CAPITOL STREET

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Biden Healthcare Budget Wish List

Expanding Drug Negotiation, CPI Rebates & Permanent ACA Subsidies

Relevant Companies: All Healthcare

Our Take & Next Up

Expanded drug negotiation, extension of drug and insurance policies (OOP cap) to commercial and permanent ACA subsidies feature big in Biden's FY25 budget. The President's budget is an opening salvo, frequently aspirational and almost never enacted as proposed. Drug pricing and healthcare service reforms seen are largely a rehash of policies in the FY 2024 Presidential budget. On the current budget status, Congress has yet to pass the final six appropriations bills for the current fiscal year. We are likely to be flat funded until the end of FY 2024 due to the continuing resolution(s). We expect budget proposals from both chambers (House & Senate) as well as hearings on Capitol Hill with HHS Secretary Javier Becerra, FDA Commissioner Rob Califf and CMS Administrator Chiquita Brooks-LaSure. Link to HHS budget here.

Key Points

Biden wants to expand to commercial plans many drug reforms as well as affordability policies. They are largely aspirational as he can't act on the commercial markets without Congressional action. His proposals to expand to the commercial market include:

- Expansion of the $35 insulin out of pocket cap in Part D
- Expansion of the $2,000 maximum co-pay cap in Part D
- Expansion of the IRA inflationary rebates to include commercial units
- Expansion of surprise medical billing from the No Surprises Act to ground ambulance services
- Requiring coverage of three behavioral health visits without cost-sharing

For FY 2025, $130.7 B in HHS discretionary funding is requested. This is a $2.2 B (+1.7%) increase from the 2023 level. As a reminder, Congress has yet to finalize the FY 2024 HHS funding level as negotiations for the second funding tranche are ongoing.

DRUG PRICING

- **Expanding IRA inflationary rebates & Medicare $2,000 out of pocket cap to commercial and increasing the number of eligible drugs for negotiations ($200 B in savings over 10).** The budget requests significantly increasing the pace of negotiation and bringing drugs into negotiation sooner after they launch. While not specified, we assume that the administration is looking to increase the number of

negotiated drugs to 50 per year (per Biden's State of the Union) and reduce the exclusivity period (with negotiations potentially going into effect 7 years after launch, versus 9 for small molecules).

- **$35 OOP insulin cap expansion to commercial ($31 M in costs over 10)**. The budget proposes extending the $35 Medicare cost-sharing cap to insulin products in commercial markets. This is the same request seen in last year's Presidential Budget and is very unlikely to pass, however, in 2023, insulin manufacturers (LLY, NVO, SNY) voluntarily agreed to $35 price caps for commercial insurance. States are the more likely frontier of insulin cost limitation as 25 states (NY, DC, VA, TX, NJ, MD, among others) passed legislation to cap the monthly copayment for insulin for state-regulated plans (with some states impacting individual and large group commercial contracts).
- **$2 Medicare drug list for generics expansion to commercial market ($1.3 B in costs over 10).** This proposal adds a new permanent benefit to Part D coverage and requires all Part D plans to offer a Medicare standard list of generic drugs at a maximum copayment of $2 for a 30-day supply across all phases. As a reminder, last year, the President's budget called for the expansion of the $2 drug list as a permanent Medicare benefit. The administration is going one step further this year by asking for installment as a permanent Part D benefit and an expansion to commercial plans.

National Institute of Health (NIH) funding request increase of $2.4 B compared to 2023. NIH request total is $50.1 B in funding for FY 2025. ARPA-H budget total is $1.5 B in FY 2025.

The budget reauthorizes the 21st Century Cures Act Cancer Moonshot through 2026 and proposes $2.9 B in funding for FY 2025. The National Cancer Institute (NCI) has a proposed $716 M in discretionary funding, a $500 M increase above FY 2023. The administration is also proposing to increase funding for women's health with a $76 M increase for the Office of Research on Women's Health.

The proposal allows biosimilar substitution without prior FDA determination of interchangeability ($0). This proposal would amend the Public Health Service Act to no longer include a separate statutory standard for a determination of interchangeability and to deem all approved biosimilars to be interchangeable with their respective reference products.

MEDICARE

Addressing Medicare solvency through increased taxation on investment gains, high earner self-employment income (extends solvency indefinitely). Beginning in 2025, the budget directs revenues from the net investment income tax, including tax code reforms that make high income earners (those making above $400,000) pay additional taxes, into the Part A Trust Fund. The Budget also directs an amount equivalent to the savings from the Budget's proposed Medicare drug reforms into the HI trust fund.

Like last year, the administration is proposing to establish medical loss ratio (MLR) requirements for supplemental benefits (not scoreable). This proposal requires Medicare Advantage plans, excluding Employer Group Waiver Plans, to meet a minimum medical loss ratio of 85% specifically for supplemental benefits beyond basic Part A and B benefits, which aligns with the existing 85% medical loss ratio across all types of benefits.

MEDICAID

Budget provides Medicaid-like coverage ("Gap") to individuals in non-expansion states ($200 B in costs over 10 years). This includes financial incentives to encourage states to maintain existing expansions. Medicaid

Gap" enhanced premium tax credits would aid those who do not have Medicaid expansion (CNC, MOH, UNH, ELV, CVS, THC, UHS). There are currently 10 states that have not expanded Medicaid.

Federal supplemental rebate program is proposed ($5.2 B in savings over 10). Currently, states may negotiate supplemental rebates, but there is no federal program to negotiate supplemental rebates for high-cost drugs. The proposal establishes a process under which CMS and participating state Medicaid programs partner with a private sector contractor to negotiate supplemental rebates from drug manufacturers, thereby pooling negotiation power.

Investments to expand Medicaid home and community-based services ($150 B over 10) are the same as last year's proposed amount. The proposal is to support quality of life improvements for elderly, individuals with disabilities, and home care workers. This new funding is unlikely in a divided Congress.

Like last year, the Budget proposes limiting the portion of Medicaid and CHIP managed care dollars spent on administration by establishing a medical loss ratio ($8.4 B in Medicaid savings and $1.7 B in CHIP savings over 10). Medical loss ratios passed as a part of the Affordable Care Act. MLRs already exist in Medicaid, but plans are not currently required to remit payments if they miss. This proposal requires Medicaid and CHIP managed care plans to meet a minimum MLR of 85%, the industry standard for MA and large employer plans in the private health insurance market, and requires states to collect remittances from managed care plans if they fail to meet the minimum MLR.

MARKETPLACE

The administration hopes to make ACA marketplace tax credits permanent (CNC, MOH, UNH, ELV, CVS) ($273 B in costs over 10). Enhanced premium tax credits were established under the American Rescue Plan Act and extended under the Inflation Reduction Act through 2025. The proposal would permanently expand premium tax credit eligibility by eliminating the required contribution for individuals and families making 100%-150% of the poverty level and limiting the maximum income contributions towards benchmark plans to 8.5% of income. The proposal also removes the 400% of the poverty level ($120,000 for a family of 4) cap on premium tax credit eligibility. The annual indexing of the required contribution percentage is also eliminated.

MENTAL HEALTH

Applying the *Mental Health Parity and Addiction Equity Act (MHPAEA)* to MA *(no score)*. See *MHPAEA* here. Unlike private and employer-sponsored plans, Medicare does not require parity of mental health and substance use disorder (SUD) benefit parity with medical and surgical benefits. This proposal ensures that the parity requirements of the law apply to the mental health and substance use disorder benefits offered by Medicare Advantage plans and would be a win for providers.

Eliminating the 190-day Lifetime Limit on Psychiatric Hospital Services ($2.9 B in costs over 10). Under current law, once an individual receives Medicare benefits for 190-days of care in a psychiatric hospital during their lifetime, no further benefits of that type are available to that individual.

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