Pres Biden Signs Drug Pricing Executive Order

Messaging Document, Requests CMMI Go One Step Further

President Joe Biden is expected to sign an executive order Friday (Oct. 14) that directs HHS to lower drug prices with administrative actions.

- **The EO is here and is said to put drug makers on notice…**that the administration is ready to address areas that might be created if manufacturers sue over government price controls Biden recently signed into law.

- **The EO references July 9, 2021 Executive Order 14036 (Promoting Competition in the American Economy), signed by the President**. It directed various actions in pursuit of Administration's policy to improve competition, increase wages, and reduce prices for prescription drugs, among other goods and services. In response to EO 14036, the Department of Health and Human Services submitted a report to the White House Competition Council calling for bold legislative and administrative actions to lower drug prices.

- **The EO asks the Center for Innovation at CMS (CMMi) to go one step further with payment demonstrations to address drug pricing.** It says "As my Administration works to implement the IRA, it is critical that we take additional actions to complement the IRA and further drive down prescription drug costs. Within HHS, the Center for Medicare and Medicaid Innovation ("Innovation Center") tests health care payment and delivery models to improve health care quality and make the delivery of health care more efficient. In June 2022, the Innovation Center announced a new model to improve cancer care and lower health care costs for cancer patients, including prescription drug costs. The Innovation Center provides my Administration and the American people with a useful set of tools to help lower health care costs and improve quality of care, and its work can advance the continued policy of my Administration to lower the cost of prescription drugs."

- **The CMS Center for Innovation has been hard at work on value based care models e.g., ACO Reach.** We do not envision CMMI working on additional Rx reform models at this time, as IRA is a significant step forward as it pertains to Drug price reform.

- **OUR TAKE:** We see this as a messaging document, with the goal of reminding voters what has been done on Drug pricing ahead of the mid-terms.

BACKGROUND

- **The *Inflation Reduction Act* passed the House and Senate this summer, and was enacted into law August 16, 2022.** The Senate voted 50-50 to pass the Inflation Reduction Act. VP Kamala Harris broke the tie to cast the 51st vote. Senators cheered as the votes were tallied via voice vote on a rare August Sunday session. The **House vote took place Friday 8/12.**

- **We had been bullish on ACA & Drug reforms passing in a bill by 9/30.** We spiked odds to 70% on June 21, with an upward revision in mid-July to 75%. This included the three Drug provisions – Part D restructuring, CPI Rebates & Rx Negotiation -- along with ACA subsidies. This is certainly a domestic achievement for Biden and Congressional Democrats to enact EV and other environmental reforms, close tax loopholes.

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- **NeXT UP: CMS shall implement prescription reform by "program instructions."** The regulatory wheels will start turning. While CMS is only required to provide program instructions (as written in the bill), it is not required to initiate rulemaking. However, we anticipate regulations as this will be a complicated law to implement without stakeholder input, particularly Rx negotiation in Parts B&D. CPI Rebate provision in Part D started 10/1, and Part B starts 1Q23.

- **What happens to Biopharma innovation?** We all know that certain products and companies being more impacted than others by Drug negotiation starting in 2026 (AZN, BMY, MRK, LLY, GSK NVS, ROG, SNY, AMGN, BIIB, GILD, REGN). We could see higher launch prices, as well as investment in therapeutic areas that are more of a commercial & orphan nature (versus government program exposure). We believe that the CBO may not have correctly projected innovation impact from IRA (Rx negotiation). We do not believe industry will abandon R&D for unmet needs in cancer, Alzheimer's and so forth due to IRA. We could see more M&A as a result of this bill. Time will tell but the impact is nuanced; and we do not discount the fact that price discounts could be 30-50% as the minimum discount is 25% per the law. See specifics below.

- **With three years of extended ACA subsidies (2023-25), enrollment will only balloon, good news for CNC, MOH, UNH, ELV, others.** The PHE provisions resulted in rolls swelling by 20%. We could see this trend continue, particularly with Medicaid Redeterminations in 2024/25. Those deemed Medicaid ineligible 12-14 months after the end of the COVID emergency will be pleased to see reasonably priced Exchange products on the market. We note that the Medicaid Gap was not included at the end of the day, nor did we think it would be despite pleas by Sen Warnock (D-GA), as well as advocates. Plans are not outwardly peeved by the enhanced 60% and 67% liabilities in the initial & catastrophic phases of the "new and improved" Part D benefit.

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Background

RECAPPING THE WEEKEND

- **Early Saturday morning 8/6, the Parliamentarian concluded review of the *Inflation Reduction Act*.** While most of the healthcare package (Medicare negotiations Part D reform, vaccine coverage) was cleared, commercial inflationary rebates and last-minute insulin provisions failed the Byrd review by Elizabeth MacDonough.

- **There were 35 amendments introduced this weekend, only one passed at the bitter end.** All were voted "no," apart from Thune's (R-SD) amendment to extend SALT Cap extension. The amendment exempts certain PE (private equity) backed companies to be excluded from 15% tax.

- **ONE GOP (TAX) AMENDMENT PASSED: Small businesses are protected from the 15% corporate minimum tax rate**. Exemption of some businesses owned by private equity from the 15% corporate minimum tax rate if they are smaller businesses that don't meet the $1 B minimum, extension of deduction caps for SALT to 2027 (1-year extension). The issue was with unrelated companies of any size held by fund or partnership having to combine their unrelated income to determine if they meet an aggregate $1 B income threshold, subjecting each company to the 15% minimum tax even if their individual income is low. A Sen. Warner (D-VA) amendment subsequently struck an offset from the Thune amendment, and replaced with 2 year loss limitation policy.

- **Commercial $35 OOP Cap on Insulin failed the Byrd Bath & subsequently failed to pass as an Amendment on Sunday Aug 7.** As predicted, the Parliamentarian ruled that applying the deductible exclusion and $35/monthly OOP cap to insulin in commercial (employer sponsored) plans did not meet the Byrd rule.

- **This bill places a $35/month insulin co-pay cap (MA & Part D).** Inflation rebates in Medicare: Part D inflation rebates will begin October 2022. Start of Part B inflation rebates starts in January 2023. Rebates originally saved $62 B over ten and raised $38 B in revenue. The revenue increase will shrink significantly as it represented the effects on reducing drug costs for employer-sponsored health plans. Commercial rebate excision will likely reduce the overall net savings of $100 B.

WHAT'S IN

- **Drug negotiation (saves $101 B over ten) process starts 2026 with ten qualifying drugs in 2026, fifteen in both 2027 & 28, with minimum discounts.** Note that both the 95% excise tax and judicial review remains intact. Co. will face strong enforcement to comply as HHS determination of negotiation-eligible drugs will not be subject to a judicial review.
  - Negotiated prices will go into effect in 2026, First year of negotiation is moved up to 2023
  - 10 qualifying drugs must be negotiated in 2026, 15 additional drugs in 2027-28 and 20 each year in 2029 and beyond
  - Small biotech protections in effect
  - For drugs subject to Medicare negotiation, there will be minimum discount of 25% in years 9-11, 35% for years 12-15, and 60% for year 16+ based on a 'maximum fair price' while there is no cap on the negotiated discount.
  - Manufacturers not participating in negotiation will be subject an excise tax beginning at 65% and increasing 10% quarterly up to 95%.
  - There is a negotiation exception for vaccines and orphan drugs

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- **Part D improvements and $2,000 maximum out-of-pocket cap (costs $25 B due to insurance interactions) for Medicare beneficiaries starts 2025.**
  - Redesign of Part D benefit will take place in 2025, which drug makers largely embrace
  - Small manufacturer phase in and Part D premium stabilization will take place starting and ending a year later, to conform with new implementation dates.
  - Starting in 2024, beneficiaries will owe $0 out-of-pocket in the catastrophic phase; by 2025, beneficiary total out-of-pocket spending for Part D drugs will be capped at $2,000 per year.
  - Expands Part D LIS. The income threshold for eligibility for the Part D low-income subsidy has been expanded from 135% to 150% of the federal poverty level.
  - Stabilizes premiums. Premium growth will be capped at 6% per year through 2029, instead of 4% through 2027.
  - To provide beneficiary premium protection in the long run, the Secretary is authorized make a one-time adjustment to the beneficiary Part D premium % in 2030.
  - $0 cost-sharing for vaccines will go into effect in January 2023.
  - Instead of 70% in the donut hole, manufacturer discounts are 10% in initial phase and 20% in the catastrophic phase

- **Biosimilar market entry, helpful to industry & ASP+8%.** Allows the Secretary to delay negotiation of a biologic drug for up to two years, if a biosimilar demonstrates a high likelihood of entering the market before the negotiated price would take effect. A rebate will be owed by the biologic manufacturer if the biosimilar does not enter the market within delay period. ASP+8% for biosimilars as a reimbursement incentive to prescribe.

- **Rebate Rule repeal in ten tear year window (to 2032) and generates $122 B over ten (paper savings).** The Rebate Rule was unlikely to happen anyway; it is currently delayed to 2027 (via Gun reform legislation passed in June: from 2026, saving $20 B for an incremental year). *See our June 22 memo for details.*

- **Insurance Subsidies: Three years of ACA subsidies (2023-25) is better than two years (CNC, MOH, UNH, ELV, others), and means that growth in membership will only explode.** The text allows for three years of ACA subsidy extension, which we had expected, versus only two, costs $33 B over 10 with a revenue loss of $31 B over 10. The CBO score allowed for more generous subsidies ($288 deficit reduction from drug reform) and positively there is no means testing of the extension.

- **MCOs bear more responsibility in the Part D benefit, but plans did not come out kicking and screaming with Part D restructuring details**. The Part D benefit plan design lowers reinsurance and shifts more risk onto MCOs, but they should be able to offset with premium increases (within limitations of new cap) and formulary management as incentives flip to favor more generics over high rebate brand drugs to get into the catastrophic phase.

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