TheZetemaProject

Drugs

Pharmaceutical Pricing Reforms, Debate, and Possibilities

Key Takeaways:
The administration has recently proposed plans to control drug prices. Some experts believe that the recommendations are toothless, while pharmaceutical companies warn about the future of the drug industry if the plans come into effect.

Biologics and biosimilars are gaining more attention due to current healthcare needs. Changes to Medicare Part B have been proposed in order to promote innovation, competition, and access while bringing prices down for specialty drugs.

PBMs and the pharmaceutical manufacturers have been criticized for a lack of transparency in their contractual arrangements. The removal of rebates increases transparency, but could raise drug prices and premiums for beneficiaries.

The Administration's Blueprint

In May 2018, the Trump Administration released a document called American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. The Blueprint describes the administration's general approach toward prescription drugs, breaking down its priority areas into four "challenges," named below:

1. High list prices for drugs
2. Seniors and government programs overpaying for drugs due to lack of the latest negotiation tools
3. High and rising out-of-pocket costs for consumers
4. Foreign governments free-riding off of American investment in innovation

The Blueprint then identifies four key strategies for reform:

1. Improved competition
2. Better negotiation
3. Incentives for lower list prices

4. Lowering out-of-pocket costs

Finally, the Blueprint breaks down its approach into two phases:

1. Actions the President may direct HHS to take immediately
2. Actions HHS is actively considering, on which feedback is being solicited

Pharmaceutical Research and Manufacturers of America (PhRMA), the group representing many of the companies under scrutiny, responded to the release of the Blueprint with a list of comments to which they hoped the Department of Health and Human Services would respond. PhRMA suggested that some of the changes would ultimately harm patients. Examples of PhRMA's position included the arguments that:

- Rebates create an opaque supply chain and should be eliminated or reformed
- Medicare Part D should be protected and improved by strengthening out-of-pocket protections, maintaining current formulary protections, and continuing current treatment of coverage gap discounts in the calculation of true out-of-pocket spending
- The administration should address trade practices, including negotiating and enforcing stronger trade agreements and ensuring foreign government pricing and reimbursement policies are transparent and do not condone compulsory licensing
- The 340B Program be reformed
- The administration issue an Anti-Kickback Statute safe harbor for value-based arrangements and clarify the rules for the reporting of Medicaid best price
- Medicare Part B should be protected from reforms such as moving coverage of medicines from Part B to Part D, limits on patients' access to the full range of treatment options, and the implementation of a competitive acquisition program
- The administration should maintain the cap on Medicaid rebates
- The mandated disclosure of list prices in direct-to-consumer ads would not benefit patients as they are often not the prices insurers pay and are generally not a good indicator of what patients will pay at the pharmacy counter.

Discussion Questions

- Will requiring drug companies to post prices during advertisements influence prices?
- How would limiting or eliminating rebates affect drug prices and costs?
- Will adding step edits for Part B drugs affect drug costs?
- Would centralized Medicare negotiation of drug prices be more effective than the current PBM-based system?
- Will removal of pharmacist 'gag clauses' materially affect drug costs?
- How can the FDA increase competition from biosimilars?
- Could FDA facilitation of over-the-counter transitions for branded drugs lead to lower costs?
- To what degree should the government focus on generic drug prices vs. brand prices?
- What role could value-based contracts play in reducing drug costs?