount. That unit rebate amount is itself a function of Best Price. If Best Price moves down, 340B ceiling prices move down, and manufacturers face a deeper discount on every 340B unit dispensed. In 2023, 340B-covered entities purchased 66.3 billion dollars in outpatient drugs, so the cascade is not theoretical.

Now imagine an MFN regime where a manufacturer voluntarily offers a state Medicaid program a price two thirds below current Medicaid net. Without a carveout, that price becomes the new Best Price, the basic rebate gets recomputed across every state, the 340B ceiling drops in lockstep, and the manufacturer gets crushed twice for every concession. No CFO signs that deal. The voluntary model collapses on day one.

The carveout is what makes the whole thing run. Buried in 42 U.S.C. 1396r-8(c)(1)(C), Best Price already excludes Medicaid supplemental rebates. The statute draws a line. The basic rebate captures the broad commercial pricing landscape. Supplemental rebates negotiated between states and manufacturers (typically tied to formulary placement or preferred drug list status) live in a separate channel and do not ripple into Best Price math. That is the channel CMS chose to operationalize MFN through. The November 6, 2025 GENEROUS Model (GENERating cost Reductions fOr U.S. Medicaid) is the rule that does the operationalization. Under GENEROUS, CMS negotiates standard coverage criteria and key terms with manufacturers, manufacturers offer states an MFN-aligned net price benchmark, states sign supplemental rebate agreements with the manufacturer, and the rebate flows through the supplemental channel rather than through Best Price.

CMS made the carveout explicit in its own announcement. The model's published guidance states that supplemental rebates provided under GENEROUS will not affect Medicaid Best Price and therefore do not affect 340B ceiling prices. That single sentence is the entire reason seventeen pharma CEOs signed agreements without statute. It is also why the CEA report can claim 64.3 billion dollars in Medicaid savings over ten years without manufacturers walking out of the room. The 340B cascade has been surgically isolated from the MFN flow.

The legal authority for GENEROUS is Section 1115A of the Social Security Act, the CMMI demonstration authority. This is not new ground. CMMI has used 1115A for ACO models, bundled payments, oncology care, kidney care, primary care, and value-based purchasing demonstrations going back to 2010. The novel use here is to deploy CMMI's authority to engineer a permanent workaround for a Best Price problem that statute does not directly address. Manufacturer applications closed March 31, 2026. State Plan Amendments and supplemental rebate agreements with participating manufacturers are supposed to be executed by August 31, 2026.

The architecture is elegant. It is also fragile. Two threads should keep readers up at night. The first is that the carveout depends on the continuing administrative interpretation that GENEROUS supplemental rebates qualify as the kind of supplemental rebate Congress intended to exclude from Best Price under 1396r-8(c)(1)(C). Nothing in the statute contemplates a CMS-orchestrated, MFN-anchored, manufacturer-to-state supplemental rebate at the volume and depth that GENEROUS produces. A future administration could reinterpret. A litigant could challenge. Either path collapses the manufacturer participation calculus overnight.

The second thread is that the parallel 340B litigation that played out in early 2026 is a tell. HRSA tried in late 2025 to convert 340B itself from an upfront discount model to a back-end rebate model through the 340B Rebate Model Pilot Program. The American Hospital Association, the Maine Hospital Association, and four safety-net hospitals filed suit in the District of Maine on December 1, 2025. By December 29, Chief Judge Lance Walker enjoined the pilot nationwide. On January 7, 2026, the First Circuit denied the government's emergency stay motion. By February 10, the program was vacated and remanded. The court's reasoning is the part that should worry GENEROUS architects: the administrative record was found to be threadbare, HRSA failed to consider thirty years of hospital reliance interests, and the cost analysis was inadequate.

GENEROUS is structurally different from the 340B Rebate Pilot. It uses pre-existing supplemental rebate channels rather than restructuring 340B itself. But the *AHA v. Kennedy* precedent shows what happens when administrative engineering touches

anything 340B-adjacent. Hospital plaintiffs litigate aggressively, courts apply APA scrutiny, and voluntary pilots get vacated. The CEA report is silent on the durability question. It should not be. Anyone modeling the ten-year savings projection has to ask whether the carveout survives a second-term administration of either party, an APA challenge brought by a coalition of safety-net hospitals, or a Best Price reinterpretation by a future CMS Administrator. The answer to all three is uncertain, and the answer to all three matters.

What does this mean operationally? The Best Price carveout sits at the center of the manufacturer participation calculus, the 340B-eligible provider economics, the state Medicaid net spend trajectory, and the rebate aggregation business model that PBMs and rebate aggregators have built over the past two decades. If GENEROUS scales, MFN supplemental rebates start displacing volume that previously flowed through the rebate aggregation channel. If GENEROUS collapses, the entire MFN edifice comes with it. The lynchpin is one statutory clause, one administrative interpretation, and one Section 1115A demonstration. That is a thinner foundation than the ten-year savings projection implies.

Section Three. The IQVIA Problem, or Why Five Hundred Twenty Nine Billion Dollars Sits on Sand

The 64.3 billion dollar Medicaid number is the smaller of the two big savings projections. The headline number is 529 billion dollars over ten years from prospective MFN, meaning the commitment that future drug launches will price in the U.S. comparable to the second-lowest reference country price in a basket of G-7 nations plus Denmark and Switzerland.

The methodology is laid out in pages eight and nine of the report and footnotes 26 through 29. The CEA team simulated MFN being applied to FDA novel drug approval cohorts from 2021 to 2025, used IQVIA MIDAS data to obtain U.S. and reference country sales, projected an additional five years assuming a 3 percent growth rate in pharmaceutical spending, and assumed that 10 percent of each cohort had no sales due to non-pricing-related delays in U.S. market entry. Then they assumed a 30 percent decrease in U.S. net prices by the end of the ten-year period, justified as the midpoint of an estimated 2.5x current price differential between the U.S. and reference countries.

That 30 percent assumption is doing essentially all of the work in the projection. The whole 529 billion dollar number is, mathematically, the integral over ten years of an

assumed 30 percent net price decline applied to projected U.S. sales of novel drugs from cohorts going back to 2021. Different convergence assumption, different headline. Tweak the convergence to 20 percent and the headline collapses to roughly 350 billion. Tweak it to 10 percent and the headline barely registers. The report acknowledges this implicitly by noting that an alternative projection starting with the 2025 cohort, which has more current innovation pipeline mix, generates 733 billion dollars instead of 529 billion. Pick your starting cohort, pick your number.

The deeper problem is the data. MFN is defined throughout the report as a net price construct. The whole rationale for excluding gross list prices is that they do not reflect what manufacturers actually realize after discounts, rebates, and concessions. Footnote 26 of the report describes IQVIA MIDAS as estimated product volumes of registered medicines with sales estimates projected from IQVIA's audits of standardized list prices and manufacturer, wholesaler, and other invoices. Footnote 29 makes it explicit. MIDAS data reflect local industry standard source of pack prices, which might be list price or average invoice price depending on the country and the available information. They do not take into account rebates or clawbacks, details of which are normally confidential, and therefore these estimated prices do not reflect net prices realized by the manufacturers.

So the policy is defined in net prices. The savings projection is denominated in net prices. The data underneath the projection are not net prices, by the report's own acknowledgment. The CEA team adjusted by assuming a 2.5x current price differential rather than the 3.08x reported in the 2024 ASPE international price comparison study, justifying the lower assumption with a hand-wave about MFN methodology involving a different country basket and GDP adjustment. This adjustment is presented in a single footnote, footnote 11. It is the difference between a 14.4 billion dollar annual Medicaid savings projection and something materially lower.

The ASPE 2024 numbers themselves are worth examining. RAND Health Care, under contract to ASPE, analyzed IQVIA MIDAS data for 2022 and found U.S. prices for brand drugs were at least 3.22 times as high as prices in 33 OECD comparison countries, even after adjusting for estimated U.S. rebates. Note the qualifier. U.S. rebates adjusted, foreign rebates not adjusted. Foreign rebate data is generally unavailable because most reference countries treat post-list discounts as confidential commercial information. So the 3.22x figure is the gross-foreign versus net-U.S. ratio, not a true net-to-net comparison. If foreign net prices are, say, 30 percent below their list prices (which is plausible given how aggressive German VPAG-style clawbacks and French CEPS rebates can be), the actual net-to-net ratio is closer to 2.3x.

This is the frame in which Tomas Philipson's June 7, 2025 University of Chicago policy brief lands. Philipson chaired the Council of Economic Advisers under Trump in the first term. He is not a Democratic policy wonk. His paper, co-authored with Deyu Zhang and Qi Zhao, makes a sharp methodological argument. Previous comparisons focus on brand-name prescription prices, but generic drugs are 93 percent of U.S. prescriptions and the U.S. has the lowest generic drug prices in the developed world. When you measure across the full prescription distribution and focus specifically on public payers like Medicare and Medicaid, U.S. prescription prices are actually 18 percent lower than in these nations. The five peer countries in the analysis are Germany, France, the U.K., Canada, and Japan, which substantially overlap the CEA reference basket.

Philipson's paper does not refute the brand-drug-specific finding. It reframes the question. If the policy concern is what the U.S. public payer system spends per prescription, the U.S. is already winning. If the policy concern is brand drug net prices specifically for sole-source originators, the U.S. is paying more, but the comparison data is incomplete because foreign net prices are confidential. The CEA report treats the 3.22x brand-only number as the policy-relevant frame. Philipson would argue the 18 percent net advantage on the full distribution is the more honest one. Both can be true. The CEA framing is the one that justifies the savings projection.

The deeper structural observation is that MFN is forcing into existence a global pharmaceutical net price reporting regime. The report itself acknowledges that net prices will be voluntarily reported by manufacturers following methodological guidance issued by CMS, and that the process for reporting and auditing has been designed to avoid conflicts with foreign confidentiality laws, modeled on the German Arbitration Board approach. Translation: the data needed to verify the 30 percent convergence assumption does not yet exist as a usable dataset. It is being built, voluntarily, by the same manufacturers being asked to commit to MFN-aligned net prices, under CMS-defined methodology.

This is the most underrated structural consequence of MFN. PBM reform could not produce this domestically. State price transparency laws have not produced it. The IRA's Maximum Fair Price negotiation does not produce it. The thing that finally cracks the global drug net price black box is a U.S. trade policy lever that uses MFN-anchored Medicaid supplemental rebates to make manufacturer cooperation a condition of avoiding Section 232 tariffs. Whether the savings projection holds up is one question. Whether the reporting infrastructure becomes a permanent fixture of global drug pricing is a different and much more interesting question.

Section Four. CMMI BALANCE, or How a Bridge Becomes a Permanent Workaround

Most coverage of the GLP-1 piece of MFN focuses on the Medicare GLP-1 Bridge demonstration starting July 1, 2026, with the 50 dollar monthly copay headline. That focus is wrong. The Bridge is a six-month plumbing exercise. The actual mechanism is the BALANCE Model, which is where the durable architecture lives.

A quick walk through the Bridge first. The Medicare GLP-1 Bridge is a Section 402 demonstration authorized under the Social Security Amendments of 1967, separate from Part D. Eligible Medicare beneficiaries get access to specific GLP-1 drugs at a flat 50 dollar per month copay between July 1, 2026 and December 31, 2027. The Bridge operates outside the Part D benefit's coverage and payment flow, which means Part D plan sponsors carry no risk for eligible GLP-1 products furnished under the demonstration. It also means the 50 dollar copays do not count toward the Part D deductible or the 2,100 dollar annual out-of-pocket cap that the IRA established. Beneficiaries pay 50 dollars per month every month, regardless of where they sit in the benefit phase. CMS administers the entire payment flow.

The Bridge is short, narrow, and operationally simple. It exists to give the Trump administration a fast win, to start collecting GLP-1 utilization data, and to bridge to BALANCE. The durable architecture starts on January 1, 2027.

BALANCE (Better Approaches to Lifestyle and Nutrition for Comprehensive hEalth) is a CMMI demonstration authorized under Section 1115A. CMS announced it on December 23, 2025. Notices of intent for manufacturers were due January 8, 2026. State Medicaid agencies could submit notices through April 20, 2026. Part D sponsor applications closed April 20, 2026 as well. The model is scheduled to run through December 31, 2031.

Here is what BALANCE actually does. CMS negotiates directly with eligible GLP-1 manufacturers, specifically those with products that are GIP, GLP-1, or glucagon receptor agonists with FDA-approved or anticipated weight management labels and clinical evidence of at least 9.5 percent body weight reduction. Negotiations cover pricing, eligibility criteria for patients, prior authorization frameworks, and length of agreement. Participating manufacturers offer the negotiated terms to participating state Medicaid programs and participating Part D sponsors. State Medicaid coverage launches as early as May 2026. Part D coverage launches January 1, 2027.

The eligibility criteria are not loose. Patients must have a provider confirm they have type 2 diabetes, MASH with moderate to advanced liver fibrosis (stages F2 to F3), obstructive sleep apnea, or be on lifestyle modification. Plus they must clear one of three BMI thresholds with corresponding comorbidities. BMI of 35 or higher with no additional condition. BMI of 30 or higher with HFpEF, uncontrolled hypertension, CKD stage 3a or above, moderate or severe OSA (apnea-hypopnea index of 15 or higher without central or mixed sleep apnea), or noncirrhotic MASH F2 to F3. BMI of 27 or higher with pre-diabetes, prior MI, prior stroke, or symptomatic peripheral artery disease. The drug list is specific. All formulations of Mounjaro, Ozempic, Rybelsus, and Wegovy, the KwikPen formulation of Zepbound, and orforglipron in tablet form if approved.

The structural detail nobody is talking about is the 80 percent Part D sponsor critical mass requirement. BALANCE only goes live for Medicare Part D if at least 80 percent of Part D plan sponsors apply and are accepted. CMS notifies applicants whether the threshold is met by April 30, 2026. This is the contingent mechanism that converts voluntary into effectively mandatory. Once eight in ten Part D sponsors are in the model, the remaining two in ten face severe adverse selection. Their members who want 50 dollar GLP-1 access will defect to participating plans during open enrollment. Plans that sit out lose membership. The voluntary architecture is a Schelling point, and 80 percent is the trigger.

Step back from the operational mechanics and the bigger structural pattern becomes visible. Part D, as enacted in the Medicare Modernization Act of 2003, statutorily excludes coverage of weight loss drugs. That exclusion is in 42 U.S.C. 1395w-102(e)(2)(A), which incorporates by reference the Medicaid statute's list of drugs that may be excluded from coverage. The Biden administration in late 2024 proposed to reinterpret the Part D statute to require coverage of anti-obesity drugs through proposed rule CMS-4208-P, projected by CMS itself to add 25 billion dollars in Medicare and 15 billion dollars in Medicaid spending over ten years. The Trump administration did not finalize that proposal. Instead, it deployed Section 1115A demonstration authority through BALANCE to do operationally what the statute prohibits regulatorily.

This is the third time in roughly two years that CMMI has used 1115A to do structural work the legislative branch could not deliver. The ACO Lifecycle Engagement and Accountability Demonstration (ACO LEAD) used 1115A to push two-sided risk into MSSP populations the statute did not contemplate. The ACCESS Model used 1115A to fold specific oncology populations into a per-member-per-month construct that Medicare fee-for-service architecture could not natively support. Now BALANCE uses 1115A to expand Part D coverage to a population the

Part D statute explicitly excludes. The pattern is the same. Identify the statutory constraint. Reframe the policy goal as a demonstration. Sign manufacturers, plans, or providers up voluntarily. Use the 80 percent or equivalent critical mass threshold to make voluntary stick.

The legal vulnerability is real. Section 1115A authorizes the Secretary to test innovative payment and service delivery models expected to reduce program expenditures while preserving or improving quality. The statute requires that models meet certain criteria and prohibits implementation that increases overall Medicare or Medicaid spending in ways that violate certain budget neutrality conditions. Whether BALANCE's particular structure clears those bars is a litigable question. Whether a future administration could rescind the demonstration via standard CMMI program management is also a real question. The Bridge demonstration is operationally robust because it is short and narrow. BALANCE is the long-tail risk.

The implication for plans, providers, and pharmacy infrastructure is that the next twelve months will determine whether GLP-1 dispensing in Medicare Part D becomes a routine feature of the benefit or stays an exception. If the 80 percent threshold is met and BALANCE goes live, every Part D sponsor needs formulary architecture, prior auth workflows, claim adjudication logic, and clinical documentation pathways for GLP-1 weight management indications. Specialty pharmacy networks need to plan for the volume. Manufacturers need to integrate negotiated MFN-aligned net prices into their commercial-Medicare-Medicaid reconciliation. Brand teams have to manage three pricing surfaces (commercial PBM rebate, Medicaid GENEROUS supplemental rebate, Medicare BALANCE negotiated price) without contaminating Best Price. None of this is in the press release.

Section Five. The Trade Flywheel and the Carveout Inside the Carveout

The CEA report frames MFN as working in tandem with U.S. trade policy efforts. The proof point in the report is the U.S. and U.K. Pharmaceutical Pricing Arrangement, announced in principle on December 1, 2025 and formalized on April 2, 2026. The structure of that arrangement is worth understanding because it reveals what the U.S. is actually trading for foreign pricing concessions, and because it contains a carveout that materially undermines the CEA's claim of a stable, formulaic MFN benchmark.

The U.K. arrangement does several things at once. The U.K. agreed to lower its Voluntary Scheme for Branded Medicines Pricing, Access and Growth (VPAG) rebate rate from 22.9 percent in 2025 to 14.5 percent for newer medicines in 2026, capped at 15 percent for the duration of the scheme. The U.K. also committed to raising the

National Institute for Health and Care Excellence's quality-adjusted life year cost-effectiveness threshold from the 20,000 to 30,000 pound range that has been in place since 1999 to a 25,000 to 35,000 pound range starting April 2026. And the U.K. committed to doubling its investment in new medicines from 0.3 percent of GDP in 2026 to 0.6 percent by 2036. In return, the U.S. agreed not to apply Section 232 tariffs to pharmaceutical products of U.K. origin during the period from January 1, 2026 through January 19, 2029, conditional on major U.K. pharmaceutical companies entering and adhering to MFN agreements with HHS. The U.S. also committed not to use UK pharmaceutical pricing practices as the target of any future Section 301 trade investigation during the same period.

Read the official text on gov.uk and there is a sentence that nobody is quoting. Paragraph three of the arrangement contains this provision. Consistent with the provisions of the GENEROUS Model, where the United Kingdom's price for a New Medicine is the lowest in the reference basket of comparator countries, the Medicaid MFN price will not anchor on this lowest price. Translated out of trade-document language, the U.S. agreed that if the U.K. ends up being the lowest-priced country in the reference basket for a given new drug, the U.S. will not use the U.K. price as the MFN benchmark for Medicaid. This is the carveout inside the carveout. It is a manual override clause, written into a bilateral trade arrangement, that lets the U.S. exempt specific country-drug combinations from the second-lowest-price methodology that the CEA report describes as the bedrock of MFN benchmark stability.

The implication is that the MFN benchmark methodology is not actually formulaic. It is negotiable on a country-by-country basis, written into trade arrangements that can be modified by future administrations. This matters for two reasons. The MFN savings projections in the CEA report are denominated in benchmarks that are politically negotiable, not technically deterministic. And it suggests that other reference country governments will negotiate similar carveouts as a precondition for accepting MFN-driven price increases on their end. Germany, Japan, France, Italy, and Canada all have larger pharmaceutical markets than the U.K. and stronger leverage. The CEA report assumes the trade flywheel will replicate. The U.K. precedent suggests it will replicate with a long tail of manual override clauses that erode the formulaic claim.

The arrangement also references two CMMI models that have been part of the broader MFN narrative but were not finalized at the time of the U.K. signing. The official text states that the U.S. expects that, if the GLOBE and GUARD Models are finalized, companies will make use of the provisions in those models to mitigate the risks of launching new medicines in lower priced countries. GLOBE (Global Outcomes-Based Equitable Access) and GUARD (Generic and Unbranded Access for

Reliable Discounts) have been previewed in administration policy documents but not formally launched. Their function is to give manufacturers operational tools to manage launch sequencing across reference countries without triggering MFN benchmark resets. The fact that they are referenced in the U.K. arrangement but not yet finalized is itself revealing about the speed at which the architecture is being built.

The structural question is whether the trade flywheel scales. The CEA report leans heavily on the U.K. precedent as proof that the architecture works internationally. One country in seventeen months of negotiations is a thin sample. The U.K. has unique features that made it a logical first deal. Heavy reliance on U.S. pharmaceutical exports. An industrial strategy that prioritizes life sciences investment. A constrained NHS budget with active VPAG renegotiation underway. A government that needed something to show pharmaceutical companies threatening to pause U.K. R&D investment. Other reference countries do not share this profile. Whether they accept MFN-aligned price increases without securing similar or larger trade concessions is an open question, and the CEA report does not address it.

Section Six. What All of This Means for People Building Around It

The MFN architecture, taken as a whole, is more interesting as a structural intervention than as a savings number. Anybody building, investing, or operating in the U.S. pharmaceutical, payer, or distribution stack should be thinking about a handful of consequences that the press cycle will not surface.

Start with TrumpRx as a distribution channel. The CEA report notes that as of April 26, 2026, sixteen of seventeen companies with voluntary MFN agreements have integrated their discounts into TrumpRx.gov. The site connects patients to direct-to-patient offers, with coupons generated on TrumpRx or directly through manufacturer websites, redeemable at participating pharmacies. Today, TrumpRx is not integrated with insurance, which means commercial deductibles and out-of-pocket maximums do not credit. The CEA report explicitly previews proposed legislation that would require commercial health insurance companies to count single-source drug purchases at MFN prices toward beneficiary deductibles and out-of-pocket maximums. If that legislation passes, TrumpRx becomes a parallel commercial drug distribution rail with negotiated MFN-aligned prices that compete directly with PBM-mediated formulary access. This is structurally similar to Mark Cuban's Cost Plus Drug Company at scale, but with administration backing and seventeen voluntary manufacturer agreements behind it.

The manufacturer compliance and reporting infrastructure is the next layer. MFN requires manufacturers to voluntarily report confidential foreign net prices following CMS methodological guidance. There is no existing dataset for this. Manufacturers will have to build internal data infrastructure to track, calculate, and report MFN-aligned net prices across reference countries on a continuing basis, in a format that CMS can audit. This is a real buildable. Specialty consultancies, regulatory technology firms, and pricing analytics platforms have an opening to construct the manufacturer-side compliance stack. The German Arbitration Board model that CMS used as its reference operates with substantial third-party support. The U.S. version will not be different.

The implication for 340B-eligible providers cuts a different direction. The Best Price carveout means that GENEROUS supplemental rebates do not flow into 340B ceiling price recalculation. That sounds like neutral news for 340B-covered entities. It is not. The carveout means that 340B providers do not get the benefit of MFN price reductions on the drugs they purchase under 340B. Manufacturers continue to charge 340B providers at the existing ceiling price (calculated from AMP and unit rebate amount based on standard rebate math), while offering state Medicaid programs significantly lower MFN-aligned net prices through the supplemental rebate channel. The relative discount that 340B-covered entities enjoy versus state Medicaid net prices narrows or inverts. For some drugs, state Medicaid MFN net prices may end up lower than 340B ceiling prices. This creates pressure on the historical economic logic of 340B and will accelerate the existing manufacturer push to convert 340B from upfront discount to back-end rebate, which is exactly what the AHA v. Kennedy litigation just blocked. The litigation is over for now. The economic pressure is not.

Then there is what happens to the rebate aggregation business model. PBMs, GPOs, and rebate aggregators have built businesses on capturing a slice of the rebate flow between manufacturers and payers. MFN-aligned net prices delivered through GENEROUS supplemental rebates and through TrumpRx direct-to-consumer channels reduce the volume of rebate flow that moves through the traditional aggregation infrastructure. The PBM rebate retention model is already under pressure from Inflation Reduction Act provisions, FTC investigations, and state-level rebate transparency laws. MFN adds a structural layer to that pressure. Whether incumbent PBMs adapt by shifting to fee-based pricing or whether new entrants capture share is the open question. Either way, the rebate aggregation flow is going to look different in 2030 than it does today.

Plan participation in BALANCE is its own decision tree. Part D sponsors face a strategic decision in the next ninety days about whether to participate in the BALANCE Model. The 80 percent critical mass threshold means that the decision is

partially game-theoretic. A plan that sits out while 80 percent of competitors join will face severe adverse selection during the 2027 open enrollment cycle. A plan that joins gives up some formulary discretion in exchange for participation. The decision interacts with broader Medicare Advantage strategy. MA-PD plans that participate in BALANCE can use 50 dollar GLP-1 access as a marketing differentiator against MA-PD plans that do not. PDP-only plans face a sharper version of the same calculus. Plans that have already publicly committed to obesity coverage as a strategic priority will join early. Plans that are dragging their feet on GLP-1 utilization management may use BALANCE as a way to shift downside risk to CMS while maintaining membership.

The durability framing wraps everything else. The entire MFN architecture is a voluntary, executive-branch, demonstration-authority construct. It does not rest on statute. It can be unwound by a future administration through standard administrative process. It can be challenged through APA litigation, especially around 340B-adjacent components. It depends on a Best Price carveout that is one administrative reinterpretation away from collapse. It depends on a methodological convergence assumption that academic critics will continue to attack. It depends on trade reciprocity that has been demonstrated only with the U.K. None of this means MFN will fail. It does mean that anyone modeling ten-year savings, planning around ten-year manufacturer commitments, or building infrastructure that depends on MFN persisting should be thinking about durability scenarios with more rigor than the CEA report applies.

The seventeen voluntary manufacturer agreements are real. The 86 percent branded market coverage is real. The seventeen CEOs who signed are not idiots. They are betting that the carveout holds, the trade flywheel scales, the BALANCE Model goes live, and the durability risks are manageable. If they are right, the architecture is a plausible candidate for the most consequential drug pricing reform of the past two decades. If they are wrong on any of three pieces, the savings projection comes apart and the seventeen agreements become a collection of voluntary commitments without a regulatory floor.

The press release said six hundred billion dollars. The architecture says it depends. Read the report again, and the second reading is the one that matters.

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