Summary of Changes to Prescription Drug Pricing Reforms

Part 1 – Lowering prices through drug price negotiation

- ***Firms up the number of drugs the Secretary must negotiate.*** The 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.
- ***Updates implementation timelines***
    - 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 dates
- ***Allows for delay of negotiation for biosimilar market entry.*** 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.
- ***Removes special provisions for insulins.*** Insulins are not treated as a separate class for the purposes of negotiation.
- ***Clarifications, including:***
    - Adds 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 price
- ***Technical edits*** to reflect intent, including corrections to conforming amendments and excise tax.

Part 2 – Prescription drug inflation rebates

- ***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 3 - Part D improvements and maximum out-of-pocket cap for Medicare beneficiaries

- ***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.
- ***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.
- ***Updates repeal of the rebate rule.*** The repeal of the rebate rule will begin January 2027 to accommodate the delay included in recent gun safety legislation.
- ***Insulin copay cap.*** The $35 copay cap for insulin has been removed.