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

> **Patent Abuses and Anticompetitive Behaviors**

> **Market Distortions**

> **High Launch Prices and Unjustified Price Increases**

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.

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** branded drugmakers can defend in court to discourage anticompetitive patent thickets that delay competitor market entry. These patents are often filed long after drug approval and do not protect the active drug ingredient.
- **Limit the patentability of so-called secondary patents** — which don't improve the safety or efficacy of a drug — through patent and exclusivity reform.
- **Reduce the FDA-granted exclusivity** for biologics.
- **Grant FDA greater authority to address abuses** of the Citizen's Petition system.
- **Reform FDA policy to ensure that a "product hop" is not approved** until a generic version of the brand product is on the market. A "product hop" occurs when a manufacturer successfully moves patients from one of its branded drugs nearing its patent expiration to another patent-protected formulation of the drug.

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. Plans collect rebates from brand name drug manufacturers that lower their cost well below the list price. However, many patients are forced to pay cost-sharing based off of high list prices, which creates affordability and access problems. Manufacturers also use distortive tactics such as co-pay coupons, patient-assistance programs, and free samples to incentivize the use of their therapies over cheaper alternatives on the market, and manufacturers pay millions of dollars a year to patient groups to help advocate on their behalf.

Medicare Part D Benefit Structure

- **Redesign the risk structure of the Part D benefit** in order to realign program incentives that reduce taxpayer liability and provide better beneficiary protections.

Tax Incentives

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

Transparency

- **Require that payments made to patient groups**, provider groups, and free drug samples given to physicians are disclosed under the Sunshine Act.
- **Require justification and reporting from manufacturers** for drug price increases that surpass certain minimum price thresholds.

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.
- **Require full disclosure and pass through of all rebate payments** (and other types of payments from manufacturers to PBMs) at the aggregate level to health plans in the commercial market and require pass-through pricing models for payment arrangements with PBMs under Medicaid.

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 well above inflation year-over-year, while clinical efficacy stays the same.

Medicare

- **Protect beneficiary out-of-pocket costs** by requiring manufacturers to pay an inflationary rebate on drug purchases to discourage excessive price increases.
- **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.
- **Allow Medicare to use reference prices** or to negotiate prices for certain high-cost drugs.
- **Change the Average Sales Price (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.

Medicaid

- **Allow states more flexibility in managing** their drug benefit while maintaining access to the statutory rebate.
- **Include authorized generics in Medicaid's definition** of a line extension of a brand name drug.
- **Increase the inflationary rebate** on accelerated approval drugs if the manufacturer has not yet completed confirmatory trials within a certain period of time.

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.
- **Require manufacturers to pay an inflationary rebate** for brand name drugs purchased by commercial sector plans.