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Drug Pricing Policy Trends To Expect In 2025 And Beyond

By **Margaux Hall and Emma Coreno** (February 4, 2025, 6:05 PM EST)

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The Trump administration and new Congress are currently in high gear, mobilizing and setting forth their policy and legislative agendas for the next several years.

It is a time of rapid, potentially monumental change in multiple arenas. But drug pricing is different from many other policy topics. It has been subject to a flurry — many would say a storm — of legal and policy actions for years running. That is unlikely to change and, in that regard, the Trump administration and 119th Congress may bring more of the same.

President Donald Trump has said he will focus his first 100 days in office on easy wins. Those are unlikely to be secured in an area as heavily regulated, complex and politically and commercially fraught as drug pricing.

Nonetheless, "the same" for drug pricing would mean a sustained, high level of legal and policy developments affecting the pharmaceutical supply chain.

In that regard, we predict that 2025 will be another busy year for drug pricing across all branches of government, with legal developments affecting the federal healthcare program and commercial market segments.

Year two of the Inflation Reduction Act drug negotiation program is kicking off, and the Centers for Medicare & Medicaid Services and industry are still working to determine how to implement a first-year, i.e., 2026, Medicare negotiated price in the supply chain. We anticipate that litigation on the IRA, as well as the scope and requirements of the Section 340B program, will continue to play out nationwide.

The new Congress is likely to try to unpack the sources of high healthcare and drug costs for consumers, including the role that pharmacy benefit managers play in creating and sustaining high prices and restricting competition.

Congressional investigations may hold particular appeal as a public stage to examine the sources of high patient out-of-pocket costs and perceived bad actors in the supply chain. And some topics, like the BIOSECURE Act, remain prime targets for early legislative action given their bipartisan appeal and protectionist underpinnings.

The leadership of key agencies, including the U.S. Department of Health and Human Services and the U.S. Food and Drug Administration will dictate policy contours, but we predict the following drug pricing topics will dominate the next several years.

The Inflation Reduction Act

For several years, CMS has been gearing up to implement the IRA. When the IRA was enacted in August 2022, it reflected the most significant drug pricing legislation in years and the culmination of a longstanding campaign by Democrats to lower prescription drug prices.[1]

Among other drug pricing changes, the IRA provides the Medicare program with authority to directly negotiate with manufacturers for, and functionally mandate, lower prices for certain high-spend Medicare drugs.

In August 2024, CMS announced the negotiated prices for the first set of 10 Part D drugs, which, according to the agency, accounted for $56.2 billion in total Part D gross covered prescription drug costs, or about 20% of total Part D gross covered prescription drug costs during 2023.[2]

These drugs will be subject to negotiated prices starting on Jan. 1, 2026. In mid-January 2025, CMS announced the second round of drugs subject to negotiation for the 2027 price applicability year, spanning multiple therapeutic areas including diabetes and obesity, chronic obstructive pulmonary disease, oncology and mental illnesses.[3]

It is still too early to distill the full impact of the IRA on the pharmaceutical industry. CMS has reported an estimated $6 billion in savings in connected with the negotiated prices for 2026, had those prices been in effect in 2023,[4] but these types of estimates have their skeptics.

Indeed, there are growing questions about the true impact of the IRA on the Medicare program. Some critics contend that the government's estimated savings are overstated since many selected drugs are near the end of their life cycle and subject to imminent competition.[5]

Further, the IRA itself is affecting the pipeline of future therapies, with several companies announcing abandonment of research pursuits,[6] and the program will have inevitable spillover impacts to nonselected drugs and the commercial market.

Multiple lawsuits continue to proceed through the courts challenging the program based on constitutional and Administrative Procedure Act claims. To date, the legal challenges have had limited success, with most being dismissed on procedural or jurisdictional grounds, without meaningful consideration of the merits of the underlying claims.

However, a September 2024 ruling by the U.S. Court of Appeals for the Fifth Circuit in National Infusion Center Association v. Becerra provided a glimmer of hope by finding that industry group plaintiffs had demonstrated sufficient injuries to have standing to bring their claims.[7] The Fifth Circuit remanded the case to the district court for consideration of the merits of many of the original claims.[8]

From a legislative perspective, various Republicans have suggested they may attempt to repeal the IRA,[9] although doing so may be costly given the government's projected savings from the program.

Select amendments to the IRA seem more likely, with potential candidates for amendments including

expansion of the orphan drug exclusion and possible reconsideration of the statutory differential in treatment of small molecule versus biologic products.[10]

Other IRA drug pricing reforms go into effect in 2025, including the advent of a first-ever patient out-of-pocket cap on Medicare Part D drug costs at $2,000 — one of the most popular features of the restructured Part D benefit.[11]

The Section 340B Program

We expect that the Section 340B program will continue to be a focal point for litigation involving manufacturers, providers and government, particularly with respect to contract pharmacy arrangements.

In recent years, litigation between the Health Resources and Services Administration and manufacturers has challenged the use of contract pharmacies in the Section 340B program.

Under the program, participating manufacturers must offer covered outpatient drugs at a ceiling price to covered entities. Rather than, or in addition to, distributing Section 340B drugs through their own in-house pharmacies, some covered entities dispense drugs through third-party pharmacies with which they have a contractual relationship.

The Section 340B statute is silent on the use of contract pharmacies, but HRSA has issued guidance permitting these contract pharmacy arrangements.[12]

Manufacturers have contended that the Section 340B statute does not expressly mandate, or even permit, the use of contract pharmacies and that restrictions on these pharmacies are necessary to prevent duplicate discounts and diversion — activities that are prohibited under the statute. Various manufacturers have responded to expansion in the use of contract pharmacies by imposing restrictions on their use.

Litigation regarding manufacturers' ability to impose such restrictions has ensued, with the U.S. Court of Appeals for the Third Circuit finding in Sanofi Aventis v. U.S. Department of Health and Human Services in 2023 that manufacturers are not mandated to comply with unlimited contract pharmacy requirements and can impose some restrictions.[13]

In May 2024, the U.S. Court of Appeals for the D.C. Circuit also authorized certain manufacturer conditions on the use of contract pharmacies in Novartis Pharmaceuticals Corp. v. Johnson.[14] An appeal dealing with similar issues, Eli Lilly v. HHS, is pending in the U.S. Court of Appeals for the Seventh Circuit.[15]

With federal litigation ongoing, several state legislatures have enacted so-called contract pharmacy mandate laws, starting in 2021 with Arkansas.

Arkansas' law survived a legal challenge, with the U.S. Court of Appeals for the Eighth Circuit finding Pharmaceutical in Research and Manufacturers of America v. McClain that the Section 340B statute did not preempt the law.[16] The U.S. Supreme Court declined to take up the appeal on Dec. 9, 2024.

Other lawsuits challenging state contract pharmacy mandate laws on preemption and other grounds

continue to proceed in other jurisdictions, including Louisiana, Maryland, Minnesota, Mississippi and Missouri.

Recently, in Pharmaceutical Research and Manufacturers of America v. Morrisey, a judge granted motions for preliminary injunction against West Virginia in applying its Section 340B law finding that plaintiffs are likely to succeed on the merits because the law "creates an impermissible obstacle to executing the federal program."[17]

If courts continue to reach different decisions, or decisions on different grounds, this would increase the likelihood the Supreme Court takes up this issue.

BIOSECURE Act

While the BIOSECURE Act currently remains in legislative limbo, there continues to be bipartisan attention on Chinese influence in life sciences, and the act could be enacted in some form.

In its latest bill format, the BIOSECURE Act would ban federal agencies from, among other things, contracting with entities that use, or contract for arrangements that require use of, equipment or services provided by a company of concern — i.e., one of five enumerated Chinese companies, among others.[18]

Despite not passing last term, the act garnered significant bipartisan support and is likely to reemerge, in some form, in this next Congress. If enacted in its current form, the act likely would fundamentally shift long-term drug manufacturing and supply chain operations for many biopharmaceutical manufacturers.

Continuing PBM Scrutiny

PBMs are likely to remain in the spotlight. The first Trump administration took aim at PBMs, and bipartisan criticism of PBMs and their role in supply chain pricing and competitive dynamics has grown louder over the past four years.

The Federal Trade Commission has been investigating the role of the large PBMs in the marketplace, and, despite the PBMs failing to yet produce various FTC-requested information, the FTC has issued two interim reports finding that unchecked consolidation has created a market where several large PBMs significantly influence which drugs are available and at what price,[19] charge significant markups for oncology, HIV and other critical specialty generic medicines, and enable PBM-affiliated specialty pharmacies to generate significant revenue.[20]

Further scrutiny of PBMs is likely under the new administration and Congress. Potential PBM legal reforms could include the following, each of which has been debated in policy discussions in recent years: (1) banning spread pricing, (2) limiting PBMs' ability to restrict pharmacy choice, (3) requiring PBM rebate pass through, and (4) delinking PBM compensation from list prices.

At the same time, PBMs have continued to employ utilization and cost-management controls, especially in connection with higher-cost specialty drugs.

In addition to long-standing practices such as formulary exclusions and tiers, prior authorization and step therapy, other controls have emerged, including designating separate specialty drug lists that are subject to distinct cost-sharing terms, and mandating the use of specialty pharmacies — including payor-affiliated specialty pharmacies — as a condition of accessing drugs.

The proliferation of accumulator, maximizer and alternative funding programs continues to generate controversy, with manufacturers and patient groups, on the one hand, attacking such programs as tools to enrich payors at the expense of patients, and plans and PBMs, on the other hand, critiquing manufacturer-sponsored assistance programs as mechanisms that they believe sustain higher drug prices.

Caught in the crossfire are regulators and courts. In ongoing litigation, manufacturers have challenged alternative funding program vendors, alleging that their practices are deceptive and that they tortiously interfere with the contract between the manufacturer and the patient under the manufacturer patient assistance program.

Briefing and discovery remain ongoing in two key litigation matters on this topic, and cases such as these could lend additional visibility into alternative funding program practices.[21]

Along with litigation challenging alternative funding programs, patient organizations, including the HIV and Hepatitis Policy Institute, have successfully challenged HHS' 2021 rule permitting marketplace plans to adopt accumulator programs.[22]

As a result, individual market, small and large group, and self-insured group health plans are now permitted to adopt accumulator programs only for brand prescription drugs that have a medically-appropriate generic equivalent, as permitted by state law.[23]

Additionally, in April 2024, HHS released a new final rule, codifying its policy that all covered prescription drugs are essential health benefits.

The legal and market access environment for PBMs will continue to evolve — likely at a rapid pace — over the next few years.

Prescription Drug Affordability Boards

Mirroring the federal government's activity, state governments have continued to be active in pursuing drug pricing measures. According to the National Academy for State Health Policy, approximately 400 drug pricing-related bills were introduced in 48 state legislatures in 2024.[24]

Like in previous years, popular topics for state legislation include imposing price reporting obligations on manufacturers and others in the supply chain, regulating PBM activities, and establishing prescription drug affordability review boards, some of which have authority to impose upper payment limits on drugs sold or reimbursed in the state.

In 2019, Maryland became the first state to authorize a prescription drug affordability review board to study and regulate the costs of prescription drugs in the state.[25]

Since then, other states, including Colorado and Washington, have enacted laws authorizing prescription drug affordability review boards.

As states mobilize their prescription drug affordability review boards to examine, and potentially set, upper payment limits, there will continue to be questions regarding the lawfulness of the prescription drug affordability review board statutes and their potential spillover consequences for broader pharmaceutical markets and various participants, including healthcare providers that may risk being

underreimbursed under an upper payment limit.

Colorado's prescription drug affordability review board is the furthest along in its process of setting upper payment limits. In late 2023, Colorado's prescription drug affordability review board selected five prescription drugs for affordability review and in 2024, started the implementation process for three of these drugs.[26] Upper payment limit rulemaking for the first drug, Enbrel, is currently slated to begin in March.[27]

The rapid emergence of prescription drug affordability review boards has led, and will continue to lead to, litigation.

Last spring, inAmgen Inc. v. Colorado Prescription Drug Affordability Review Board, Amgen challenged the Colorado statute authorizing the board and granting it price control authority, and alleging that the statute preempted by federal patent laws and laws governing federal healthcare programs, and violated due process rights and the commerce clause.[28]

In August 2024, Colorado responded to the complaint, rejecting the plaintiff's arguments. Briefing in the case remains ongoing.

As discussed previously, states also continue to attempt to regulate participants in the Section 340B program, with ongoing litigation challenging these state laws.

CMMI Demonstrations

In 2022, President Joe Biden issued an executive order directing HHS to pursue new demonstration models through the Center for Medicare and Medicaid Innovation to "lower drug costs and promote access to innovative drug therapies" for Medicare and Medicaid beneficiaries.[29]

Under the executive order, CMS described three models that tested new payment and pricing models: a model intended to reduce out-of-pocket costs for Medicare Part D enrollees on certain generic drugs; a cell and gene therapy access model, aimed to assist state Medicaid programs in participating in outcomes-based contracts; and the accelerating clinical evidence model, aimed to reduce Medicare payment in connection with accelerated approval drugs.[30]

CMMI had started work on some of these models, with focus on the cell and gene therapy access model. On his first day in office, Trump rescinded Biden's CMMI executive order.[31] Notwithstanding this rescission, CMMI has statutory authority to pursue demonstrations on its own and could continue to pursue these or other drug pricing demonstrations, depending upon the goals of its new leadership.

More Action Ahead

With Republican leadership in the White House and Congress, federal policy is likely to change in most arenas.

Drug pricing remains a bipartisan issue that is likely to have enduring importance. Of course, the priceless question across administrations and congresses is how to provide incentives for robust pharmaceutical innovation and also allow patients to have affordable access to that innovation.

We expect 2025 to be an eventful year as the Trump administration and new Congress pursue an answer

to this question, while industry stakeholders continue to grapple with similar considerations, including in the courts.

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[1] Inflation Reduction Act of 2022, H.R. 5376, 117th Cong. (2021-2022),https://www.congress.gov/bill/117th-congress/house-bill/5376/text.

[2] Medicare Drug Price Negotiation Program: Negotiated Prices for IPAY 2026, Centers for Medicare & Medicaid Services (Aug. 15, 2024), https://www.cms.gov/newsroom/fact-sheets/medicare-drug-price-negotiation-program-negotiated-prices-initial-price-applicability-year-2026.

[3] HHS Announces 15 Additional Drugs Selected for Medicare Drug Price Negotiations, Centers for Medicare & Medicaid Services (Jan. 17, 2024), https://www.cms.gov/newsroom/press-releases/hhs-announces-15-additional-drugs-selected-medicare-drug-price-negotiations-continued-effort-lower.

[4] Medicare Drug Price Negotiation Program: Negotiated Prices for IPAY 2026, Centers for Medicare & Medicaid Services (Aug. 15, 2024), https://www.cms.gov/newsroom/fact-sheets/medicare-drug-price-negotiation-program-negotiated-prices-initial-price-applicability-year-2026.

[5] Understanding the Inflation Reduction Act Negotiation Prices After the Dust Has Settled, LEK (Sept. 27, 2024), https://www.lek.com/insights/hea/us/ei/understanding-inflation-reduction-act-negotiation-prices-after-dust-has-settled.

[6] See e.g., The Inflation Reduction Act is Already Killing Potential Cures, Wall Street Journal (Nov. 3, 2022), https://www.wsj.com/articles/the-inflation-reduction-act-killing-potential-cures-pharmaceutical-companies-treatment-patients-drugs-prescriptions-ira-manufacturers-11667508291;see also Updated: Eli Lilly blames Biden's IRA for cancer drug discontinuation as the new pharma playbook takes place, Endpoints (Nov. 1, 2022), https://endpts.com/eli-lilly-rolls-snake-eyes-as-it-axes-two-early-stage-drugs-including-a-40m-cancer-therapy-from-fosun/; How the IRA disincentivizes new indications – and how to fix it, BioCentury (Feb. 2, 2024), https://www.biocentury.com/article/651339/how-the-ira-disincentivizes-new-indications-and-how-to-fix-it.

[7] Opinion, National Infusion Center Association et al. v. Becerra et al., No. 24-50180 (5thCir. Sep. 20, 2024) (finding that the industry group plaintiffs had alleged sufficient facts to have standing based on (1) the economic harm they would suffer due to the IRA's negotiation program and (2) the procedural harm from the lack of notice-and-comment procedures in the implementation of the negotiation program.)

[8] Id.

[9] See e.g., Hill GOP sets sights on scrapping drug price talks, Axios (Sep. 17, 2024), https://www.axios.com/2024/09/17/trump-drug-prices-gop-concerns (quoting Sen. Mike Crapo (R-Idaho), Rep. Buddy Carter (R-Ga), Sen. Thom Tillis (R-N.C.), and Sen. John Cornyn (R-TX)); Roger Severino, Project 2025 465

(2024), https://static.project2025.org/2025_MandateForLeadership_CHAPTER-14.pdf.

[10] ORPHAN Cures Act, H.R. 5539, 118thCongress (2023-2024); H.R. 7174, 188th Congress (2023-2024).

[11] 42 U.S.C. § 1395w-102(a)(B)(i)(VII).

[12] 75 Fed. Reg. 10272 (Mar. 5, 2010).

[13] See Sanofi Aventis v. U.S. Department of Health and Human Services, 58 F.4th 696 (3rd Cir. 2023).

[14] See Novartis Pharmaceuticals Corporation v. Johnson,102 F.4th 452 (D.C. Cir. 2024).

[15] Eli Lilly v. U.S. Department of Health and Human Services, No. 21-3405 (7th Cir.). See Congressional Research Service, Litigation Continues Over Use of Contract Pharmacies in 340B Drug Discount Program (May 23, 2024), https://crsreports.congress.gov/product/pdf/LSB/LSB11163.

[16] See Pharmaceutical Research and Manufacturers of America v. McClain, 95 F.4th 1136 (8th Cir. 2024).

[17] Pharmaceutical Research and Manufacturers of America v. Morrisey, 2024 WL 5147643 (S.D. W.Va.).

[18] BIOSECURE Act, H.R. 8333, 118th Cong. (2023-2024), https://www.congress.gov/bill/118th-congress/house-bill/8333. Company of concern is defined to a group of five Chinese contract manufacturers (i.e., BGI, MGI, Complete Genomics, Wuxi Apptec, and Wuxi Biologics), as well as any entity that is (i) subject to the jurisdiction, direction, control, of the government of a foreign adversary; (ii) involved in the manufacturing, distribution, provision, or procurement of a biotechnology equipment or service; and (iii) poses a national security risk. Id.

[19] Federal Trade Commission, Pharmacy Benefit Managers: The Powerful Middlemen (July 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

[20] Federal Trade Commission, Specialty Generic Drugs: A Growing Profit Center for Vertically Integrated Pharmacy Benefit Managers (Jan. 2025), https://www.ftc.gov/system/files/ftc_gov/pdf/PBM-6b-Second-Interim-Staff-Report.pdf.

[21] See Complaint, AbbVie Inc. v. Payer Matrix, LLC, No. 1:23-cv-2836 (D. N. Ill. May 5, 2023); Complaint, Johnson & Johnson Health Care Systems v. SaveOnSP, No. 2:22-cv-2632 (D. N.J. May 4, 2022).

[22] See Complaint, HIV and Hepatitis Policy Institute v. Becerra, No. 1:22-cv-2604 (D.D.C. Aug. 30, 2022). See also Opinion, HIV and Hepatitis Policy Institute v. Becerra, No. 1:22-cv-2604 (D.D.C. Sep. 29, 2023) (vacating HHS 2021 rule).

[23] 84 Fed. Reg. 17454, 17545 (Apr. 25, 2019).

[24] See National Academy for State Health Policy, 2024 State Legislative Action to Lower Pharmaceutical Costs, https://nashp.org/state-tracker/2024-state-legislation-to-lower-pharmaceutical-costs/ (last updated Jan. 16, 2025).

[25] Maryland HB 768 (2019), https://mgaleg.maryland.gov/2019RS/bills/hb/hb0768e.pdf.

[26] Colorado Board Picks First Five Drugs for Affordability Reviews, The Sum & Substance (Aug. 7, 2023), https://tsscolorado.com/colorado-board-picks-first-five-drugs-for-affordability-reviews/.

[27] PDAB Rulemaking, Colorado Division of Insurance, https://doi.colorado.gov/insurance-products/health-insurance/prescription-drug-affordability-review-board (last accessed Jan. 28, 2025).

[28] See Complaint, Amgen, Inc. v. Colorado Prescription Drug Affordability Review Board, N. 1:24-cv-00810 (D. Colo. Mar. 22, 2024).

[29] Executive Order on Lowering Prescription Drug Costs for Americans (Oct. 14, 2022),https://web.archive.org/web/20250116063218/https://www.whitehouse.gov/briefing-room/presidential-actions/2022/10/14/executive-order-on-lowering-prescription-drug-costs-for-americans/.

[30] Centers for Medicare & Medicaid Services, A Report in Response to the Executive Order on Lowering Prescription Drug Costs for Americans (2023), https://www.cms.gov/priorities/innovation/data-and-reports/2023/eo-rx-drug-cost-response-report; Centers for Medicare & Medicaid Services, A Report in Response to the Executive Order on Lowering Prescription Drug Costs for Americans Frequently Asked Questions (2023), https://www.cms.gov/priorities/innovation/data-and-reports/2023/eo-rx-drug-cost-response-report-faqs.

[31] Initial Rescissions of Harmful Executive Orders and Actions (Jan. 20, 2025), https://www.whitehouse.gov/presidential-actions/2025/01/initial-rescissions-of-harmful-executive-orders-and-actions/.