

Prescription Drug Pricing and Costs

Physicians experience and see first-hand the difficulty and burden high pharmaceutical costs have imposed on our patients, on physician practices, and the broader health care system. Patients delay, forgo, or ration their medication when treatments are cost prohibitive, putting their health at risk. Despite legislation to address the high prescription drug prices and costs (*see blue callout box below*), the AMA believes that increased competition and fair and transparent markets are more important than ever. The AMA continues to work with Congress and the Administration to develop and implement well-crafted and effective public policy solutions to address the rising cost of prescription drugs that will improve access, lower costs, and reduce the administrative burdens without stifling innovation.

Increase Pharmaceutical Market Competition and Combat Anticompetitive Practices

- Prohibit pay-for-delay settlements, whereby a brand-name drug manufacturer pays a potential generic competitor to abandon its patent challenge and delay offering a generic drug product for a number of years.
- End the ability of generic manufacturers to indefinitely “park” the 180-day exclusivity period granted to them by the Federal Food, Drug, and Cosmetic Act by delaying final approval of their application by the Food and Drug Administration (FDA) as part of a settlement agreement with a brand manufacturer.
- Shorten the exclusivity period for biological products.
- Further expand the ability of the FDA to combat anticompetitive abuse of Risk Evaluation and Mitigation Strategies (REMS) by brand manufacturers.
- Further expand Federal Trade Commission authority to limit anticompetitive behavior by pharmaceutical companies attempting to reduce competition from generic manufacturers through manipulation of patent protections.
- Make necessary refinements to law to prevent the inappropriate extension of the exclusivity and patent life of pharmaceuticals.

Require Pharmaceutical Supply Chain Transparency

- Require pharmaceutical manufacturers to provide public notice before increasing the price of any drug by 10 percent or more each year or per course of treatment and provide justification for the price increase.
- Require pharmaceutical manufacturers to publicly disclose a variety of information, which could include research and development costs; expenditures on clinical trials; total costs incurred in production; and marketing and advertising costs.
- Require pharmacy benefit managers to apply manufacturer rebates and pharmacy price concessions to drug prices at the point-of-sale to ensure that patients benefit from discounts as well as eliminate some incentives for higher drug list prices.
- Improve transparency in formularies, prescription drug cost-sharing, and utilization management requirements for patients and physicians.
- Unless a change is made for safety reasons, prohibit drugs from being removed from the formulary or moved to a higher cost tier during the duration of the patient’s plan year.

The Inflation Reduction Act of 2022 (IRA)

In 2022 the IRA was signed into law and covered a wide variety of topics including renewable energy, deficit reduction, and prescription drug pricing. The implementation of the IRA should have significant impacts on the price of prescription drugs for millions of Americans, especially Medicare beneficiaries.

- **Improvements to Medicare**
 - The cost of insulin will be capped at \$35/month for Parts D and B
 - Out-of-pocket prescription costs will be capped at \$2,000/year for Part D
- **Medicare Drug Price Negotiation**
 - CMS will be able to negotiate “maximum fair prices” for certain brand-name, single source drugs.
 - Negotiations will begin for Medicare Part D in 2023 with implementation in 2026.
 - Negotiations plan to be implemented for Medicare Part B in 2028.
- **Medicare Inflation Rebates**
 - Should the price of a prescription raise faster than inflation, the drug company will be required to pay a rebate to Medicare.