AHIP Recommendations to Reduce Drug Prices and Costs for All Americans

Everyone should be able to get the medications they need at a cost they can afford. But drug prices are out of control, and hardworking families and patients feel the consequences every day. Health insurance providers are working hard to lower drug prices and costs for all Americans. The problem is the price—set and controlled solely by pharmaceutical manufacturers that choose how high to set launch prices, as well as the timing, frequency, and magnitude of price increases.

Rising prescription drug costs hurt everyone. Prescription drugs represent the largest segment of health care spending in the commercial market by accounting for almost 22% of premiums **and about** 20% of all Medicare costs**. We need effective market-based solutions that deliver real competition, create more consumer choice, and ensure that open and honest drug prices are driven by the value they bring to patients.**

Principle #1: Promote Real Competition to Reduce Costs and Improve Affordability

- ✓ **Foster a More Robust and Competitive Biosimilars Market:** End anti-competitive strategies, such as "patent thicketing," and tactics aimed at delaying the availability of biosimilars. Shorten the exclusivity period for biologics from 12 years to 7 years to promote earlier biosimilar availability and greater price competition. Ensure physicians and patients have unbiased information available to them about the benefits of biosimilars.
- ✓ **Reduce Rules Blocking Biosimilar and Generic Entry:** Prohibit anti-competitive tactics such as "pay for delay" settlements that hinder generic and biosimilar competition and "product hopping." Encourage appropriate switching to lower-cost biosimilars by revisiting the biosimilar regulations along with clinical evaluation guidance to promote interchangeability and therapeutic substitution in addition to revising the biosimilar "naming" rules to streamline prescriber uptake of biosimilar products.
- ✓ **Support Positive Part D Reforms that Protect Beneficiaries and Taxpayers**: Build on Part D's success and innovation and support congressional efforts to improve affordability by capping seniors' annual out-of-pocket costs while keeping premiums stable, expanding plan choice and competition, and maintaining high generic dispensing rates and enrollee satisfaction. Ensure costs are not shifted to seniors and taxpayers via higher premiums by increasing pharma manufacturer liability during the initial and catastrophic benefit phases.
- ✓ **Limit Third-Party Payment Schemes that Raise Costs:** Examine and address the impact of drug coupons and copay card programs – and related charitable foundations – on overall pharmaceutical cost trends. Ensure that existing protections aimed at prohibiting their use in all federal programs are sufficient.
- ✓ **Revisit and Revise Orphan Drug Incentives:** Ensure that the Orphan Drug Act's incentives are used by those developing medicines to treat rare diseases – not as a gateway to premium pricing and blockbuster sales beyond orphan indications. In cases of rare diseases for which no effective therapy yet exists, ensure that newly approved drugs are priced in accordance with their efficacy.

Principle #2: Open & Honest Pricing Information and Helping Patients Make More Informed Decisions

- ✓ **Publish Rx Prices, True R&D Costs, and Price Increases:** Require manufacturers to disclose information regarding intended launch price, use, and direct/indirect R&D costs as part of the FDA approval process. After approval, require manufacturer reporting of list price increases over a percentage threshold amount that explains why such price increases are justified.
- ✓ **Reform DTC Advertising by Focusing on Health Literacy and Equity:** Health literacy has a significant impact on informed health care decision making, including decisions about which drug a patient should choose. Health literacy also has a significant impact on health equity. Rules governing direct-to-consumer advertising should be reformed to ensure all consumers understand the purpose of the drug advertised and its price/cost.
- ✓ **Better Inform Patients on Effectiveness and Value:** Increase funding for private and public efforts to provide information on the comparative and cost-effectiveness of different treatments to physicians and patients; these tools can help them make appropriate assessments about the value and effectiveness of different treatment approaches, particularly those with very high costs.

Principle #3: Deliver Greater Value to Patients

- ✓ **Eliminate Barriers to Value-Based Arrangements and Expand Value-Based Formulary Programs:** Remove additional barriers to improve and accelerate adoption of value-based arrangements through additional safe harbors. Promote value-based payments in public programs like Medicare for drugs and medical technologies, based on agreed-upon standards for quality and outcomes. Evaluate expanding CMMI demonstrations similar to the Part D Insulin Senior Savings Model to other applicable therapeutic categories.
- ✓ **Provide Greater Formulary/Utilization Management Flexibility in Medicare:** Provide Part D plans with more flexibility on formulary/utilization management. End the two-drugs-per-class requirement, permit select exclusions from protected class requirements, and allow plans to offer additional design options so there are more plan choices for beneficiaries. Expand the use of clinically-appropriate, evidence-based tools for certain high cost "protected class" drugs and employ these tools for physician-administered medications covered by Medicare Advantage plans.
- ✓ **Fix "Buy and Bill" Incentives that Disadvantage Lower-Cost, Equally Effective Medications:** Modify the buy-and-bill system that reimburses providers for using more costly drugs based on average sales price plus a percentage of the drug's price rather than rewarding the use of higher-value medicines. Support the use of specialty pharmacies for just-in-time delivery to save money for patients and improve premium affordability.
- ✓ **Improve FDA Post-Market Surveillance Requirements:** Require (FDA) manufacturers to conduct additional clinical trials post-approval in cases when expedited approval pathways are used (and typically involve smaller clinical trials with surrogate endpoints and narrower patient populations). Impose specific timelines for completion of post-market trials that reflect the diversity of our nation's patients and subject manufacturers to penalties/fines if those commitments are not completed. Limit coverage (CMS) to the patient populations included in the studies that resulted in expedited approval.