It's Happening: Healthcare Byrd Bath Friday

Drug Reforms & ACA Subsidies: *Inflation Reduction Act* Motion to Proceed & Senate Vote Teed Up

- **IT'S ON: We believe that 51 Senate votes exist as final preparations are made.** Sen. Sinema (D-AZ) opposes carried interest provision, and wants $5 B in drought resistance funding to be added. We do not see the bill as being derailed due to Sinema's minor asks. Carried interest generates $14 B so it won't matter much in the context of a $300 B deficit reducing bill.

- **On Fri, Aug 5, healthcare provisions are scheduled to be considered by the Parliamentarian.** The timetable has slipped, and these assessments take longer, particularly with climate and tax in the mix. Tomorrow, the Senate Finance Committee provisions e.g., Drug Reform, Rebate Rule (partial repeal), Insulin and ACA subsidies, are scheduled to be heard. It is difficult to know when we will hear "what's in" and "what's out" unless Senators issue a press release, which Sen. Wyden (D-OR) said he would articulate, as they work day and night on *Inflation Reduction Act*. Bill text is here, along with summaries.

- **We could see a motion to proceed and vote late Friday evening into Sat Aug 5**. Leader Pelosi (D-CA), though in Taiwan, noted she would call the House back in if needed for their vote. The House exited for recess July 28 and will be called back for votes. We do not anticipate the House asking for changes at this late hour.

- **We warn that the reforms (below) are more onerous because of the ability to add more molecules into the fold for Part B and/or D negotiation**. Prices could drop 40%, higher than many analysts have projected.

- **Impacted drugs and biologics are from AZN, MRK, LLY, PFE, AZN, GSK, NVS, RIG, SNY, AMGN, BIIB, GILD, REGN. Others**. See below for provisions in the bill.

DRUG REFORMS

- **Prescription drug inflation rebates start Oct 2022 (Part D) and Jan 2023, saves $62 B over ten.** 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 $2k maximum out-of-pocket cap (costs $25 B) for Medicare beneficiaries starts 2025.** Updates implementation timelines
  - Redesign of Part D benefit will take place in 2025, which drugmakers 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.

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  - Stabilizes premiums. Premium growth will be capped at 6% per year through 2029, instead of 4% through 2027.
  - 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
  - Instead of 70% in the donut hole, manufacturer discounts are 10% in initial phase and 20% in the catastrophic phase

- **THE BIGGIE: Drug negotiation (saves $101 B over ten) process would be sped up to start in 2023 with negotiated prices going into effect in 2026 (vs. 2025 previously).** The prices would have to be locked down in 2025 for AEP.

  - HHS will be directed to negotiate a specific number of drugs every year, rather than "up to" the required number of drugs.
  - Negotiated prices will go into effect in 2026, instead of 2025. First year of negotiation is moved forward 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 will go into effect and end a year later to match the shift in negotiation implementation data
  - 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 exercise tax beginning at 65% and increasing 10% quarterly up to 95%.
  - There is a negotiation exception for vaccines and orphan drugs

- **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.

- **We have said that the Rebate Rule repeal may not make it in entirely, due to the ten year window.** This is due to Budget rules, versus not meeting Reconciliation standards. We think that delay and partial repeal is very likely. And that 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.*

- **$35 OOP Cap on Insulin & Insulin in Drug negotiation.** The Parliamentarian will assess the insulin OOP cap as well. What's in the Warnock (D-GA) proposal

  - **The bill excludes insulin products from applying to deductibles starting in 2023**. Starting in 2023 and 2024, Part D and MA plans will have to provide coverage for insulin products regardless of whether they reached the initial coverage limit or the OOP threshold. Starting in 2025, plans will have to provide benefits for covered insulin products prior to the out-of-pocket threshold. Note that 2025 is the year when Part D restructuring goes into effect and eliminates the initial coverage limit.

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- **This bill places a $35/month insulin co-pay cap (MA, Part D).** From 2023-2025, Part D prescription drug plans and MA-PD plans will have to limit co-pay amount to $35 for covered insulin products. Starting in 2026, plans will have to limit co-pay amount to $35 or 25% of the maximum fair price or 25% of the negotiated price. Covered insulin product includes any insulin product that is a covered part D drug or biologic, or biosimilar. Insulin is not specified in the Medicare negotiation provision like previous text, but this text leave the door open for insulin products to be included in negotiations in the future based on their time on the market and their cost to Medicare.

- **We are unsure if commercial will be included on $35 OOP cap, but insulin being included in Part B&D negotiation (2026+) is likely to be included.** Commercial rules could be struck by the Parliamentarian as the budget impacts need to incur to the federal government and typically involve Medicare/Medicaid/Marketplace.

HEALTH INSURANCE

- **Insurance Subsidies: Three years of ACA subsidies (2023-25) is better than two years (CNC, MOH, UNH, ANTM, others), which we thought may happen so as to get past the Presidential election.** The deal announced 7/27, allows for three years of ACA subsidy extension, which we had expected, versus only two. The CBO score allowed for more generous subsidies ($288 deficit reduction from drug reform) and positively there is no means testing of the extension.

- **Medicaid Gap is not included here**. Advocates pressed a the 11th hour for Medicaid coverage to 2 M or so folks in states that opted out of the expansion.

- **MCOs bear more responsibility in the Part D benefit**. 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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BACKGROUND

- **There is some consternation that the inflationary rebates will not make it past the Byrd Rule i.e., not eligible for 51 votes.** We do not view as inflationary rebates as detrimental to the Biopharma industry, with companies tamping down on price increases and US inflation at a 50 year high. That is because it goes beyond saving the government money. Some think the bill's inflation caps for Medicare beneficiaries are safe. Losing the private market piece of the bill could shrink the amount of money.

- **The new, expanded, deal (July 27) with climate & tax was truthfully surprise to us.** Inflation reduction includes all of the below:
  - Enacts deficit reduction to fight inflation
  - Lowers energy costs, increases cleaner production, and reduces emissions by 40 % by 2030
  - Allows Medicare to negotiate drug prices and caps OOP costs to $2,000 • Lowers ACA health care premiums for millions
  - Make biggest corporations and ultra-wealthy pay their fair share
  - There are no new taxes on families making $400,000 or less and no new taxes on small businesses – Congress is closing tax loopholes and enforcing the tax code

- **The bill removes special provisions for insulins**. Insulins are not treated as a separate class for the purposes of negotiation. Clarifications: 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.

- **PBM Rebate Rule (Saves $122 B) is repealed.** The repeal of the rebate rule ($122 B) will begin January 2027 to accommodate the delay included in recent gun safety legislation.

- **As we said on June 30 note, 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 July 6 (weeks of July 11 & 18): 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).

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- **NEXT STEPS:** There is little fanfare as the bill pushes ahead, likely because there are more reconciliation steps required before a win can be announced. Energy & tax provisions remain to be ironed out, or not given inflation data. 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

- **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).**

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- **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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