COUNCIL FOR AFFORDABLE
HEALTH COVERAGE

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Prescriptions for Competition, Value, and Innovation:

Increasing Prescription Drug Access and Affordability

The healthcare system is undergoing a monumental shift as payers move aggressively to reward value and deliver affordable, quality care to consumers. In such value-based systems, payment for a medicine is linked to patient outcomes, rewarding affordability and quality. Uptake of these approaches have been needlessly slow for prescription drugs, hindered by laws that were built for an era that discouraged coordination and team based approaches.

At the same time, FDA approval of new brand and generic drugs takes significant time and effort for both the Agency and manufacturers. Partly due to complexity and resource constraints, and the system's lack of capacity for throughput, a backlog of generic drug applications awaits review and approval at FDA. More products on the market would result in more competition, more options and lower costs and prices for consumers.

Patients are not uniform; their needs are as diverse as their diseases. Flexible benefit designs enable consumers to choose plans that best meet their health needs and budgets. Similarly, greater transparency - on benefit design, price, quality, and safety - can empower consumers to make better health choices. Current federal and state policies limit plan flexibility and consumer choices, and fall short in leveraging the latest technology and access to data that drive price transparency.

Solutions that support competitive markets will lower drug costs, promote innovation, and support appropriate access to treatment. We support changes to current law and regulations that:

1. ***Increase Competition.*** Reduce regulatory barriers and create incentives to speed biopharmaceutical development and approval.
   - Establish expedited timeframes for FDA review of generic and biosimilar applications.
   - Create a generic priority review voucher for products addressing medical shortages or price spikes that requires review and action within 150 days.

2. ***Reward Value.*** Reform outdated laws that prevent rewards for better outcomes and lower costs.
   - Create a safe harbor under the Anti-Kickback statute to allow payers and manufacturers to collaborate.
   - Provide an exception from the Stark law to allow providers to participate in value-based arrangements.
   - Encourage price competition by adjusting "Best Price" and ASP rules to exempt value-based arrangements.
   - Clarify anti-discrimination laws to allow value-based insurance designs.
   - Empower consumers by equipping them with information to better understand their drug choices, such as whether a drug is covered and at what level of cost sharing, and, for those without coverage, an average retail price.

3. ***Improve Data Infrastructure and Utilization.*** Create better infrastructure and streamline processes needed to bring value-based arrangements and higher value treatments to market.
   - Improve and encourage interoperability, data infrastructure, sharing, and availability.
   - Reduce provider regulatory reporting burdens.
   - Facilitate electronic recruitment and enrollment in clinical trials.

4. ***Preserve What Works.*** Reject policies that undermine functioning markets, hamper innovation, or jeopardize safety or access, such as importation, price or benefit caps and interfering in price negotiations.

Collectively, we estimate these changes will save taxpayers between $2.6 and $5.6 billion over ten years, while reducing national health expenditures by as much as $36-71 billion by the year 2026.

For a more in depth discussion on our policy recommendations and to read our policy proposals, visit www.CAHC.net.