# Drug Deal: Legislation Released

## Rx Negotiation Starts ’26 (vs ’25); Part D Redesign Starts ’25 (vs ’24); Rebate Rule Goes

- **Today the Senate Parliamentarian started the Byrd Bath of the Drug reforms portion of the BBB.** Bill text is here; it was released this morning.

- **Drug negotiation process would be sped up to start in 2023 with negotiated prices going into effect in 2026 (vs. 2025).** This feels somewhat aggressive to us and CMS may be displeased to be set up for failure. The prices would have to be locked down in 2025 for AEP.

    - Firms up the number of drugs the Secretary must negotiate: HHS Secretary will be directed to negotiate a specific number of drugs every year, rather than “up to” the required number of drugs. This removes Secretarial discretion and ensures budgetary aims of the provision are met.
    - Start of first year of negotiation has been moved forward to 2023, instead of 2024
    - Negotiated prices will go into effect in 2026, instead of 2025
    - Small biotech protections will go into effect and end a year later to match the shift in negotiation implementation data

- **Allows for delay of negotiation for biosimilar market entry, helpful to industry.** 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.

- **The bill removes special provisions for insulins**. Insulins are not treated as a separate class for the purposes of negotiation. Clarifications, including: Adding language to clarify that manufacturers are not required to provide price concessions that exceed the lower of a drug’s 340B price or the Medicare negotiated price. Specifies the calculation of the non-Federal average manufacturer prices. Technical edits to reflect intent, including corrections to conforming amendments and excise tax.

- **Prescription drug inflation rebates delayed slightly to Oct 2022 (Part D) and Jan 2023 (Part B, same as before).** Implementation of inflation rebates. Part D inflation rebates will begin October 2022 (rather than July 2022). Start of Part B inflation rebates remains January 2023. Part B coinsurance protection. Application of inflation growth cap to beneficiary coinsurance in Part B will begin in April 2023 (rather than January 2023).

- **Part D improvements and maximum out-of-pocket cap for Medicare beneficiaries starts 2025 (versus 2024).** Updates implementation timelines
    - Redesign of Part D benefit will take place in 2025, rather than 2024
    - Small manufacturer phase in and Part D premium stabilization will take place starting and ending a year later, to conform with new implementation dates.
    - Beneficiary maximum out-of-pocket cap begins in 2024. 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.

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  - Beneficiary premium percentage adjustment. To provide beneficiary premium protection in the long run, the Secretary will be authorized make a one-time adjustment to the beneficiary Part D premium percentage in 2030.
  - Part D vaccine out-of-pocket protection. $0 cost-sharing for vaccines will go into effect in January 2023. I
  - insulin copay cap. The $35 copay cap for insulin has been removed.

- **PBM Rebate Rule is repealed.** The repeal of the rebate rule will begin January 2027 to accommodate the delay included in recent gun safety legislation.

- **The bill is getting smaller not bigger at this point.** Energy & Tax provisions are not fleshed out. Leadership's goal is to get it to the floor by August recess. The "Byrd Bath" is starting TODAY July 6 (weeks of July 5 & 11): this is the process of determining whether budget reconciliation metrics are met i.e., whether a policy adds or subtracts from the deficit.

- **We have always said that the Drug reforms are more likely than ACA subsidies.** It's a wasted opportunity however in our view not to include ACA subsidies as premiums would spike up to 50% for Americans during election season this fall. See background below on how Medicaid Redeterminations plays into this conversation. Recall the big 3 drug reforms in earlier version of BBB (1) Part B&D limited negotiation (2) CPI inflationary rebates and (3) Part D restructuring with $2,000 OOP cap as well as new liabilities (plans/pharma/gov't/consumers) in the Medicare Drug benefit.

- **As we wrote on June 2, we still think that a skinny BBB makes it in 2022 but there are myriad remaining steps (See below).** Specifically, we said that ACA Subsidies (means-tested) + Drug Reform may actually pass in 2022 with limited other provisions. The enhanced subsidies, enacted through the $1.9 T COVID relief bill, sunset Dec 31, 2022. We think that for election purposes, both parties want to see the subsidies extended to 2023, even if it's not a blanker extension. Drug pricing reforms also offset subsidies evenly (see below for #s), and it could be a legislative win ahead of the November election. Reconciliation instructions expire as of Oct 1, 2022 (the start of FY23).

- **NEXT STEPS:**

  - There was little fanfare today re a drug reform deal, likely because there are more reconciliation steps required before a win can be announced. Energy & tax provisions remain to be ironed out. We think they get there, possibly by Sept 30 versus ahead of August recess. Congress has had some momentum by passing Gun reform legislation, and we believe FDA User Fee Bills as will pass on a bipartisan basis this fall. Drug pricing reforms have eluded policymakers for years; despite it being a bipartisan issue. This deal is one that could be stomached by PhRMA, BIO, AHIP/BCBSA, essentially the major stakeholders, as well as Americans. Conventional wisdom is that ACA + Drug Price reforms (plus anything on Climate + Tax) would have to be completed by Aug recess but this may take time. The FY22 Reconciliation instructions expire 9/30 so bill passage is possible after August recess, but would be complicated given proximity to Nov 8 mid-term election.
  - On Reconciliation itself, there are some major steps (1) Byrd Bath (2) Senate 20 hours of debate on Reconciliation (3) vote-or-rama (plus amendments, introduced by unanimous consent) (4) House passes final deal. We believe if the Senate has 51 votes then it will likely pass the House, meaning that Progressives who may have wanted more onerous reforms will not let the perfect be the enemy of the good.

BACKGROUND

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- **Our outlook sharply changed post Mem Day, after Sen. Joe Manchin (D-WV) noted his interest in Drug Pricing reform not only at Davos, but again in his home state of West Virginia (here), speaking at a forum hosted by AARP.**
  - At the World Economic Forum's annual meeting in Davos, Switzerland Manchin noted his interest in addressing inflation, drug pricing and climate, with an emphasis on fossil fuels
  - Manchin listed three major priorities: (1) inflation and deficit reduction, (2) lowering drug prices, and (3) energy/climate
  - Speaking at an AARP hosted event in WV Tuesday 5/31 Manchin said he believes that the Congressional drug reforms in BBB do not go far enough
  - Points made by Manchin (1) Pharma blames PBMs and middlemen blame big Pharma (2) Veteran's Affairs negotiation is an alternative solution (3) Pharmacy DIR redefines negotiated price and eliminates the retroactive nature of claw back fees; legislation to reform here) (4) Supports the insulin copay cap bill at $35 per month (5) Supports importing drugs from Canada (6) Medicare Trust fund solvency relies on things like drug price/spend reform.

- **Sen. Manchin has said repeatedly that BBB drug reforms do not go far enough & that the overall Reconciliation bill should be deficit-reducing.** He supports Medicare negotiation of drugs. The WV Senator believes that the Rx pricing reforms could go deeper. Manchin supports unwinding Trump tax cuts, but we do not envision that happening this year, given Sen. Sinema's (D-AZ) lack of support for tax hikes. While Manchin would still like to raise the corporate tax rate from 21% to 25%, he knows Sinema is opposed and may settle for establishing a domestic minimum rate of 15%.

- **A 'clean' way to pay for ACA subsidies is drug pricing reforms.** One roughly offsets the other:
  - ACA subsidies made permanent cost over $200 B (here) and $25 B/ten (for one year, 2023)
  - Drug reforms in the prior version of *Build Back Better Act* save about $170 B/ten
    - CPI (Inflationary) rebates generates $80 B/ten
    - Part D restructuring generates $2 B/ten
    - Limited Part B&D drug negotiation saves $83/ten

- **Why this could happen: Drug reforms are bipartisan and discussions have dragged on (for years).**

  - **3 M Americans lose insurance if ACA enhanced subsidies go away Dec 31, with a disproportionate amount of African American, young adults & residents of Southern States impacted.** There are 14 M enrolled today via Marketplace plans (source: KFF). Both Republicans and Democrats would like for those who obtained insurance during COVID to keep it, hence election politics may not matter here. HHS estimated in March (here) 3 M people will lose coverage past Dec 31, nearly 9 M would receive lower subsidies and 1.5 M would lose their subsidies entirely (but remain insured). A Robert Wood Johnson estimate notes that a disproportionate share of young adults, low-income, Black Americans and residents of Southern states will lose coverage if Congress doesn't extend enhanced *Affordable Care Act* subsidies.
  - **Thinking ahead to 2023, as Medicaid redeterminations ensue with PHE unwind, there is little appetite for Americans to be punted to expensive Marketplace plans.** As a reminder the additional subsidies allowed Americans to be less price sensitive as $0 premiums are available on state based exchanges, as well as the federal marketplace. Expensive marketplace insurance products for those rolling off Medicaid would lead to likely higher uninsured rates, as folks may decide not to enroll in a new, more pricey Marketplace plan.

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**BACKGROUND**

- **CMS announced in March a special enrollment period (SEP) will be available for low income Americans, providing government dollars for insurance coverage.** Today, on the *Affordable Care Act's* 12th anniversary, the Biden Administration announced that subsidies to access low or $0 premium care will be available for those <150% FPL.

- **The new policy is helpful to plans such as CNC, MOH, UNH, HUM, as well as others.** Americans with incomes less than 150% of the federal poverty level -- $19,320 for an individual and $39,750 for a family of four -- can select policies via Healthcare.gov through a SEP, the Centers for Medicare and Medicaid Services announced Monday, after previewing the policy to CNN this morning (here).

- **Free coverage for Americans during a SEP that lasts through Dec 31, 2022**. Most people will be able to select plans with no premiums, while others may have to pay a few dollars. CMS is launching advertising and outreach campaigns about the new special enrollment period, which lasts for the rest of the year. The effort will also target those experiencing certain life changes, such as losing job-based coverage, getting divorced or aging out of a parent's policy, which have always allowed them to sign up for Obamacare policies during the year.

- **As a reminder, longer term "Medicaid Gap" funding waits in the wings.** As a reminder, BBB would have provided coverage to those 12 holdout states. With BBB stalled, given Manchin & Sinema commentary, as well as Biden low approval during a significant geopolitical situation, we note that the coverage band aid announced today is helpful.

- **American Rescue Plan subsidies have boosted enrollment during the public health emergency (PHE).** CMS has worked to expand health care coverage to a record 14.5 M people through the Health Insurance Marketplaces, encouraged states to extend Medicaid coverage for a full 12 months after childbirth, and expanded access to home and community-based services for seniors and people with disabilities.

- **ARP related sign-ups were particularly strong in States that have not expanded Medicaid to low-income adults**. It has been popular among those with lower incomes nationwide: Some 4.6 M consumers who earned up to 150% of the poverty line enrolled in 2022 coverage, a 21% increase from the prior year.

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