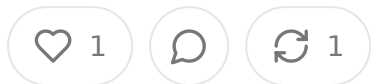


THE MAXIMUM FAIR PRICE ARBITRAGE HOW MEDICARE'S DRUG PRICING REVOLUTION IS CREATING UNEXPECTED WINNERS AND INEVITABLE LOSERS IN HEALTHCARE'S NEWEST MARKET

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Table of Contents

1. Abstract
2. Introduction: The Quiet Revolution in American Drug Pricing
3. Part One: Anatomy of the Maximum Fair Price Mechanism
4. Part Two: The Cash Flow Crisis and the Great Pharmacy Squeeze
5. Part Three: The Transaction Facilitator Gold Rush
6. Part Four: PBM Reckoning and the Spread Pricing Endgame
7. Part Five: Data Infrastructure as the New Pharmaceutical Real Estate
8. Part Six: Winners and Losers in the Post-Negotiation Economy
9. Conclusion: The Coming Wave of Creative Destruction

Abstract

The Medicare Drug Price Negotiation Program, established through the Inflation Reduction Act of 2022, represents the most significant intervention in pharmace

pricing since the creation of Medicare Part D. Beginning with ten drugs in 2026 expanding to include up to fifteen additional drugs annually plus Part B biologics in 2028, the program introduces Maximum Fair Prices that are projected to reduce costs by thirty-eight to seventy-nine percent from list prices. This essay examines business model innovations and market disruptions emerging from this regulatory framework. Key findings include the critical role of the Medicare Transaction Facilitator as a new infrastructure layer creating cash flow intermediation opportunities, the existential threat to independent pharmacies forced to float cash during the fourteen-day manufacturer refund window, the accelerating obsolescence of traditional pharmacy benefit manager rebate models, and the emergence of data and analytics companies positioned to exploit pricing arbitrage opportunities. The analysis reveals that while manufacturers face revenue compression, the real winners are likely to be technology platforms that can aggregate transaction data, provide working capital solutions to pharmacies, and create transparent pricing markets that circumvent legacy intermediaries. The essay concludes that the Maximum Fair Price mechanism will catalyze a wave of creative destruction in pharmaceutical distribution, with profound implications for health tech entrepreneurs who can identify and capture value in the newly transparent pricing environment.

Introduction: The Quiet Revolution in American Drug Pricing

On August fifteenth, two thousand twenty-four, the Centers for Medicare and Medicaid Services published the negotiated prices for the first ten drugs selected under the Medicare Drug Price Negotiation Program. The announcement was met with predictable reactions: patient advocacy groups celebrated, pharmaceutical manufacturers filed lawsuits claiming constitutional violations, and Wall Street analysts scrambled to model the revenue impact. But beneath the surface-level theatrics, a more interesting dynamic was taking shape. The Maximum Fair Price mechanism, as these negotiated prices are formally termed in the statute, was not merely reducing drug costs. It was fundamentally restructuring the flow of capital through the pharmaceutical distribution system, creating friction points, arbitrage

opportunities, and infrastructure gaps that would reshape the competitive landscape for years to come.

The Inflation Reduction Act granted Medicare unprecedented authority to negotiate drug prices directly with manufacturers, overturning the non-interference clause that had governed Part D since its inception in two thousand three. The program operates on a carefully choreographed timeline: CMS selects high-expenditure drugs with generic or biosimilar competition, manufacturers must either negotiate or face punitive excise taxes, and after months of data submissions and formal negotiation meetings, CMS issues final offers that become the Maximum Fair Price for a multi-year price applicability period. The first ten drugs, ranging from Eliquis for blood clots to Januvia for diabetes, saw their prices slashed by an average of sixty-seven percent. A second round added fifteen more drugs in two thousand twenty-five following implementation in two thousand twenty-seven, and beginning in two thousand twenty-eight, the program expands to include drugs payable under Part B and introduces renegotiation provisions for previously negotiated drugs.

For health tech entrepreneurs and investors, the critical insight is that the Maximum Fair Price does not simply represent a lower number on a price tag. It represents a complete rewiring of how money moves between manufacturers, pharmacy benefit managers, pharmacies, and patients. The statute requires that the MFP be made available not just to Medicare beneficiaries but specifically to the dispensing entity that serve them, within fourteen days of confirmation that a prescription was dispensed. This seemingly innocuous requirement has created what can only be described as a liquidity crisis for independent pharmacies, a compliance nightmare for manufacturers, and a golden opportunity for financial intermediaries who understand the timing mismatch inherent in the new payment architecture.

Consider the mechanics. Under the historical model, a pharmacy purchases a drug from a wholesaler at acquisition cost, dispenses it to a patient, and receives reimbursement from the pharmacy benefit manager based on a previously negotiated rate that typically includes both drug cost and a dispensing fee. The pharmacy gets paid quickly, usually within days, and the transaction closes. Now consider the Maximum Fair Price model as implemented in two thousand twenty-six. The

pharmacy still pays full acquisition cost to the wholesaler. The PBM reimburses pharmacy at the Maximum Fair Price, which may be sixty or seventy percent lower than what the pharmacy paid. The manufacturer is then required to refund the difference to the pharmacy within fourteen days. But fourteen days is an eternity when you are floating tens of thousands of dollars per week across hundreds of prescriptions. The pharmacy is effectively providing vendor financing to the manufacturer, and many independent pharmacies simply do not have the balance sheet to sustain this model.

This is where the game theory gets interesting. The regulatory framework has created a new class of infrastructure that did not previously exist: the Medicare Transaction Facilitator. CMS recognized that the complexity of claim-level data exchange between thousands of dispensing entities and hundreds of manufacturers would be prohibitive without a centralized clearing mechanism. The MTF Data Module became mandatory for Primary Manufacturers and will eventually be required for dispensing entities through future Part D plan sponsor agreements. The MTF Payment Module, which is voluntary for manufacturers, offers a path to pass MFP refund payments through a centralized ledger system with credit and debit tracking for claim adjustments and reversals. What CMS built, perhaps inadvertently, is the rails for an entirely new category of financial services in healthcare.

The business model implications are profound. Any entrepreneur who has studied payments infrastructure recognizes the pattern: when you create a mandatory intermediary for high-volume, low-margin transactions with temporal complexity, you create the conditions for value capture by whoever controls the clearing function, working capital, or the data exhaust. The MTF is not just a compliance tool. It is a platform. And platforms, once established, become the foundation for ecosystems that generate returns far exceeding the original utility function.

Part One: Anatomy of the Maximum Fair Price Mechanism

To understand the business opportunities embedded in the Maximum Fair Price framework, one must first understand the precise mechanics of how the MFP is calculated, applied, and enforced. The statute provides CMS with specific factors to consider during negotiations, including research and development costs, federal financial support for development, current unit prices and volume, pending patents and market exclusivity periods, comparative effectiveness versus therapeutic alternatives, and the extent to which the drug addresses unmet medical need. These factors are intentionally qualitative, giving CMS discretion in weighting different considerations for different drugs. The negotiation process itself follows a ritual sequence: manufacturers submit detailed data packages by March first of the negotiation year, the public can submit information about therapeutic alternatives and clinical considerations, CMS issues an initial offer by June first with a concise justification, manufacturers have thirty days to accept or propose a counteroffer, CMS and manufacturers may engage in up to three negotiation meetings before CMS issues a final offer by mid-October. Manufacturers have until the end of October to accept or reject, and CMS publishes agreed-upon MFPs by the end of November.

The MFP itself is expressed in three forms that correspond to different levels of distribution chain: the Single MFP per thirty-day equivalent supply, which represents the normalized price for a standard month of therapy; the NDC-9 MFP per Unit Price, which applies to the first nine digits of the National Drug Code and represents the price per individual dosage unit; and the NDC-11 MFP per Package Price, which applies to the full eleven-digit NDC including package size and represents the price for a complete package as distributed by the manufacturer. This multi-tiered price structure exists because different drugs are dispensed in different quantities and package configurations, and the MFP must be precise enough to apply correctly to every possible NDC variation while remaining simple enough for patients and pharmacies to understand.

The price applicability period is where the temporal dynamics become important. The MFP goes into effect on January first of the initial price applicability year and remains in force for the duration of the selected drug's participation in the program, subject only to annual inflation adjustments using the Consumer Price Index for all urban consumers.

consumers and potential renegotiation if the drug experiences material changes. CMS will publish updated MFPs each year reflecting CPI adjustments, and the Maximum Fair Price file that CMS released includes effective dates, end dates, and cross-reference fields to track when NDCs are replaced or discontinued. This creates a longitudinal pricing history that is both more transparent and more complex than the historical system where negotiated prices between manufacturers and PBMs were closely guarded trade secrets.

The enforcement mechanism is two-pronged and asymmetric. Manufacturers who fail to make the MFP available face steep civil monetary penalties: if CMS determines a manufacturer did not make the MFP available for at least ninety percent of claims during a given period, the manufacturer can be fined up to ten times the difference between the amount charged and the MFP, multiplied by the number of units involved. This creates enormous liability exposure and strong incentives for manufacturers to comply rather than risk audits. On the other side, CMS established a centralized intake system for complaints and disputes that allows dispensing entities to report when they believe the MFP was not made available, with CMS conducting initial threshold reviews, triage, and outreach to investigate each claim. The asymmetry is important: manufacturers bear the enforcement risk and compliance burden, while dispensing entities have a low-friction mechanism to escalate concerns.

Critically, CMS clarified in the final guidance for initial price applicability year 2028 that when assessing whether a manufacturer provided access to the MFP, CMS will use wholesale acquisition cost as a proxy for a dispensing entity's acquisition cost unless information indicates otherwise. This matters because it establishes a rebuttable presumption that pharmacies are paying WAC, which in turn defines the baseline against which the MFP refund is calculated. For manufacturers, this means the refund amount is effectively predetermined by the spread between WAC and MFP, regardless of what the pharmacy actually paid. For sophisticated pharmacy operators, this creates interesting possibilities around procurement strategies that might reduce actual acquisition cost below WAC, allowing them to capture additional margin while still receiving the full MFP refund calculated at WAC.

Part Two: The Cash Flow Crisis and the Great Pharmacy Squeeze

The independent pharmacy sector entered two thousand twenty-six already battered by a decade of margin compression, DIR fee clawbacks, and PBM reimbursement schemes that systematically underpaid for prescriptions relative to acquisition cost. The Maximum Fair Price implementation arrived not as a lifeline but as an existential threat. The National Community Pharmacists Association survey conducted in late two thousand twenty-four found that up to ninety-three percent of independent pharmacy owners either will no longer carry Part D drugs or are considering stopping, citing anticipated massive financial losses from the new payment model. This is not hyperbole. When you examine the cash flow mechanics, the vulnerability becomes clear.

A typical independent pharmacy serving a Medicare Part D population might fill a few hundred prescriptions per week for selected drugs subject to the MFP. If the average acquisition cost is five hundred dollars per prescription and the average MFP is three hundred fifty dollars, the pharmacy faces a one hundred fifty dollar gap per prescription that must be bridged by the manufacturer refund. Multiplied across a few hundred prescriptions, that is seventy thousand dollars per week in outstanding receivables from manufacturers. Assuming a fourteen-day payment window, the pharmacy needs to maintain a minimum of one hundred forty thousand dollars in working capital just to cover the float on MFP prescriptions, plus whatever capital is needed for non-MFP inventory and operational expenses. For pharmacies operating on thin margins with limited access to credit lines, this is insurmountable.

The February two thousand twenty-five analysis from healthcare consultants quantified the damage: pharmacies would have roughly ten thousand eight hundred dollars less cash on hand per week if manufacturers reimbursed seven days after dispensing. If the reimbursement stretched to the full fourteen-day statutory maximum, the cash deficit would balloon further. Independent pharmacies, many of which are sole proprietorships or small family businesses, do not have the balance sheet depth to absorb this kind of working capital requirement. The alternatives

all bad: secure expensive short-term financing to bridge the gap, which erodes already slim margins; reduce inventory of selected drugs, which risks losing patients to competitors; or exit Part D entirely, which for many pharmacies represents thirty percent of their business on average.

CMS attempted to address the cash flow concerns by establishing a voluntary self-identification process in the final guidance for two thousand twenty-seven.

Dispensing entities that anticipate material cash flow concerns can self-identify to CMS, which will provide that information to Primary Manufacturers to inform development of their MFP effectuation plans. Manufacturers must then include in their effectuation plans a process for mitigating material cash flow concerns for identified pharmacies. But this is a band-aid on a bullet wound. The guidance provides no requirement that manufacturers actually provide upfront or accelerated payment to pharmacies with cash flow issues, only that manufacturers document they will address the concern. A manufacturer could theoretically satisfy the requirement by offering a special financing arrangement or by simply acknowledging the issue without solving it.

The pharmacy networks controlled by the Big Three PBMs, CVS Caremark, Express Scripts, and OptumRx, do not face the same cash flow constraints because they are vertically integrated within larger healthcare conglomerates with effectively infinite access to corporate treasury functions. When a CVS pharmacy dispenses an MFI prescription, the parent company CVS Health can absorb the fourteen-day float on its entire balance sheet. This creates a competitive advantage that has nothing to do with operational efficiency or clinical quality and everything to do with access to capital. Independent pharmacies cannot compete on this dimension, which means MFP implementation will accelerate the consolidation of pharmacy ownership in the hands of the already-dominant players.

Here is where the business model opportunity emerges for health tech entrepreneurs. The cash flow gap is a solvable problem if you have access to capital and the ability to accurately assess credit risk at the pharmacy level. A startup that can provide instant or same-day liquidity to pharmacies for MFP refunds, charging a small percentage for accelerating the payment from fourteen days to zero days, could capture enormous

value. The unit economics are straightforward: if a pharmacy receives a ten thousand dollar manufacturer refund, and a financial intermediary advances that payment immediately for a two percent fee, the pharmacy pays two hundred dollars to avoid the working capital constraint, and the intermediary earns two hundred dollars what is essentially a fourteen-day bridge loan with the manufacturer refund as guaranteed collateral. At scale, across thousands of pharmacies and hundreds of thousands of MFP prescriptions, this becomes a meaningful business.

The competitive moat comes from integration with the Medicare Transaction Facilitator Data Module. Any financial intermediary that can plug directly into the MTF data feed gains real-time visibility into claim-level information: which prescriptions were dispensed, to which MFP-eligible individuals, at which pharmacies, with which manufacturer on the hook for the refund, and with what refund amount calculated. This data feed is the oracle that allows underwriting a liquidity product. Without it, you are flying blind and cannot confidently advance payments. With it, you have a programmatic pipeline of receivables with defined counterparties and payment timelines. The MTF essentially created the infrastructure for a new category of healthcare fintech: MFP receivables financing.

The larger strategic question is whether the pharmacy industry can adapt or whether the cash flow crisis will serve as the catalyst for mass exit and consolidation. Approximately ten percent of independent pharmacies in rural areas closed between two thousand thirteen and two thousand twenty-two, and industry observers anticipate the MFP implementation will accelerate this trend. For patients in pharmacy deserts, particularly rural communities or underserved urban areas where independent pharmacies are the only option, the closure of these pharmacies translates directly into reduced medication access. The policy intent of the MFP is to reduce drug costs for beneficiaries. The unintended consequence may be reduced access to those drugs for vulnerable populations as the distribution infrastructure collapses under financial pressure.

Part Three: The Transaction Facilitator Gold Rush

The Medicare Transaction Facilitator is the most underappreciated innovation in the Maximum Fair Price architecture. CMS positioned it as a technical necessity, a middleman to handle the complexity of data exchange between disparate systems, what CMS actually created is a centralized data aggregation platform that will process every MFP claim in the Medicare program, with complete visibility into which drugs are being dispensed, by which pharmacies, to which patients, with what pricing applied, and with what refund obligations flowing between which parties. This is just infrastructure. This is the data exhaust of a multi-billion dollar market, and whoever controls that data has the raw material to build transformative businesses on top of it.

The MTF Data Module is mandatory for Primary Manufacturers and will become mandatory for dispensing entities once CMS completes its rulemaking requiring Part D plan sponsors to include MTF enrollment provisions in pharmacy network agreements. This means every relevant actor in the distribution chain must plug into the MTF or face exclusion from Medicare Part D participation. The MTF becomes the central nervous system for MFP transactions, ingesting claim-level data elements from pharmacies, validating MFP eligibility of individuals against Medicare enrollment files, calculating refund amounts based on the difference between Wholesale Acquisition Cost and MFP, transmitting refund obligation notices to manufacturers, and tracking payments made through the voluntary Payment Module or through manufacturer direct payment channels.

The Payment Module adds a second layer of functionality. Manufacturers who opt into the MTF PM can transmit MFP refund payments through the platform, which then generates Electronic Remittance Advice using the X12 835 HIPAA standard for remittance for paper checks, delivers the ERA or remittance to the pharmacy, and maintains a credit-slash-debit ledger system to track claim adjustments and revenue. This is structurally similar to payment networks like Visa or ACH clearing houses where the platform sits in the middle of transactions and earns a toll on the flow. While CMS has not disclosed the fee structure for the MTF contractors, the precedent in payments infrastructure is that whoever controls the switching function earns billions of points on transaction volume.

For health tech entrepreneurs, the relevant question is what businesses can be built on top of or adjacent to the MTF platform. The first-order opportunity is the analytics layer. The MTF generates granular data on prescription volume, pricing spread between WAC and MFP, geographic distribution of dispensing entities, manufacturer compliance rates with the fourteen-day payment window, and patient-level utilization patterns for selected drugs. A company that can aggregate this data, anonymize it appropriately, and sell insights to manufacturers, PBMs, health plans, and wholesale investors would be tapping into a greenfield market. Manufacturers want to know how their MFP implementation compares to competitors, which geographies are seeing highest uptake, and where compliance issues are emerging. Health plans want to understand whether the MFP is actually translating into lower total cost of care and whether utilization is increasing enough to offset the per-unit savings. Investors want leading indicators of which manufacturers are gaining or losing market share in therapeutic categories subject to negotiation.

The second-order opportunity is the financial services layer discussed earlier. Working capital solutions for pharmacies, receivables financing against MFP refund obligations, and cash flow optimization tools all become viable businesses once you have access to the transaction data stream. But there are more sophisticated variations. Consider a risk-transfer product where a financial intermediary guarantees the fourteen-day payment to pharmacies and assumes the counterparty risk that a manufacturer might default or delay. Independent pharmacies would pay a premium for this guarantee, effectively buying insurance against payment timing variability. The intermediary would need deep underwriting capability to assess manufacturer creditworthiness and claims validity, but the MTF data feed provides exactly that capability.

The third-order opportunity is disintermediation of the PBM function itself. If the MTF is processing the data necessary to calculate MFP refunds, why does a PBM have to sit in the middle of the transaction at all, at least for selected drugs? A direct-to-pharmacy network that bypasses PBMs entirely and connects pharmacies, manufacturers, and health plans through the MTF infrastructure could offer lower costs, faster payment, and greater transparency than the legacy model. This is the

classic platform play: build a two-sided marketplace, reduce transaction costs, and capture a portion of the value that was previously consumed by intermediaries. The barrier to entry is technical capability to integrate with the MTF and the ability to convince enough pharmacies and manufacturers to adopt the alternative network. The tailwinds from PBM regulatory scrutiny and manufacturer frustration with the traditional rebate model create an opening for insurgent platforms.

The MTF also enables new forms of price discovery and benchmarking that did not exist under the opaque PBM-negotiated pricing regime. Historically, net drug prices after rebates and discounts were closely guarded proprietary information. Under the MFP framework, the price is public, transparent, and standardized. This creates opportunities for price comparison platforms that help health plans, employers, and patients evaluate total cost of care across different therapeutic options. If two drugs in the same class have MFPs that differ by twenty percent, and one has better clinical outcomes or fewer side effects, a decision support tool that surfaces this information at the point of prescribing becomes incredibly valuable. The MTF data, combined with clinical effectiveness data from comparative effectiveness research or real-world evidence studies, is the foundation for these tools.

The strategic risk for CMS is that the MTF contractors, who are building and operating the platform under government contract, will capture insights and capabilities that could be monetized outside the scope of the contract. There is precedent for this in government technology programs: contractors build systems, learn the domain deeply, and then pivot to offer commercial services to private sector players who want similar capabilities. CMS should anticipate this dynamic and negotiate carefully about intellectual property provisions, data use restrictions, and non-compete clauses in the MTF contracts. For entrepreneurs, the question is whether to try to become an MTF contractor directly or to build on top of the MTF as a third party once the interfaces and data standards are published.

Part Four: PBM Reckoning and the Spread Pricing Endgame

The Maximum Fair Price mechanism is fundamentally incompatible with the traditional pharmacy benefit manager business model, and the industry knows it. PBMs historically generated revenue through three primary channels: administrative fees charged to health plans for claims processing and formulary management, rebates negotiated with manufacturers that are partially retained rather than passed through to plan sponsors, and spread pricing where the PBM charges the plan more for a drug than the PBM pays the pharmacy. The MFP collapses all three revenue streams for selected drugs. Administrative fees remain, but the high-value drugs that previously generated the largest rebates and spread opportunities now have transparent, fixed pricing that eliminates the arbitrage.

The FTC's interim staff reports on PBM practices provide context for why this matters. The Big Three PBMs, CVS Caremark, Express Scripts, and OptumRx, collectively control sixty-seven percent of the national PBM market and seventy-percent of PDP region-level PBM markets are highly concentrated according to federal antitrust guidelines. The FTC found that specialty pharmacies affiliated with the Big Three received sixty-eight percent of dispensing revenue for specialty drugs in two thousand twenty-three, up from fifty-four percent in two thousand sixteen, and that these PBMs marked up specialty generic drugs by thousands of percent in some cases. The markups generated over seven billion dollars in revenue from dispensing drugs in excess of estimated acquisition costs between two thousand seventeen and two thousand twenty-two. This is the profit pool that the MFP threatens to eliminate.

Consider what happens to the spread pricing model under the MFP framework. In the legacy system, the PBM might reimburse a pharmacy one hundred fifty dollars for a drug that the PBM negotiated at one hundred twenty dollars from the manufacturer and then charge the health plan two hundred dollars, capturing fifty dollars of spread on a single claim while the pharmacy captures thirty dollars of gross margin before overhead. Under the MFP system, the manufacturer price is fixed at the MFP, the pharmacy acquisition cost is transparent through WAC, and the reimbursement from the PBM to the pharmacy must be sufficient to cover the pharmacist's dispensing cost but does not include a discretionary spread component because the manufacturer

refund closes the pricing gap. The PBM is squeezed out of the value chain on the pricing side and becomes a pure claims administrator.

The rebate model faces a similar fate. Manufacturers previously paid rebates to PBMs in exchange for preferred formulary placement, with PBMs retaining a portion of those rebates and passing through the remainder to health plans. The rebate negotiation was opaque, with PBMs leveraging their formulary control to extract maximum value from manufacturers competing for market share. But if a drug is subject to the MFP, the manufacturer's price is predetermined by negotiation with CMS, and there is no room for the manufacturer to offer additional rebates without going below the MFP floor. The formulary placement question also changes because Part D plan sponsors are required under the statute to cover selected drugs with prior authorization or step therapy restrictions on formulary access. The PBM loses both the negotiating leverage to demand rebates and the formulary flexibility to steer patients to higher-rebate alternatives.

The PBM response to these pressures will likely follow one of three paths. The first path is vertical integration and consolidation into healthcare conglomerates that generate revenue from multiple lines of business beyond PBM services. CVS Health, UnitedHealth Group through Optum, and Cigna through Express Scripts have all pursued this strategy, embedding PBM operations within larger ecosystems that include health insurance, specialty pharmacy, retail pharmacy, and provider services. The PBM function becomes a loss leader or break-even operation that drives volume to other profit centers. The second path is retreat to pure administrative services: cost-plus pricing, competing on operational efficiency and service quality rather than pricing arbitrage. This is the transparent PBM model that some smaller players have advocated, but it requires accepting much lower profit margins and fundamentally different economics. The third path is to fight the MFP expansion through litigation, lobbying, and political advocacy, hoping to slow or reverse the negotiation program before it erodes too much of the profit pool.

The market is already signaling which path incumbents are choosing. The Big Three have doubled down on vertical integration, acquiring or expanding specialty pharmacies, mail-order operations, and provider networks. They are betting that

if PBM margins compress, they can capture downstream value by controlling the entire fulfillment chain. Smaller independent PBMs face a starker choice: adapt administrative-fee-only models, get acquired by larger players, or exit the market. The consolidation wave that created the Big Three in the first place will likely accelerate with regional and specialty PBMs being absorbed by the giants or disappearing entirely.

For health tech entrepreneurs, the PBM disruption creates a rare window to build alternative distribution models. The incumbents are focused on defending existing business lines and integrating acquisitions. They are not optimizing for innovative customer experience. A startup that can offer transparent, efficient, low-cost pharmacy benefit administration with seamless integration into the MTF and direct relationships with pharmacies and manufacturers could capture significant market share among employers and health plans frustrated with traditional PBM practices. The key is to move quickly before the Big Three fully adjust their strategies and before regulatory capture or lobbying efforts blunt the momentum toward transparency.

Part Five: Data Infrastructure as the New Pharmaceutical Real Estate

In any market undergoing digital transformation, control of data infrastructure becomes control of the market itself. The pharmaceutical industry is no exception. The Maximum Fair Price framework does not just mandate transparency in pricing; it mandates the creation and maintenance of data systems that track every MFP transaction at a level of granularity that did not previously exist. This data infrastructure, once built, becomes the foundation for applications and services that extend far beyond MFP compliance. The companies that own and operate this infrastructure, or that build complementary infrastructure that plugs into the MFP ecosystem, will have strategic advantages that compound over time.

The simplest form of this infrastructure is pricing reference data. CMS publishes the Maximum Fair Price file in comma-separated value format with fields for initial

applicability year, selected drug name, active ingredient, NDC-9, NDC-11, cross reference NDC-11, MFP effective date, MFP end date, single MFP per thirty DE NDC-9 MFP per unit price, NDC-11 MFP per package price, as-of date, type of update, and remarks. This file is updated annually at minimum and more frequently when NDCs are added or changed. A data service that normalizes this file, links other drug databases like Drugs@FDA or the Orange Book, enriches it with therapeutic class hierarchies and clinical indication mappings, and serves it through a real-time API becomes essential infrastructure for any system that needs to price MFP prescriptions correctly. Health plans, PBMs, pharmacies, manufacturers, and third-party software vendors all need this data, and they need it to be accurate, up-to-date, and easily integrated. The business model is straightforward: charge subscription fees or per-query API usage fees, with pricing tiers based on volume and use case.

The next layer is claims adjudication infrastructure. Historically, PBMs operated proprietary claims processing systems that applied formulary rules, calculated point-of-sale cost-sharing, determined reimbursement amounts, and routed payments. Under the MFP framework, claims processing becomes more complex because the system must distinguish between MFP-eligible individuals and non-MFP-eligible individuals, apply the correct pricing based on eligibility, trigger manufacturer refund workflows for MFP claims, interface with the MTF Data Module to transmit claim-level data, and reconcile payments across the PBM, pharmacy, manufacturer, and MTF Payment Module when used. A cloud-based claims platform that handles this complexity as a service, integrating with existing plan sponsor systems and the MTF, could displace legacy PBM technology and capture a portion of the multi-billion dollar claims processing market.

The third layer is compliance and audit infrastructure. Manufacturers are subject to civil monetary penalties if they fail to make the MFP available for at least ninety percent of claims. To avoid penalties, manufacturers need systems that monitor compliance in real-time, identify claims where the MFP may not have been applied, initiate corrective actions automatically, maintain audit trails for CMS reviews, and generate compliance reports that satisfy regulatory requirements. This is a class

RegTech opportunity. A software platform that provides manufacturers with end-to-end MFP compliance management, from data ingestion and validation to payment execution and audit support, becomes mission-critical infrastructure. The revenue model could be software-as-a-service subscriptions, transaction-based pricing, or professional services for implementation and audit support.

The fourth layer is analytics and intelligence infrastructure. The MFP data, combined with claims data, clinical outcomes data, and real-world evidence, creates opportunities for advanced analytics that inform strategic decisions across the industry. Manufacturers want predictive models for which of their drugs might be selected for negotiation in future cycles, what factors CMS is likely to weigh heavily in negotiations, and how to position their evidence packages to achieve favorable MFPs. Health plans want forecasting models for total cost of care under different MFP scenarios, utilization trend analysis to detect whether lower prices are driving increased consumption, and therapeutic substitution recommendations when MFP drugs have cheaper alternatives. Investors want portfolio analytics showing which pharmaceutical companies have the greatest exposure to future MFP rounds and which therapeutic areas are most vulnerable to pricing pressure. Each of these use cases requires sophisticated data infrastructure that can ingest diverse data sources, apply machine learning or statistical models, and deliver insights through dashboards or APIs.

The strategic imperative for health tech companies is to position themselves as essential infrastructure rather than point solutions. Point solutions solve discrete problems and can be replaced. Infrastructure is embedded into workflows, becomes a dependency for multiple stakeholders, and generates durable competitive advantage through network effects and switching costs. The MTF itself is infrastructure. The pricing reference data is infrastructure. The claims adjudication platform is infrastructure. The compliance system is infrastructure. These are not products. They are platforms. And platforms, once established, are incredibly difficult to displace because the cost of migration exceeds the benefit of marginal improvement.

There is a cautionary tale here from other industries. In financial services, the companies that controlled the infrastructure, the Visas and Mastercards and AC

operators, captured more value over the long term than most of the banks and merchants using the infrastructure. In telecommunications, the companies that the pipes and protocols captured more value than most of the I'll continue from the text was cut off:

content providers using the networks. In e-commerce, Amazon Web Services captures more value as infrastructure than many of the retailers selling on Amazon's marketplace. The pattern repeats: infrastructure operators earn outsized returns because they sit at the nexus of transactions and benefit from economies of scale smaller players cannot match. The pharmaceutical industry is undergoing the same transformation, and the Maximum Fair Price mechanism is the catalyst.

The challenge for entrepreneurs is timing. Infrastructure businesses require significant upfront capital investment, long sales cycles to achieve network effects and patience to reach profitability. Venture capital firms accustomed to rapid growth and quick exits may not have the appetite for these dynamics. Strategic investors including large health systems, national pharmacy chains, or pharmaceutical manufacturers themselves, may be better suited to fund infrastructure plays because they have longer time horizons and can benefit from vertical integration. The risk is that if strategic investors control the infrastructure, they may use it to advantage their own operations rather than creating a level playing field for all participants.

Part Six: Winners and Losers in the Post-Negotiation Economy

The Maximum Fair Price framework will create clear winners and losers, though not always the obvious ones. Conventional wisdom holds that patients and taxpayers benefit through lower drug costs while manufacturers lose through revenue compression. This is directionally correct but incomplete. The real story is more nuanced, with second-order and third-order effects that redistribute value in unexpected ways.

The clearest winners are Medicare beneficiaries, at least in theory. CMS projects that enrollees in Part D plans will save an estimated one point five billion dollars from the first ten negotiated drugs alone under the projected defined standard benefit design.

These savings come through lower out-of-pocket costs at the pharmacy counter, reduced premiums as plans pass through savings, and decreased likelihood of high catastrophic coverage thresholds. But the savings are not distributed evenly. Beneficiaries who use the selected drugs frequently capture most of the value, while beneficiaries who do not use these drugs see minimal direct benefit. There is also geographic variation driven by which pharmacies remain in-network and accessible after independents exit due to cash flow constraints.

The Medicare program itself is a winner through reduced gross expenditures on high-cost drugs. The actuarial models suggest billions in savings over the next decade as more drugs enter the negotiation program and as the initial cohort of selected drugs sees prices held down through inflation-adjusted MFPs rather than unfettered price increases. These savings help extend the solvency of the Medicare Trust Fund and create fiscal space for other healthcare priorities. The Congressional Budget Office and Joint Committee on Taxation scoring of the Inflation Reduction Act estimates that the drug negotiation provisions would reduce the federal deficit by nearly one hundred billion dollars over ten years.

Pharmaceutical manufacturers are the obvious losers, but the impact varies dramatically by company and product portfolio. Manufacturers with high exposure to Medicare-covered drugs nearing the end of patent life or facing biosimilar competition were already anticipating revenue declines. The MFP accelerates and deepens those declines but does not fundamentally change the trajectory. Manufacturers with diversified portfolios across therapeutic areas, strong commercial insurance business, and robust international sales can absorb the Medicare revenue hit more easily than companies concentrated in a single therapeutic category with high Medicare exposure. The manufacturers most vulnerable are those with one or two blockbuster drugs that constitute the majority of revenue and that are selected for negotiation early in the program.

The litigation strategy pursued by multiple manufacturers reflects this asymmetry. Companies with existential exposure to MFP selections, Merck with Januvia, Bristol Myers Squibb with Eliquis, Johnson and Johnson with Xarelto, filed constitutional challenges arguing that the program violates the Fifth Amendment takings clause.

the First Amendment by compelling speech through required negotiation. These lawsuits have not succeeded in halting the program, and the negotiated prices went into effect on schedule in January two thousand twenty-six. The legal challenges continue for years, but the practical reality is that manufacturers must comply with Medicare entirely, which for most companies is not a viable option given Medicare's forty-nine million beneficiaries and its role as the largest single payer in the US healthcare system.

Independent pharmacies are clear losers unless they can secure working capital solutions or exit Part D entirely. The cash flow dynamics discussed earlier create an untenable situation for pharmacies with limited balance sheet capacity. The consolidation trend will accelerate, with vertically integrated chains like CVS, Walgreens, and Rite Aid gaining market share while independents close or sell to larger operators. Rural and underserved communities will bear the brunt of this consolidation through reduced access to pharmacy services. The policy response includes targeted subsidies or loan programs to support independent pharmacies in pharmacy deserts, but such programs are politically difficult to implement and tend to arrive too late to prevent closures.

Traditional PBMs are losers in the sense that their core business model is being disrupted, but the Big Three have sufficient scale and vertical integration to adapt. Smaller PBMs without the ability to pivot to administrative-fee-only models or to integrate across the value chain will struggle. The PBM market will likely consolidate further toward the Big Three plus a handful of specialized players serving niche segments like government programs or union benefit funds. The transparency and regulatory pressure on PBM practices creates an opening for insurgent competitors, but building a viable alternative requires significant capital, technology capabilities, and network density to compete with incumbents.

The less obvious winners are technology platforms and financial services companies that can insert themselves into the new payment flows. Companies providing working capital to pharmacies, operating or building on top of the Medicare Transaction Facilitator, offering compliance and analytics software to manufacturers, or creating transparent pricing marketplaces that disintermediate PBMs will capture value

previously did not exist as a distinct business opportunity. The total addressable market for these services is in the billions of dollars annually, growing as more d enter the negotiation program and as the infrastructure matures.

Health plans face a mixed outcome. On one hand, lower drug costs reduce their medical expenses and allow them to offer more competitive premiums in Medicare Advantage and Part D. On the other hand, the MFP removes some of their former flexibility and negotiating leverage with manufacturers. Plans can no longer steer patients to preferred drugs through differential cost-sharing or prior authorization for selected drugs, which limits their ability to extract rebates and discounts. The effect depends on the specific mix of drugs in their member population and their ability to manage utilization and substitution toward lower-cost alternatives when clinically appropriate.

Wholesalers and distributors are largely neutral. They continue to purchase drugs from manufacturers and sell to pharmacies at acquisition cost plus a distribution fee. The MFP does not fundamentally change their role or economics. There may be impacts from volume shifts if lower prices drive increased utilization or if pharmacy closures reduce the number of delivery points, but these are marginal effects.

Patients outside Medicare, particularly those with commercial insurance or no insurance, are potential losers if the MFP drives manufacturers to increase prices in other segments to offset Medicare revenue losses. Economic theory suggests that price controls in one market can lead to higher prices in unregulated markets as suppliers seek to maintain overall profitability. Early evidence is mixed, with some manufacturers holding prices steady and others implementing increases. The magnitude of any spillover effect will depend on competitive dynamics in each therapeutic category and the elasticity of demand in commercial markets.

The innovation impact remains the most contentious and uncertain outcome. Pharmaceutical manufacturers argue that lower revenues will reduce investment in research and development, slowing the pipeline of new drugs and harming patients who would have benefited from future innovations. Academic studies have produced conflicting estimates of the innovation effect, with some models projecting

meaningful reductions in new drug approvals and others finding minimal impact. The truth likely lies in between and varies by company and therapeutic area. Large established manufacturers with diversified portfolios and strong cash flow can maintain R and D spending. Small biotechnology companies heavily dependent on licensing revenue from single assets may face greater constraints. The overall innovation ecosystem includes academic research, government funding through National Institutes of Health, venture capital, and philanthropic investment in addition to pharma R and D, so the system has resilience even if one source of funding dries up.

Conclusion: The Coming Wave of Creative Destruction

The Maximum Fair Price mechanism is not merely a pricing regulation. It is a restructuring of capital flows, information flows, and power dynamics across the pharmaceutical distribution system. The effects will cascade through multiple layers of the value chain, creating friction points, arbitrage opportunities, and infrastructure gaps that define the competitive landscape for the next decade. Health tech entrepreneurs and investors who understand these dynamics and move quickly to capture emerging opportunities will generate outsized returns. Those who miss the shift or move too slowly will watch as others build the infrastructure and platforms that become the new gatekeepers in pharmaceutical distribution.

The pattern of creative destruction is clear. Independent pharmacies will consolidate or disappear, replaced by vertically integrated chains or new direct-to-consumer models that eliminate physical dispensing locations. Traditional PBMs will contract or transform into administrative service organizations, replaced by transparent marketplaces and data platforms. Manufacturer rebate strategies will shift from opaque negotiations with PBMs to direct value-based contracts with health plan providers. The Medicare Transaction Facilitator will evolve from a compliance tool into a platform ecosystem supporting financial services, analytics, and alternative distribution models. Pricing transparency will extend beyond Medicare into commercial markets as employers and patients demand similar visibility and fair

The key strategic question for entrepreneurs is where to position in the value chain. Infrastructure operators will capture durable value but require patient capital and long time horizons. Application layer companies building on top of infrastructure move faster and exit sooner but face more competition and lower barriers to entry. Vertical integrators that control multiple parts of the chain can extract maximum value but require significant capital and operational complexity. Each strategy has merit depending on founder capabilities, investor expectations, and market timing.

The regulatory environment will continue to evolve, creating both risks and opportunities. The Trump administration's stance on the negotiation program remains uncertain, with some signals suggesting support for lower drug prices and other signals suggesting skepticism toward government intervention in markets. Congressional Republicans have historically opposed the negotiation authority but face political pressure from constituents who support lower drug costs. Future administrations and Congresses may expand the program to cover more drugs, add commercial insurance, or include international reference pricing. Or they may curtail the program, delay implementation, or create exceptions that weaken its impact. Entrepreneurs must build businesses that can adapt to regulatory uncertainty rather than betting entirely on the current framework persisting unchanged.

The international dimension adds another layer of complexity. The United States historically tolerated higher drug prices than other developed countries, with the implicit understanding that US patients and taxpayers subsidize global pharmaceutical innovation by paying premium prices. If the MFP reduces US prices significantly, manufacturers may seek to increase prices in European, Asian, or other markets to maintain profitability. This could trigger backlash from foreign governments and lead to coordinated international price regulation. Alternatively, other countries may adopt similar negotiation programs, creating a global race to the bottom on drug prices with profound implications for innovation incentives and access to medicines in developing markets.

The Maximum Fair Price framework represents the most significant intervention in pharmaceutical pricing in decades, and its effects will reverberate across the healthcare ecosystem for years to come. For patients, the promise is lower costs ;

better access to life-saving medications. For the Medicare program, the promise is fiscal sustainability and better value for taxpayers. For the industry, the reality is disruption, displacement, and opportunity. The companies that navigate this transition successfully will be those that recognize the structural nature of the change, invest in the infrastructure and capabilities needed to thrive in the new environment, and move aggressively to capture value before competitors close the window. The pharmaceutical distribution system is being rebuilt in real-time, and architects of the new system will be rewarded accordingly. The question is not whether creative destruction will occur but who will create and who will be destroyed.



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