U.S. Pharmaceutical Pricing and Market Access System

Executive summary

The United States remains the outlier among high-income drug markets because manufacturers generally set launch list prices with comparatively few ex ante national price controls, while downstream access and realized economics are shaped by a fragmented web of PBMs, insurers, Medicare, Medicaid, 340B entities, pharmacies, and providers. In practice, the price that matters strategically is rarely the posted list price alone. What matters is the full gross-to-net architecture: rebates for formulary placement, Medicaid rebates tied to AMP and best price, Medicare's ASP-based reimbursement for most Part B drugs, 340B discounts tied to the Medicaid rebate formula, and confidential commercial contracts that can materially reduce realized manufacturer revenue relative to WAC. [1]

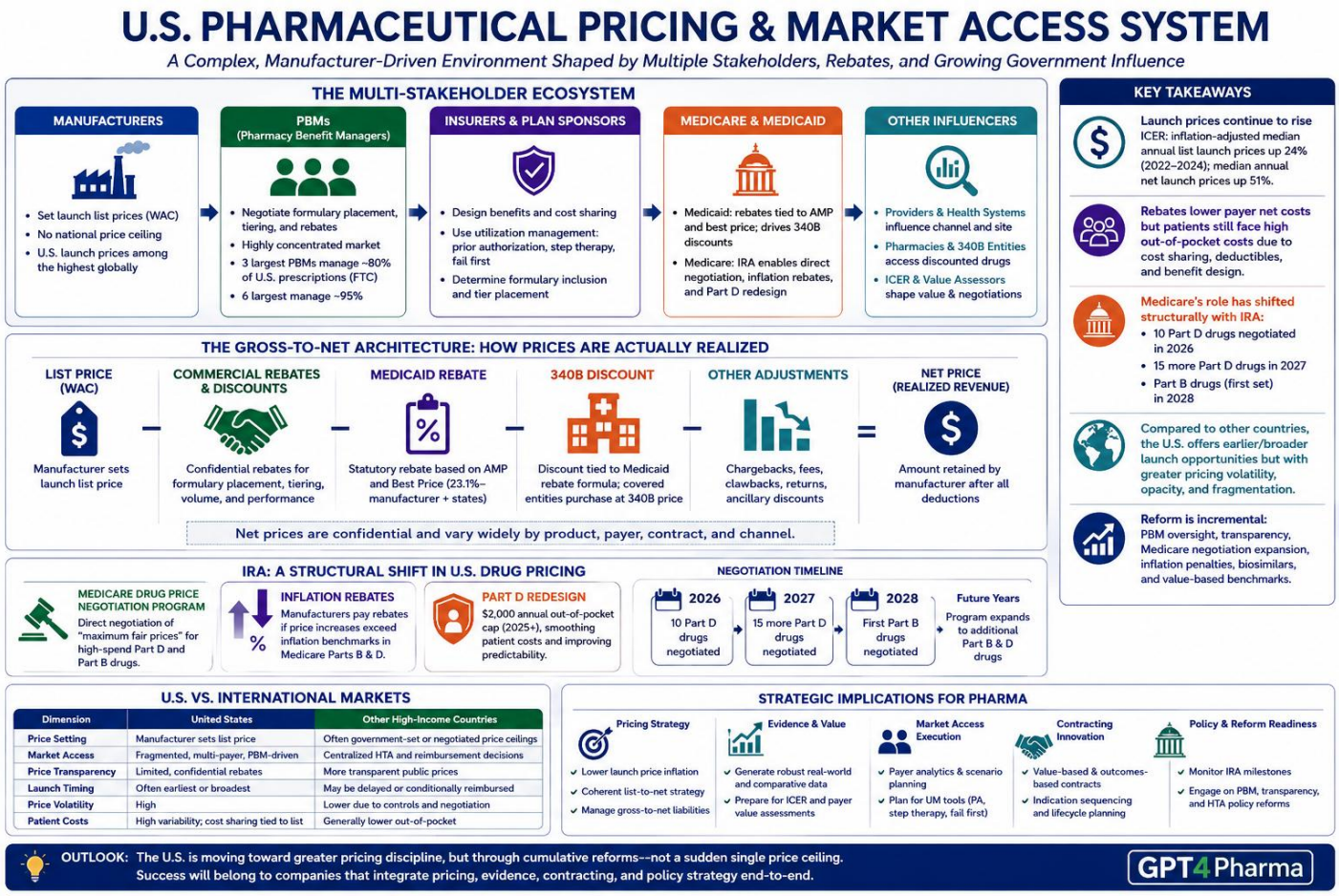
The current system is increasingly two-tiered. In the commercial and Medicare Part D markets, PBMs and plan sponsors still negotiate coverage, tiering, and rebates at scale. The FTC found that the three largest PBMs manage nearly 80% of U.S. prescriptions, while the six largest manage nearly 95%, underscoring how concentrated the benefit-management layer has become. At the same time, public programs are exerting more direct pricing pressure than at any point in Medicare's history. The IRA created a Medicare Drug Price Negotiation Program, required inflation rebates in Medicare Parts B and D, and redesigned Part D with a hard annual out-of-pocket cap. [2]

The strategic consequence for pharma is clear: U.S. market access is no longer just about winning product approval and setting a premium WAC. It is about designing a launch pathway that can withstand PBM demands, insurer utilization management, Medicaid best-price exposure, 340B leakage or disputes, Medicare negotiation risk, and growing scrutiny from value assessors such as ICER. It is also about sequencing indications, evidence generation, channel mix, contracting structures, and patient support so that list price, net price, and access policy remain internally coherent. [3]

Several high-confidence conclusions follow from the evidence. First, launch prices in the U.S. continue to rise even as many mature products experience widening gross-to-net discounts; ICER found inflation-adjusted median annual list launch prices up 24% from 2022 to 2024 and median annual net launch prices up 51%. Second, rebates materially reduce payer net costs but do not eliminate affordability problems at the patient level because many patients face cost sharing linked to list prices, benefit design, deductibles, or utilization-management barriers. Third, Medicare's role has shifted structurally: negotiated maximum fair prices already took effect for 10 Part D drugs in 2026, 15 more Part D drugs will follow in 2027, and in 2028 the program expands to include the first Part B drugs. Fourth, compared with countries that use centralized HTA and explicit price ceilings or negotiated reimbursement prices, the U.S. still offers earlier or broader launch

opportunities, but at the cost of greater pricing volatility, contracting opacity, and access fragmentation. [4]

For industry stakeholders, the operating playbook is shifting toward lower launch price inflation, more evidence-linked contracting, tighter control of gross-to-net liabilities, stronger pre-launch payer analytics, and more explicit planning for IRA milestones. The most likely reform path over the next several years is not a sudden European-style single price ceiling across the whole U.S. market. It is a cumulative tightening through PBM oversight, e-prior-authorization and transparency rules, Medicare negotiation expansion, inflation penalties, biosimilar acceleration, and continued pressure for value-based or internationally anchored benchmarks. [5]



Market architecture and stakeholder economics

At a system level, the U.S. drug market can be understood as a negotiation economy built on sequential gatekeepers. Manufacturers typically establish the launch list price, often referenced through WAC, and then negotiate access with PBMs and payers that control formulary placement, tiering, prior authorization rules, and step therapy. In contrast to many OECD systems, those access decisions are decentralized across commercial

insurers, employer sponsors, Medicare Part D plans, Medicaid programs, integrated delivery systems, and specialty channels. [6]

PBMs occupy the pivotal middle position. The FTC's interim staff report found that the three largest PBMs manage nearly 80% of prescriptions, and the six largest manage nearly 95%, while the market has become increasingly vertically integrated with insurers and pharmacies. ASPE's 2024 retail-channel margin study estimated that PBM margins in its model rose from 23% in 2020 to 31% in 2022, while wholesalers remained roughly stable at 5% to 6% and pharmacy margins declined. ASPE also cautioned that some omitted manufacturer concessions, including 340B-related discounts and certain fees, may cause PBM margins to be overstated in that model. [7]

Insurers remain the practical arbiters of utilization. In commercial specialty coverage, a 2026 JAMA Network Open study of 161 drugs across 18 large commercial health plans representing about 70% of the commercial market found that 46.3% of coverage decisions included at least one restriction, and higher net prices were associated with greater odds of restriction in multivariable analysis; rebate size, by contrast, was not significantly associated with restriction. In Medicare Advantage, KFF reported that plans made nearly 53 million prior-authorization determinations in 2024, denied 7.7% of them, and overturned more than 80% of appealed denials, illustrating the scale of utilization management even when eventual reversals are common. [8]

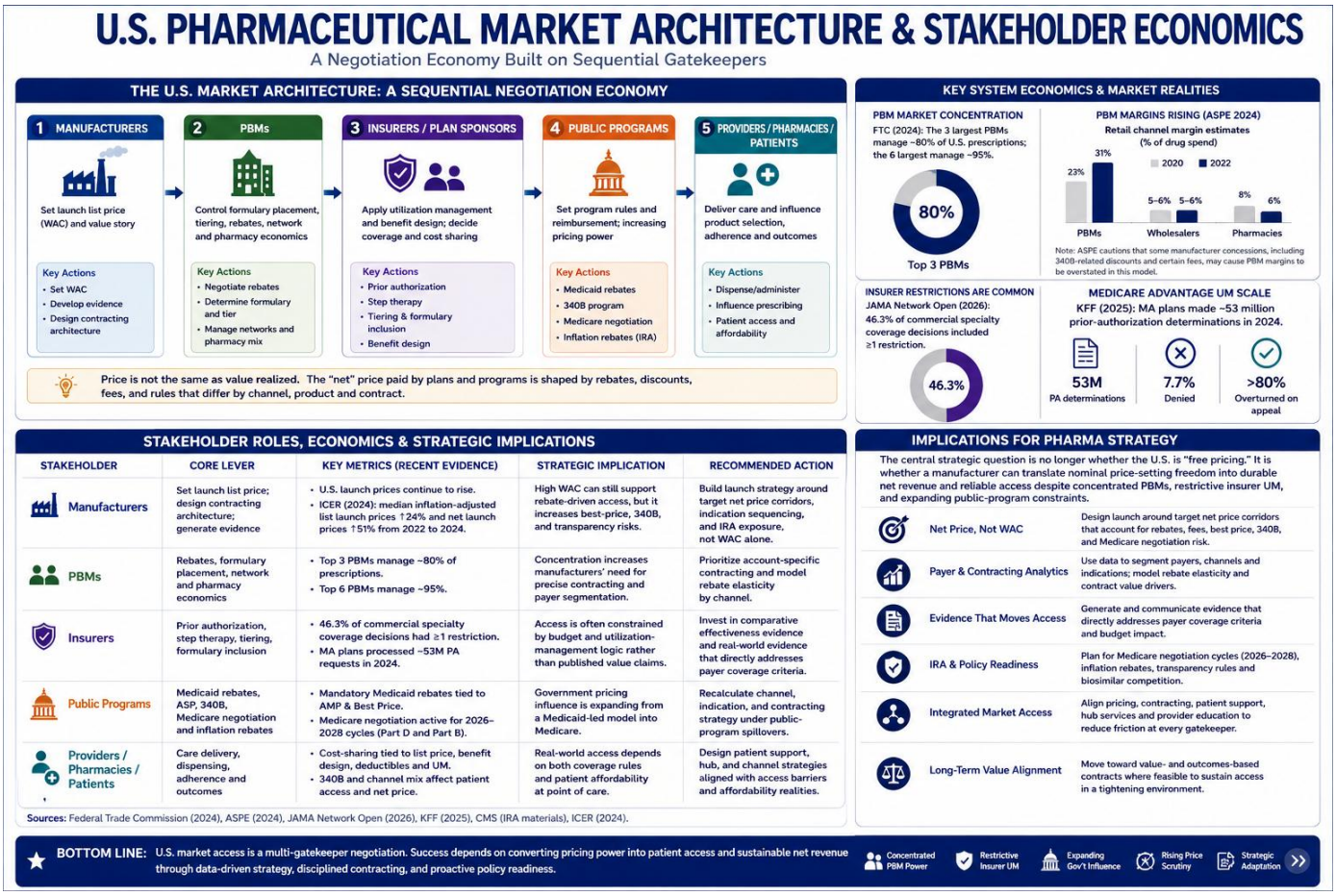
The manufacturer side of the equation is still unusually powerful in the U.S. relative to many foreign systems. JAMA Health Forum noted that brand manufacturers in the U.S. freely set list prices and then negotiate rebates in commercial and Medicare Part D markets, unlike Medicaid where Congress set mandatory rebate rules. That flexibility helps explain why the U.S. is the market where price is often launched high and then negotiated downward through confidential concessions rather than fixed near a centrally assessed reimbursable value from the outset. [9]

Stakeholder	Core lever	Key metrics	Strategic implication	Recommended action
Manufacturers	Set launch list price; design contracting architecture; generate evidence	U.S. launch prices continue to rise; ICER found median inflation-adjusted list launch prices up 24% and net launch prices up 51% from 2022 to 2024	High WAC can still support rebate-driven access, but it increases best-price, 340B, and transparency risks	Build launch strategy around target net price corridors, indication sequencing, and IRA exposure, not WAC alone
PBMs	Rebates, formulary	Top 3 PBMs manage nearly	Concentration increases	Prioritize account-specific

Stakeholder	Core lever	Key metrics	Strategic implication	Recommended action
	placement, network and pharmacy economics	80% of prescriptions; top 6 nearly 95%	manufacturers' need for precise contracting and payer segmentation	contracting and model rebate elasticity by channel
Insurers	Prior authorization, step therapy, tiering, formulary inclusion	46.3% of commercial specialty coverage decisions had at least one restriction; MA plans processed ~53 million PA requests in 2024	Access is often constrained by budget and utilization-management logic rather than published value claims	Invest in comparative effectiveness evidence and real-world evidence that directly addresses payer coverage criteria
Public programs	Medicaid rebates, ASP, 340B, Medicare negotiation and inflation rebates	Mandatory Medicaid rebates; Medicare negotiation active for 2026-2028 cycles	Government pricing influence is expanding from a Medicaid-led model into Medicare	Recalculate channel, indication, and contracting strategy under public-program spillovers

Sources for the table are drawn from FTC, ASPE, JAMA, KFF, CMS, and ICER. [10]

Implications for pharma strategy. The central strategic question is no longer whether the U.S. is "free pricing." It is whether a manufacturer can translate nominal price-setting freedom into durable net revenue and reliable access despite concentrated PBMs, restrictive insurer UM, and expanding public-program constraints. Companies with weak contracting analytics, limited budget-impact data, or poorly sequenced indication strategies are more exposed than before. [11]



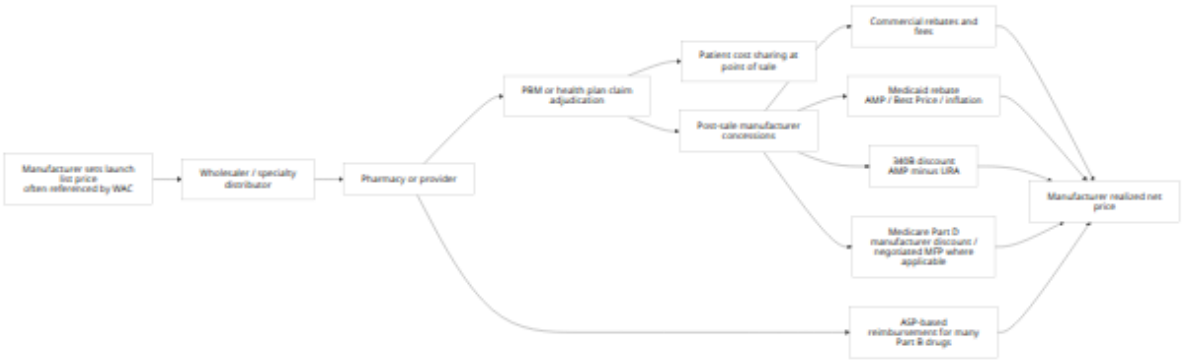
From WAC to net price and patient price

The best way to understand U.S. pricing is to separate three different prices: the launch list price, the manufacturer's realized net price, and the patient's out-of-pocket price. Those numbers often move differently. JAMA Health Forum and ASPE both emphasize that manufacturers set list prices at launch, but payers often purchase at materially lower net prices after rebates and discounts. In commercial plans from 2015 to 2019, prerebate drug spending per covered life rose faster than postrebate spending, especially in large-group coverage where median prerebate spending rose 23.9% but median postrebate spending rose only 7.6%. [12]

That divergence is the core "gross-to-net" mechanism. Manufacturers compete for formulary access by offering rebates, administrative payments, chargebacks, and other concessions. In Medicare Part D, a 2021 JAMA Health Forum analysis found that direct and indirect remuneration plus coverage-gap discounts drove estimated discounts on brand-name drugs from 25.4% of gross brand spending in 2014 to 37.3% in 2018. In the commercial specialty market, the 2026 Tufts/JAMA study estimated a median discount from list price of 27.8%, with a median annualized rebate of about $29,400 among included drugs. [13]

Medicaid and 340B add statutory mechanics that make U.S. net pricing especially complex. Medicaid's basic rebate for innovator drugs is the greater of 23.1% of AMP or AMP minus best price, plus an inflation-linked component. HRSA's 340B ceiling price then uses AMP minus the unit rebate amount. These formulas mean that a commercial contracting decision can cascade into public-program liabilities. This is one reason manufacturers often optimize across a portfolio of market segments rather than maximizing rebate generosity in any single commercial account. [14]

For physician-administered Part B drugs, the pricing logic differs again. CMS states that Medicare pays most separately payable Part B drugs at ASP plus 6%, using quarterly manufacturer submissions that already incorporate discounts. That means list-price optics matter less for Part B reimbursement than the evolution of realized average sales prices and channel mix. It also means biosimilar competition and buy-and-bill economics can reshape incentives differently than in retail Part D or commercial pharmacy benefit contracts. [15]



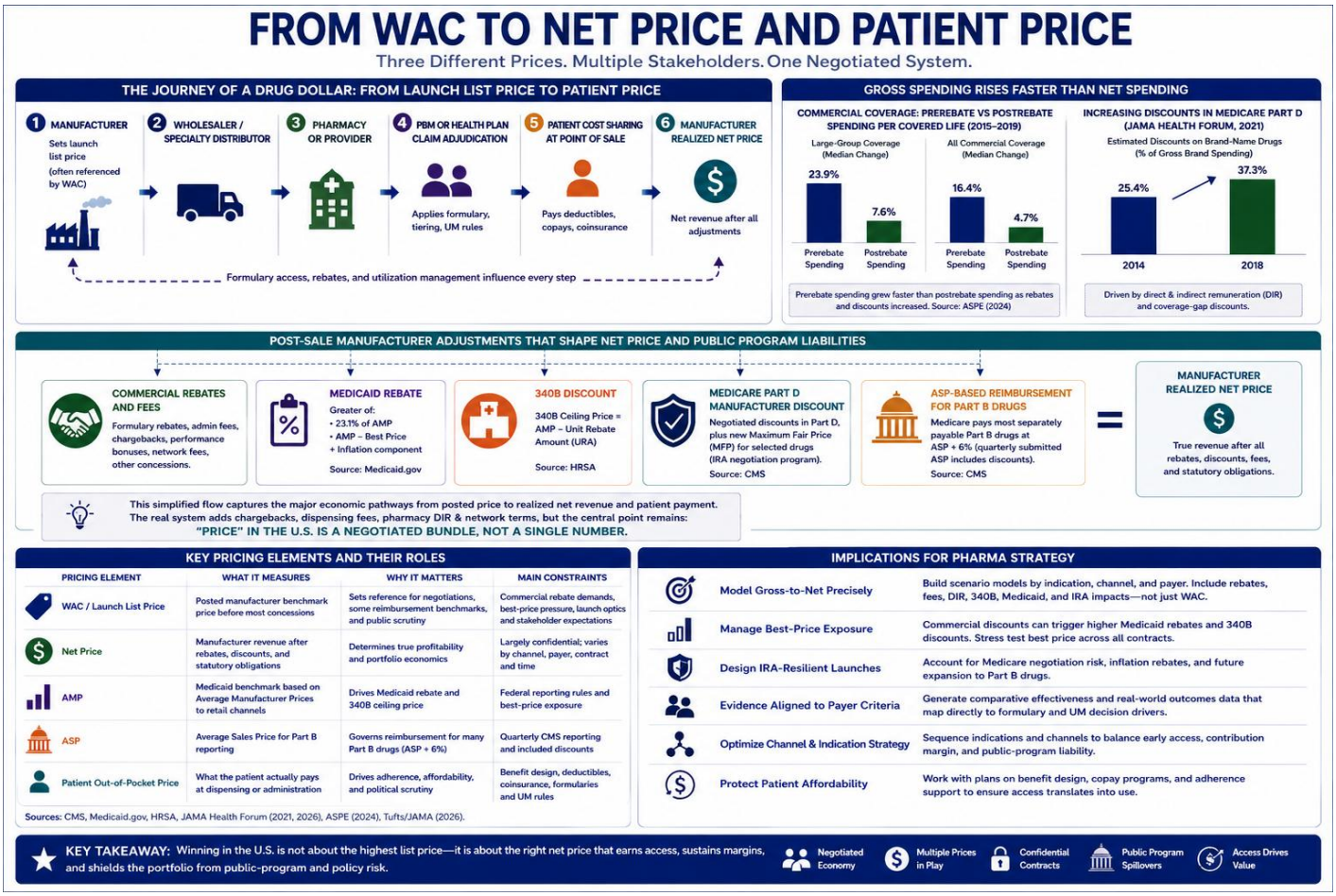
This simplified flowchart captures the major economic pathways from posted price to realized net revenue and patient payment. The real system adds chargebacks, dispensing fees, pharmacy DIR and network terms, but the central point remains: "price" in the U.S. is a negotiated bundle, not a single number. [16]

Pricing element	What it measures	Why it matters	Main constraints
WAC / launch list price	Posted manufacturer benchmark price before most concessions	Sets the reference point for negotiations, some reimbursement benchmarks, and public scrutiny	Commercial rebate demands, best-price pressure, launch optics
Net price	Manufacturer revenue	Determines true	Largely confidential;

Pricing element	What it measures	Why it matters	Main constraints
	after rebates, discounts, and statutory obligations	profitability and portfolio economics	varies by channel and payer
AMP	Medicaid benchmark based on average manufacturer prices to retail channels	Drives Medicaid rebate and 340B ceiling price	Federal reporting rules and best-price exposure
ASP	Average sales price for Part B reporting	Governs reimbursement for many Part B drugs	Quarterly CMS reporting and included discounts
Patient out-of-pocket price	What the patient actually pays at dispensing or administration	Drives adherence, affordability, and political scrutiny	Benefit design, deductibles, coinsurance, formulary and UM rules

Sources for the table are CMS, Medicaid.gov, HRSA, JAMA, and ASPE. [17]

Implications for pharma strategy. Confidential contracting remains essential, but its strategic value now comes with higher spillover risk. Launch teams should model gross-to-net at the indication, channel, and payer level; perform best-price stress tests; and explicitly integrate 340B, Medicaid, and IRA economics into deal design. A launch that "wins" commercial access but breaks public-program economics is no longer a win. [18]



Medicare, Medicaid, 340B, and the IRA

Historically, Medicare's drug-pricing role was more limited than Medicaid's. Under Part D, plans and PBMs negotiated with manufacturers, while CMS did not directly negotiate drug prices. The IRA changed that structure by requiring negotiation for selected high-spend single-source Part D and Part B drugs and by imposing inflation rebates in both programs. KFF describes this as the culmination of years of debate over whether Medicare should be granted this authority. [19]

The first negotiation cycle covered 10 Part D drugs. CMS reported that these drugs represented $56.2 billion in gross Part D covered drug costs in 2023 and were used by about 8.8 million Part D enrollees. CMS estimated that, if the negotiated prices had applied in 2023, Medicare would have saved about $6 billion in net covered prescription drug costs, or 22% for those products in aggregate, and beneficiaries would save an estimated $1.5 billion when the prices took effect in 2026. [20]

The second cycle covered 15 additional Part D drugs for 2027 implementation. CMS stated that, on a comparable net-cost basis, those negotiated prices would have saved an estimated $12 billion, with a separate inclusive estimate of about $8.5 billion when

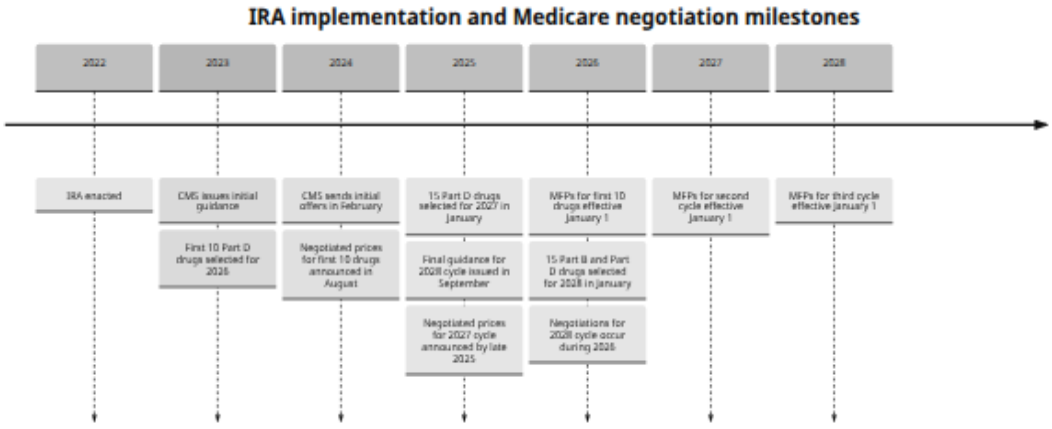
Coverage Gap Discount Program spending is included. KFF reports that the second-cycle negotiated products include high-profile GLP-1s such as Ozempic and Wegovy. [21]

The third cycle, announced in January 2026, is strategically important because it brings Part B drugs into scope for the first time. CMS selected 15 high-cost Part B and/or Part D drugs, used by about 1.8 million Medicare beneficiaries from November 2024 through October 2025 and representing about $27 billion, or roughly 6% of Part B and Part D drug spending in that period. KFF estimates that the 40 products selected across the first three cycles accounted for about 36% of overall Medicare Part B and Part D drug spending in 2024. [22]

The IRA also redesigned Part D affordability. CMS states that the annual out-of-pocket cap was $2,000 in 2025 and adjusts to $2,100 in 2026. That improves beneficiary protection even when plan, PBM, and manufacturer liability shifts elsewhere in the benefit. Separately, CMS reports that it has already assessed inflation rebates for Medicare Part B and Part D drugs whose prices rose faster than inflation, with invoicing for 2023 and 2024 quarters beginning in 2025. [23]

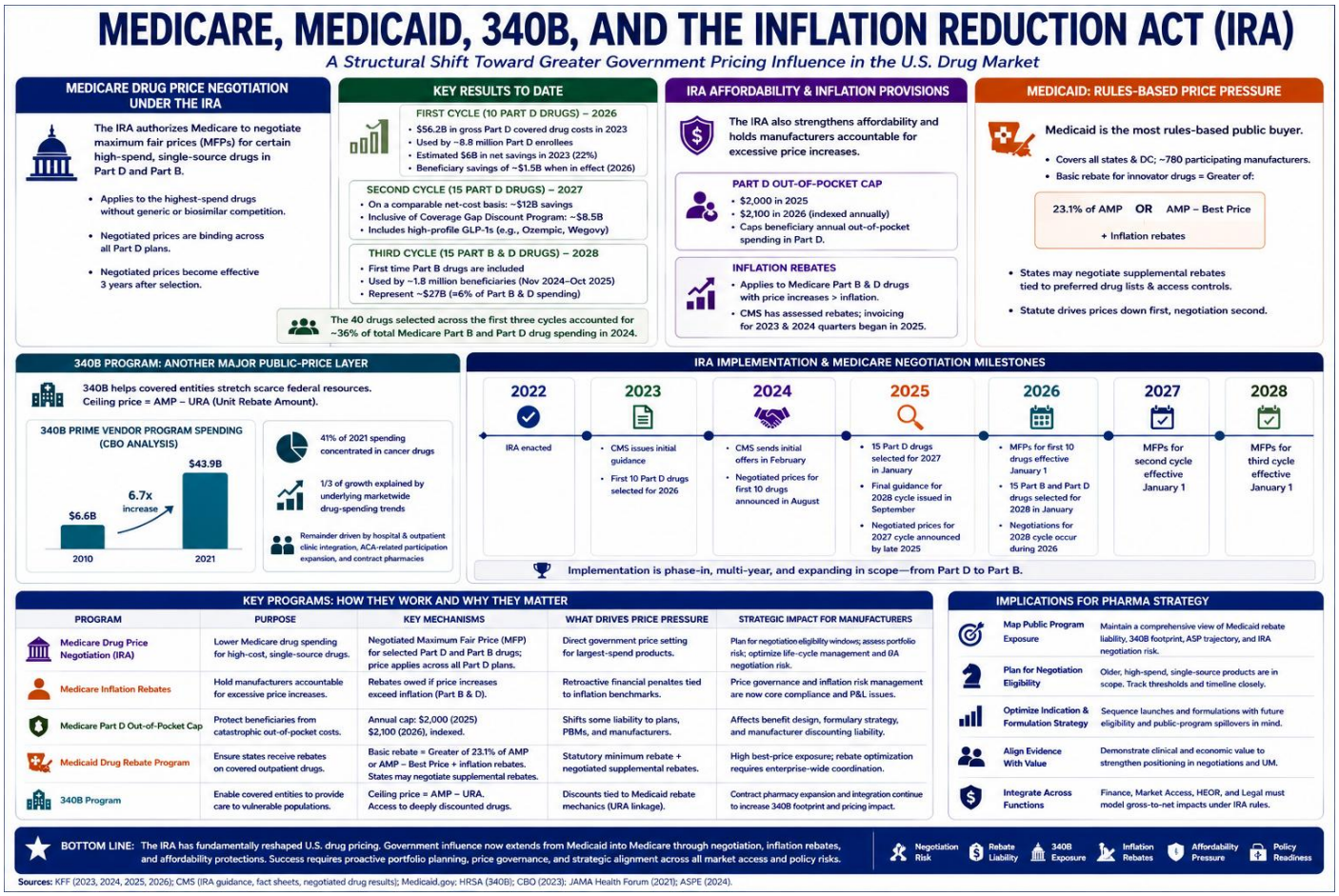
Medicaid, meanwhile, remains the most rules-based public buyer in the U.S. The Medicaid Drug Rebate Program covers all states and the District of Columbia and involves roughly 780 participating manufacturers. The basic innovator-drug rebate is the greater of 23.1% of AMP or AMP minus best price, plus inflation rebates, while states may also negotiate supplemental rebates tied to preferred drug lists and access controls. Medicaid therefore exerts downward pressure through statute first and negotiation second, the reverse of the classic commercial model. [24]

The 340B program adds another major public-sector pricing layer. HRSA describes its purpose as helping covered entities stretch scarce federal resources, while the statutory ceiling price is AMP minus URA. CBO reported that spending on drugs purchased through the 340B Prime Vendor Program grew from $6.6 billion in 2010 to $43.9 billion in 2021, with 41% of 2021 spending concentrated in cancer drugs and one-third of growth explained by underlying marketwide drug-spending trends; CBO attributes much of the remaining growth to hospital and outpatient-clinic integration, ACA-related participation expansion, and contract pharmacies. [25]



This timeline synthesizes CMS guidance, CMS fact sheets, and KFF's 2026 negotiation tracker. [26]

Implications for pharma strategy. Every U.S. brand team should now maintain a public-program exposure map: Medicaid rebate sensitivity, 340B footprint, ASP trajectory, IRA negotiation eligibility window, biosimilar-delay risk, and orphan-exclusion status. For older high-spend products, the Medicare negotiation clock is no longer theoretical. For launch brands, indication sequencing and formulation strategy must be designed with future negotiation eligibility and public-program spillovers in mind. [27]



ICER, specialty and orphan drugs, and the international contrast

ICER occupies a uniquely American position: influential but not sovereign. It has no legal pricing authority, yet its value-assessment framework and health-benefit price benchmarks shape payer discourse, employer coalitions, and some contracting conversations. ICER's framework explicitly aims to assess clinical and economic value; its benchmark prices are designed to represent a net price range aligned with estimated health benefit. [28]

ICER's 2025 Launch Price and Access Report is especially relevant to specialty and orphan products. Across 154 novel FDA approvals from 2022 to 2024, ICER found a 24% inflation-adjusted rise in median annual list launch price and a 51% rise in median annual net launch price. Orphan products, gene and cell therapies, oncology drugs, and endocrine/metabolic products were associated with higher prices. Among 23 drugs previously reviewed by ICER, about 70% had net launch prices above ICER's upper health-benefit price benchmark; aligning those prices to the benchmark range would have reduced first-year spending by an estimated $1.26 billion to $1.49 billion. [29]

Specialty and orphan products, however, are not simply "high price equals high restriction." The 2026 Tufts/JAMA study found that oncology and orphan drugs were less likely to be restricted than many other specialty products, even though overall coverage restrictions remained common. That reflects a recurring U.S. pattern: the sickest populations often receive broader nominal coverage, but the system pays for that breadth with high prices, specialized controls, and budget pressure elsewhere. [30]

The orphan-drug policy environment is also moving. KFF reported that the 2025 reconciliation law broadened the orphan exclusion from Medicare negotiation and delayed eligibility for some drugs that began as orphan-only products and later expanded into broader indications. KFF notes that the change likely delayed negotiation for Keytruda and Opdivo and cites a CBO estimate that the broader orphan exclusion will cost the federal government $8.8 billion over the coming decade. That makes orphan strategy a moving target: it can protect pricing headroom, but only within a politically contested framework. [31]

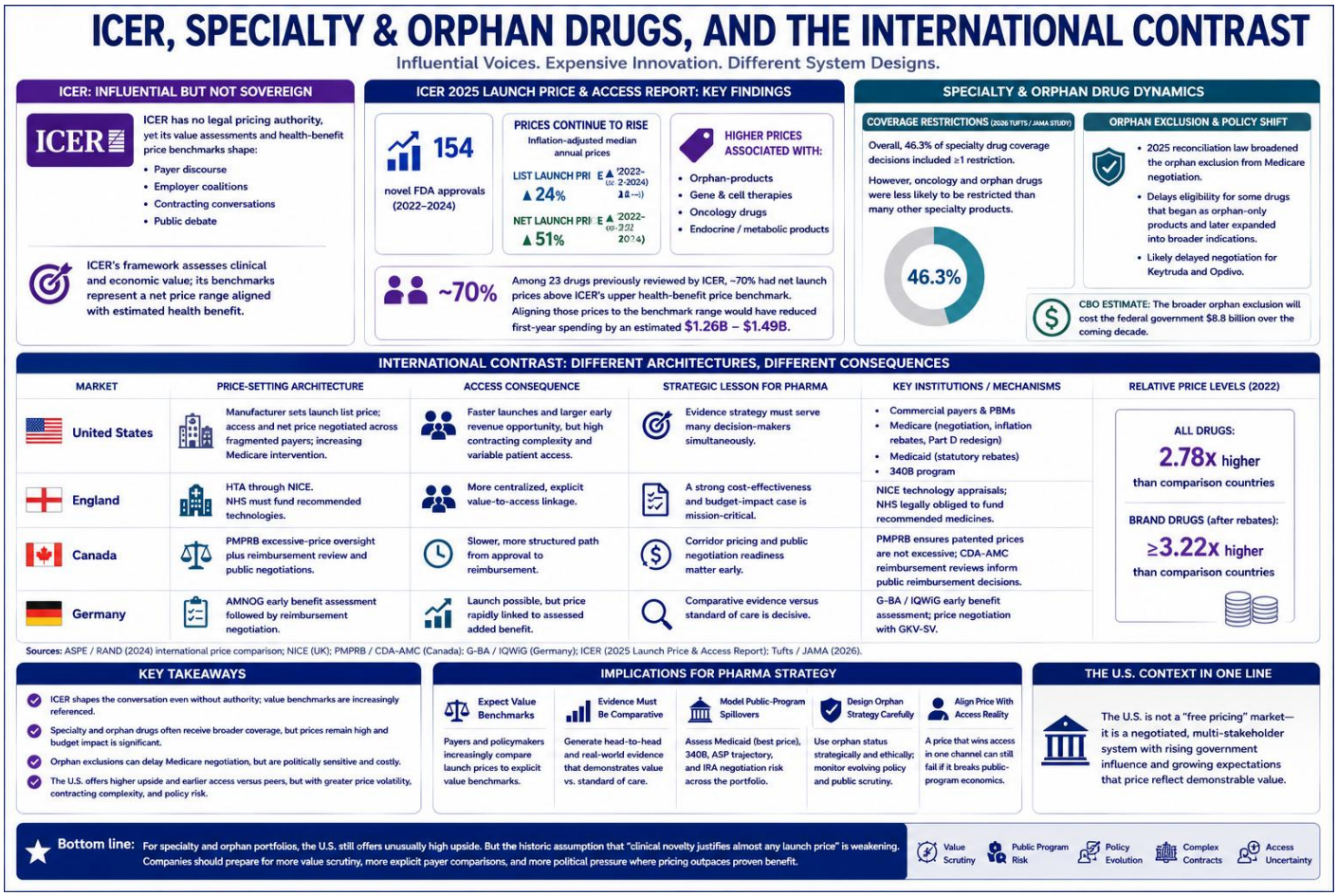
Internationally, the U.S. differs from peer systems less by having no assessment at all than by dispersing assessment power across many actors. ASPE/RAND found that in 2022 U.S. prices across all drugs were 2.78 times those in comparison countries, while U.S. brand prices were at least 3.22 times higher even after adjusting for estimated U.S. rebates; most new drugs were launched first in the U.S. By contrast, NICE technology appraisals guide use in England and the NHS is legally obliged to fund recommended medicines, Canada's PMPRB is tasked with ensuring patented prices are not excessive while CDA-AMC reimbursement reviews inform public reimbursement decisions, and Germany's AMNOG framework uses early benefit assessment and subsequent reimbursement negotiation. [32]

Market	Price-setting architecture	Access consequence	Strategic lesson for pharma
United States	Manufacturer sets launch list price; access and net price negotiated across fragmented payers; increasing Medicare intervention	Faster launches and larger early revenue opportunity, but high contracting complexity and variable patient access	Evidence strategy must serve many decision-makers simultaneously
England	HTA through NICE; NHS must fund recommended	More centralized, explicit value-to-access linkage	A strong cost-effectiveness and

Market	Price-setting architecture	Access consequence	Strategic lesson for pharma
	technologies		budget-impact case is mission-critical
Canada	PMPRB excessive-price oversight plus reimbursement review and public negotiations	Slower, more structured path from approval to reimbursement	Corridor pricing and public negotiation readiness matter early
Germany	AMNOG early benefit assessment followed by reimbursement negotiation	Launch possible, but price rapidly linked to assessed added benefit	Comparative evidence versus standard of care is decisive

Sources for the table are ASPE/RAND, NICE, PMPRB/CDA-AMC, and G-BA/IQWiG. [32]

Implications for pharma strategy. For specialty and orphan portfolios, the U.S. still offers unusually high upside, but the historic assumption that "clinical novelty justifies almost any launch price" is weakening. Companies should expect more explicit comparisons to value benchmarks, more payer skepticism of unsupported launch prices, and more political scrutiny where orphan strategy appears to be used primarily to delay broader pricing oversight. [33]



Access, affordability, and what the system delivers to patients

The U.S. system's central tension is that it can generate fast adoption of innovative drugs while still producing uneven affordability and administratively complex access. On the demand side, KFF reported in 2026 that 59% of adults are worried about affording prescription drug costs, the highest level since KFF began asking in 2018. CDC reporting has also documented persistent cost-related nonadherence, including people skipping doses, taking less medication, or delaying fills because of cost. [34]

Utilization management is a major contributor to that access friction. Medicare.gov defines step therapy as a form of prior authorization that requires patients to try a lower-cost product first, often a generic or biosimilar, before advancing to a higher-cost therapy. In Medicare Advantage, the scale of prior authorization is now enormous: KFF counted nearly 53 million determinations in 2024, with 4.1 million denials and more than 80% of appeals overturned. The high overturn rate suggests that a nontrivial share of denials represent administrative delay rather than durable clinical disagreement. [35]

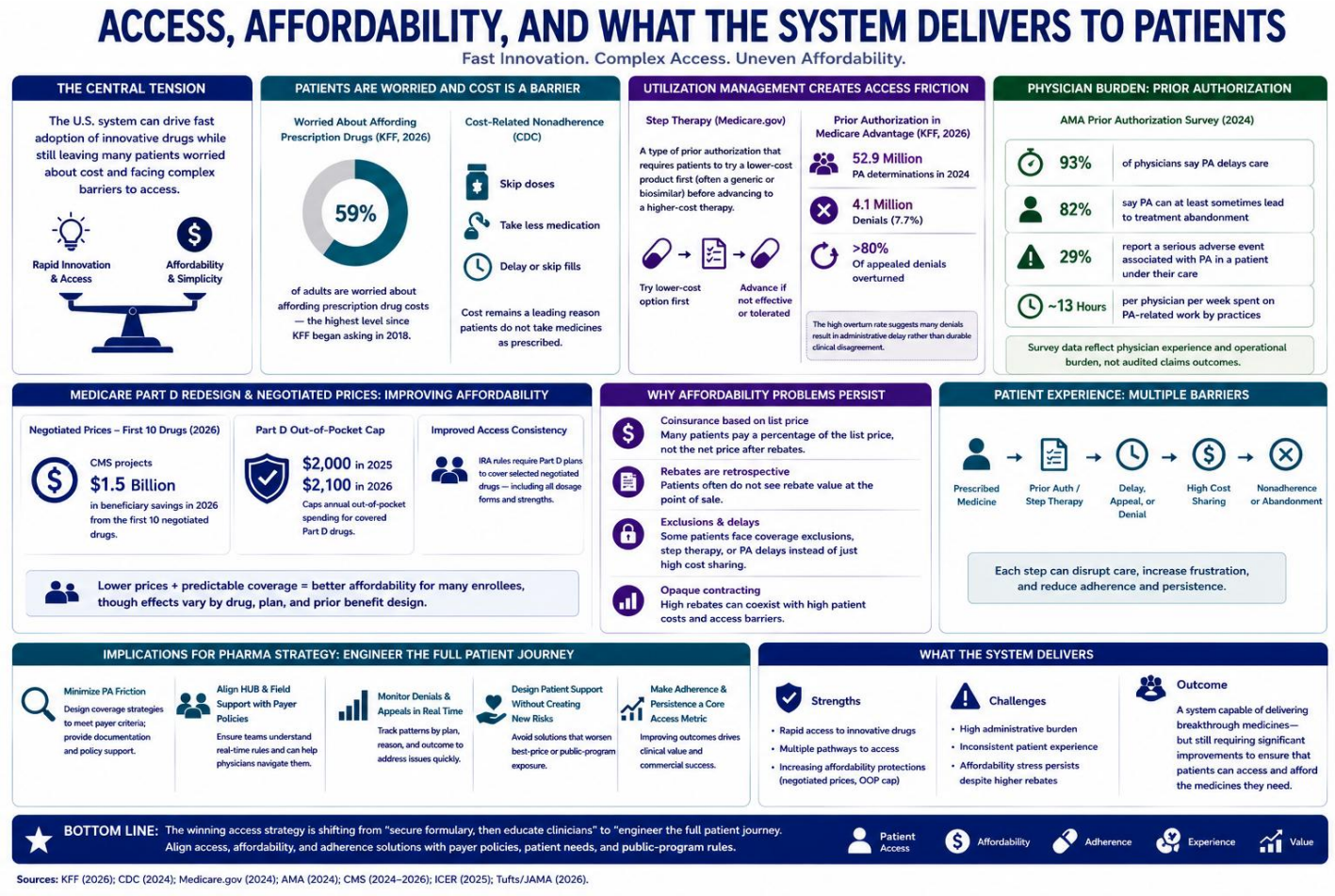
Physician-reported burden tells a similar story. In the AMA's 2024 prior-authorization survey, 93% of physicians said PA delays care, 82% said it can at least sometimes lead to treatment abandonment, 29% reported a serious adverse event associated with PA in a

patient under their care, and physician practices reported spending about 13 hours per physician per week on PA-related work. These are self-reported survey data rather than audited claims outcomes, but they matter because they reflect the operational reality prescribers face. [36]

Part D redesign and negotiated prices should improve affordability for many Medicare beneficiaries, but the effects will vary by drug, plan, and prior benefit design. CMS projects $1.5 billion in beneficiary savings from the first 10 negotiated drugs in 2026, and the Part D out-of-pocket cap materially reduces catastrophic exposure. KFF also notes that IRA rules require Part D plans to cover selected negotiated drugs, including all dosage forms and strengths, which may improve access consistency for those products. [37]

Yet not all affordability problems disappear when net prices fall. Some patients pay coinsurance based on list prices, others never realize the value of retrospective rebates at the point of sale, and some face exclusions or delays rather than high cost sharing. That is why the U.S. can simultaneously exhibit growing rebate levels and persistent patient affordability stress. It is also why plans, PBMs, and manufacturers increasingly discuss point-of-sale rebate pass-through, smoothing programs, and patient-support redesigns even when the deeper contracting system remains confidential. [38]

Implications for pharma strategy. The winning access strategy is shifting from “secure formulary, then educate clinicians” to “engineer the full patient journey.” That means minimizing avoidable prior-authorization friction, aligning hub and field reimbursement support with real payer policies, monitoring denial-and-appeal patterns in near real time, and ensuring copay or patient-support design does not inadvertently worsen best-price or public-program exposure. It also means treating adherence and persistence as commercial-market-access metrics, not just patient-support metrics. [39]



Policy scenarios, future reforms, and open questions

The most plausible U.S. reform path is cumulative, not singular. CBO's 2024 review of alternative approaches found that international reference-style price caps could reduce average U.S. retail drug prices by more than 5%, while expanding Medicare negotiation or extending inflation rebates to the commercial market would have smaller but still meaningful effects. By contrast, CBO judged importation, advertising limits, earlier generic and biosimilar entry, and transparency policies to have very small or uncertain average price effects at the market level, though individual products or classes could still be affected materially. [40]

Recent institutional signals point to five likely reform vectors. The first is deeper PBM regulation and transparency, driven by FTC findings on concentration and vertical integration. The second is more digitized and time-bound prior authorization, as CMS proposed in 2026 for affected payers. The third is steady expansion and operational normalization of Medicare negotiation, now that three cycles are underway and the Supreme Court has declined to hear several manufacturer appeals, leaving the program in place for now. The fourth is continued inflation-penalty enforcement in Medicare. The fifth

is heightened attention to orphan exemptions, biosimilar timing, and whether value arguments are translating into real coverage. [41]

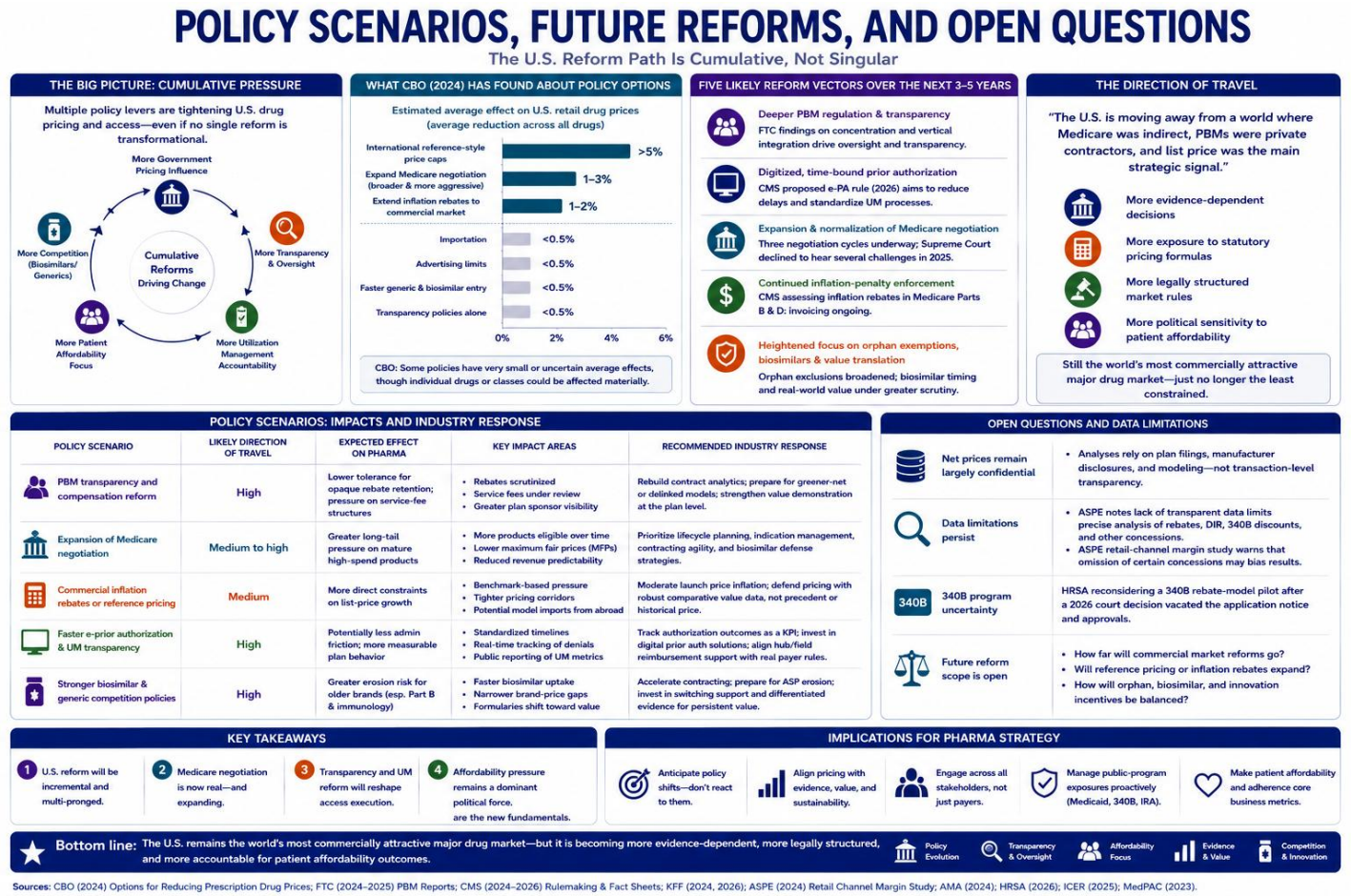
Policy scenario	Likely direction of travel	Expected effect on pharma	Recommended industry response
PBM transparency and compensation reform	High	Lower tolerance for opaque rebate retention; more pressure on service-fee structures	Rebuild contract analytics and prepare for greener-net or delinked models
Expansion of Medicare negotiation	Medium to high	Greater long-tail pressure on mature high-spend products	Prioritize lifecycle planning, indication management, and biosimilar defense
Commercial inflation rebates or reference pricing	Medium	More direct list-price growth constraints	Moderate launch inflation and defend price with evidence, not precedent
Faster e-prior authorization and UM transparency	High	Potentially less administrative friction but more measurable plan behavior	Track authorization outcomes as a KPI and adapt field reimbursement operations
Stronger biosimilar/generic competition policies	High	Greater erosion risk for older brands, especially Part B and immunology	Accelerate contracting, patient switching support, and differentiated evidence

The scenario table synthesizes CBO, FTC, CMS, and current Medicare negotiation developments. [42]

The open questions are not trivial. Net prices remain largely confidential, so many public estimates rely on plan filings, manufacturer disclosures, and modeling assumptions rather than transaction-level transparency. ASPE explicitly notes that the lack of transparent data limits precise analysis of how rebates, DIR, 340B discounts, and other concessions are distributed. ASPE's retail-channel margin study also warns that omission of certain concessions may bias margin estimates. HRSA, meanwhile, is reconsidering the future of a 340B rebate-model pilot after a 2026 court decision vacated the application notice and approvals, underscoring how unsettled some program mechanics remain. [43]

The core policy judgment, however, is already visible. The U.S. is not converging wholesale with single-payer HTA systems, but it is moving away from the older model in which manufacturers could treat Medicare as largely indirect, PBMs as mostly private contracting partners, and list price as the main strategic signal. The market is becoming more

evidence-dependent, more exposed to statutory pricing formulas, more legally structured, and more politically sensitive to patient affordability outcomes. That is the environment GPT4Pharma should frame for readers: still the world's most commercially attractive major drug market, but no longer the least constrained. [44]



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