

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. At a time of significantly increasing drug prices, the AMA believes that increased competition and fair and transparent markets are more important than ever. The AMA looks forward to working 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.