AV POLICY FOCUS: DRUG PRICING

Arnold Ventures

Lowering Drug Prices to Improve Patient Access to Affordable Medicines

Solutions Must be Comprehensive and Address THREE KEY ISSUES

1 Patent Abuses and Anticompetitive Behaviors

The federal government grants patent and market exclusivity monopolies, which manufacturers constantly fight to extend. Many of these patented products were first discovered through taxpayer-funded NIH research and grants, which contributed to the development of all new molecular entities approved by the FDA between 2010 and 2016.

2 Market Distortions

The way drugs are paid for and delivered in the U.S. can also have an outsized impact on the prices and availability of drugs to the patients who need them. PBMs are paid in part through rebates negotiated off of list prices, which can incentivize the use of higher cost therapies. Manufacturers also use rebates, in addition to co-pay coupons, and free samples to incentivize the use of higher cost therapies, and manufacturers pay millions of dollars a year to patient groups to help advocate on their behalf.

3 High Launch Prices and Unjustified Price Increases

Drugs are launching at higher prices each year, particularly for specialty products, which are becoming a larger percentage of the pharma pipeline and, in turn, drug spending. Once launched, drug list prices continue to escalate year-over-year, while clinical efficacy stays the same. This is the opposite price trend of other consumer products and of drug prices in many other countries, where drug prices fall over time.

1. PATENT ABUSES AND ANTICOMPETITIVE BEHAVIORS

Delays to Competition

- **Limit anticompetitive "pay for delay" agreements** that prevent or delay the introduction of lower cost generic or biosimilar products.
- **Reduce Medicare reimbursement** for brand-name drugs in Part B if the manufacturer enters a pay-for-delay agreement. Under this proposal, reimbursement for that product will be cut until a competitor is available on the market.

Address Anticompetitive Behaviors

- **Restrict the number of patents** that prescription drug manufacturers can defend in court to discourage the use of anticompetitive patent thickets.
- **Limit the patentability of so-called secondary patents** — which don't improve the safety or efficacy of a drug — through patent and exclusivity reform.
- **Reform the 180-day generic exclusivity,** which can currently be abused to block other competitive therapies.
- **Limit the number of orphan drug designations** a drug may be eligible for.
- **Reduce the FDA-granted exclusivity** for biologics.
- **Grant FDA greater authority** to address abuses of the Citizen's Petition system.

2. MARKET DISTORTIONS

Medicare Part D Benefit Structure

- **Alter the risk structure of the Part D benefit** to pressure PBMs to more aggressively manage the benefit in order to reduce taxpayer liability and beneficiary burden. This proposal has bipartisan support and was endorsed by MedPAC.

Tax Incentives

- **End the tax-advantaged status of co-pay coupons** and direct-to-consumer advertisements.

Transparency

- **Require that payments made to patient groups** and free drug samples given to physicians are disclosed under the Sunshine Act.
- **Allow MedPAC and MACPAC access to rebate data** so they can better inform Congress on needed reforms to Medicare and Medicaid.

Pharmacy Benefit Managers (PBMs)

- **Ensure that compensation paid to Part D plans** is fairly allocated between plans, PBMs, and the taxpayer. Currently, there are forms of compensation paid to Part D plans that may not be shared with the program due to the way Part D plans and PBMs classify certain transactions.
- **Reform the rebate system** to ensure that rebates do not block coverage of lower cost alternatives and that rebates are used to lower consumer costs.

3. HIGH LAUNCH PRICES AND UNJUSTIFIED PRICE INCREASES

Medicare Part D

- **Provide plans with more flexibility and leverage** by changing the protected classes' structure and enabling a more streamlined appeals and exceptions process to protect patients. This is bipartisan — variants were proposed in Part D rules under both the Trump and the Obama administrations.
- **Allow Medicare to use reference prices** or to negotiate prices for certain high cost drugs.
- **Create an inflation-based rebate** in Part D that is similar to Medicaid's inflation rebate.

Medicare Part B

- **Change the ASP add-on payment** from a percentage of drug cost to a flat fee to eliminate current incentives to prescribe higher priced products.
- **Create shared reimbursement codes** for biosimilars and their reference biologics to encourage price competition and the use of the lowest cost alternative.
- **Allow physicians to form purchasing groups** to exercise greater leverage in negotiations.
- **Create an inflationary rebate on drug reimbursement** to discourage price increases.
- **Set Medicare Part B drug reimbursement** based on international reference prices.

Medicaid

- **Allow states more flexibility in managing** their drug benefit while maintaining access to the statutory rebate.
- **Increase the statutory rebate cap,** which caps a manufacturer's rebate liability at 100 percent of its price. The cap in current law protects manufacturers from paying more rebate if their prices continue to grow faster than inflation.

Commercial

- **Revisit Medicaid's best price provision** to give commercial plans more leeway to negotiate lower prices while increasing the Medicaid statutory rebate to ensure drug prices paid by the Medicaid program do not go up.