Congressional Breakdown:

The House Judiciary Committee passed two bills dealing with drug-pricing and competition including:

- The Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2019, proposing to stop name brand prescription drug makers from withholding samples that generic drug makers need to get FDA review and approval. CREATES would also allow the Federal Trade Commission (FTC) to act when drug companies use practices that delay FDA approval of competing generics or biosimilar drugs.

- The Prescription Pricing for People Act of 2019, would require the FTC to study how pharmacy benefit managers (PBMs) work in the drug supply chain and how their role could be used to improve transparency and competition. Companion bills and language were also introduced in the Senate.

The House Energy and Commerce, and House Ways and Means Chairmen and Ranking members called for comments on draft legislation the committees are working on to improve the Medicare Part D program. The legislation:

- Would establish an out-of-pocket cap for Medicare Beneficiaries, and address current incentive structure in Medicare Part D and reduce the government’s share of catastrophic coverage from 80 percent to 20 percent over four years.

The House Energy and Commerce Subcommittee on Health also marked up the Fair Accountability and Innovative Research Drug (FAIR) Drug Pricing Act of 2019, which passed in the Senate as part of a drug-pricing package. The bill:

- Would require prescription drug makers to submit pricing information and the justification of their pricing in a report to HHS at least 30 days in advance of any increases on prescription drugs higher than 10 percent over one year or 25 percent over three years

- The subcommittee also proposed changes that would apply to drugs used to treat more than 200,000 people.

Speaker of the House Nancy Pelosi (D-Calif.) has also been working over the past several months on prescription drug pricing legislation including:

- Bringing HHS into negotiating on prices for at least 250 of the most expensive prescription drugs and prohibiting any price changes that are higher than inflation on drugs covered by Medicare.

- This would apply to all payers including the government, employers and insurers.

- These proposals were part of recently updated draft legislation that Pelosi’s office has been working on with members of the Democratic caucus, though some caution the negotiation piece especially in Medicare Part D is a non-starter for Senate Republicans.

The Senate Finance Committee kicked off their year with a marathon of hearings on prescription drug pricing practices and transparency. Senator Chuck Grassley (R-Iowa) was working with with Senate Finance ranking member Ron Wyden (D-Ore.) on prescription drug pricing and transparency legislation, and held several conversations with the Senate leadership, and administration staff on the proposal. The committee released the legislation, The Prescription Drug Pricing Reduction Act (PDPRA) of 2019 and had the bill scored by the Congressional Budget Office prior to the committee’s markup of it. The
legislation passed out of the committee 19-9 with all committee Democrats in favor. Some Republican members expressed concerns over proposals on reforms to Medicare Part D and pricing practices. With these concerns in the mix, Senate Majority Leader Mitch McConnell (R-Ky.) would need to make significant changes to the bill before bringing it to the floor for a vote.

In the Senate HELP Committee Chairman Lamar Alexander (R-Tenn.) and ranking member Patty Murray (D-Wash.) held hearings on drug pricing as it relates to overall rising healthcare costs. They also introduced the “Lower Health Care Costs Act of 2019.” Within the bill is a proposed ban on PBMs from charging more for a drug than what they paid for it. The bill also requires PBMs to pass 100 percent of rebates or discounts to the health insurers or employers that hire them. It also addresses current competition practices prescription drug makers use when introducing new drugs to the market.

**Administration Breakdown:**

- Earlier this spring CMS approved final changes to Medicare Advantage and Medicare Part D that will increase transparency on the cost of prescription drugs for enrollees.
- HHS finalized a rule that would have required prescription drug ads to disclose list prices if the cost was more than $35 a month. The move would have increased transparency on drug prices but did not enforce companies to lower their prices. Some drug manufacturers responded by suing the administration on the rule, and recently a U.S. District Judge blocked the rule right before it was supposed to go into effect.
- The administration introduced a drug rebate proposal that would have barred PBMs and insurers from accepting rebates from drug companies participating in Medicare and Medicaid. The new structure would have included fixed-fee arrangements with rebates going directly from prescription drug manufacturers to patients. President Donald Trump recently announced the withdraw of the proposal due to concerns that it would've raised insurance premiums for Part D enrollees. Congress has also indicated a similar proposal that was introduced in legislation this year would likely not move.
- The administration continues to push to have an international pricing index demonstration for prescription drug costs as well.

What does all this activity mean for the future of prescription drugs? Will Congress and the administration work together on a final package? Medicare Part D could find some new program flexibility to help lower costs for patients, PBMs will continue to be the focus of pricing reform from all sides, and anything beyond these areas could be shelved. Even in the instances of Medicare Part D, PBMs and pricing reform, nothing seems to be moving toward a floor vote in the near future.