

CAPITOL STREET

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ALERT: Biden Goes Big on Drug Pricing in State of the Union

Our Take on What He Can & Can't Do

Relevant Companies



»» Our Take & Next Up

Drug pricing and middleman reform is expected to a major focus during President Biden's State of the Union address at 9 pm ET tomorrow. Link to his remarks [here](#). With Biden v Trump presidential race largely solidified, Biden is doubling down on the IRA as drug pricing is a key concern for most Americans. The reforms that will be discussed in the State of the Union are largely messaging tactics and will require legislative expansions of the IRA that are very unlikely in our current political environment. Key drug pricing reforms on his agenda that could be discussed are below.

»» Key Points

CMS Negotiation Program:

- **Biden will announce that manufacturers of the 10 selected drugs remain at the negotiation table the agency.** All manufacturers have submitted counteroffers and negotiations are ongoing. He is also expected to highlight the release of new, negotiated prices that will be released by September 1 of this year.
- **He is also expected to propose expanding the negotiation program to 50 drugs per subsequent years (compared to the IRA's 20 drugs a year).** However, Biden will be unable to act unilaterally as CMS can't raise or lower the number of new drugs selected without legislative updates to the IRA (he needs Congress and only in a Democratic trifecta would this be likely). As a reminder, the IRA's drug negotiation provisions limit the number of new drugs that can be negotiated each year after 2026. The IRA allows 15 Part D drugs to be selected for 2027, 15 Part B&D drugs for 2028, 20 Part B&D drugs for 2029 and subsequent years.

Part D Redesign:

- **Biden is expected to propose an expansion of the \$2,000 Part D out of pocket cap (to commercial).** The Part D out of pocket cap goes into effect for Medicare beneficiaries starting in 2025. Biden will call on Congress to expand the benefit redesign to all private insurance. Biden cannot dictate changes to commercial plans and any commercial expansion of the IRA reforms will require legislative changes.

Inflationary Rebates:

- **He is expected to call for the expansion of the Part B & D inflationary rebates to commercial units.** Currently, commercial drug units are excluded from inflationary rebates, including them will require Congress's involvement which is unlikely. These commercial expansions of drug reform policies that netted big CBO savings are expected to be highlighted as ways that the federal government can save additional money and address the federal deficit.

CMMI Updates:

- **Biden will call on Congress to codify the Medicare \$2 Drug List Model.** As a reminder, CMMI's generic model would allow Part D plans to offer a fixed (up to \$2 per month supply) co-payment across all cost-sharing phases (up to the out-of-pocket limit) for a standard Medicare-defined list of generics. This model was [introduced](#) in February 2023 as a response to the Biden administration's October 2022 executive order on prescription drug costs. He hopes to expand this model to the entire Medicare population through codifying it.
- **He will also provide an expected update on CMMI's Cell and Gene Therapy (CGT) Access Model.** As expected, the agency is releasing the Request for Applications (RFA) for drug manufacturers of cell and gene therapies to participate in the model. The RFA are due by May 1 per CMMI's model overview [webinar](#). The states' letter of intent to participate is due April 1, and we expect to see the result of the manufacturer negotiations in December 2024.

On actions that the administration can take, this week, Biden launched a taskforce to address healthcare costs and fraud. Announcement [here](#). The Strike Force on Unfair and Illegal Pricing will be co-chaired by the Department of Justice (DOJ) and the Federal Trade Commission (FTC) and will focus on anti-competitive, fraudulent, or deceptive business practices of healthcare companies. The Strike Force announcement comes following the FTC/DOJ/HHS's [public inquiry](#) into healthcare corporate profiteering. The inquiry is collecting information on how healthcare transactions and the subsequent consolidation is affecting medical care and costs.

The White House also recently hosted a roundtable to shine the light on pharmaceutical middlemen (PBMs). PBMs continue to be a focus of healthcare cost and transparency reform. Attendees included Sandra Clarke, COO of Blue Shield of California, Mark Cuban, National Economic Advisor Lael Brainard, Domestic Policy Advisor Neera Tanden, Secretary of Health and Human Services Xavier Becerra, and Chair of the Federal Trade Commission Lina Khan. Notably, the big 3 PBMs (Caremark (CVS), Express Scripts (CI), and OptumRx (UNH)) were excluded from the discussion.

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