

UNLOCKING AN AFFORDABLE FUTURE

Building Toward a More Accessible and Affordable Health Care Future



Pharmacy benefit companies secure lower prescription drug costs, enable better health outcomes for patients, and offer employers and other health insurance plan sponsors the choices and guidance they need to expand access and provide quality prescription drug coverage for millions of Americans. Our vision of an *Affordable Future* prioritizes patients and clinicians and proposes actionable solutions to enhance the competitive market for drugs and biologics.



KEY #1

Ensure System Sustainability by Promoting Competition

A competitive private market is the best way to manage drug costs. Interventions should be focused on fixing specific market failures or gaps rather than subverting the market entirely. Policies that enhance competition will make drugs more affordable.

Stop Patent Abuse

To increase competition and lower patient and plan sponsor costs, it is imperative for policymakers to end the anticompetitive tactics used by big drug companies. To combat these harmful practices, PCMA recommends policymakers take the below actions.

- » Codify the definitions of “evergreening,” “product hopping,” “patent thicket,” “secondary patent,” and similar practices as antitrust violations under the FTC Act.
- » Eliminate anticompetitive “reverse payment settlements” or “pay-for-delay” agreements.
- » Apply stricter scrutiny to patent applications and thwart abuse by curbing “patent thickets.”

Reserve Market Exclusivities for True Innovation

Innovation without affordability undermines patient access. Congress has granted overlong exclusivity periods for biologics and orphan indications, leading

to delays in getting more affordable biosimilars to the market. To accelerate competition, PCMA recommends policymakers take the below actions.

- » End Orphan Drug Exclusivity (ODE) abuses.
- » Reduce the Biological Product Exclusivity to seven years and prohibit additional periods of exclusivity for reference biologics due to minor changes in product formulations.
- » Grant a five-year New Chemical Entity (NCE) market exclusivity only if a product’s molecular structure contains a meaningful change from the existing drug.
- » Ensure nonpatent exclusivities deliver on the promise of innovation—not higher prices.
- » Require significant clinical benefit for New Clinical Investigation Exclusivity.
- » Limit the scope of the 180-day First Generic Exclusivity.

Ensure Drugs Can Compete Fairly

Big drug companies block competitors from coming to market through a variety of anticompetitive tactics used to undermine the market in their favor. In addition to the patent games above, drug manufacturers may participate in “shadow pricing” or abusing the FDA’s citizen petition (CP) process. To ensure a level playing field, PCMA recommends policymakers take the below actions.

- » Reform the citizen petition process.
- » Enforce anti-trust laws to stop shadow pricing.

Promote Generic and Biosimilar Competition

As evidenced by the impact of generic drugs, the most effective way to reduce prescription drug costs is to increase competition in the marketplace. Similarly, when more biosimilars enter the market, increasing their uptake will help boost competition and lower costs for patients. To encourage proliferation and uptake of generic and biosimilar drugs, PCMA recommends policymakers take the below actions.

- » Remove the interchangeability designation to reduce confusion and costs.
- » Encourage biosimilars through therapeutic substitution.
- » Acknowledge that biosimilars for a single reference product are biosimilar to one another.
- » Require a common billing code for a reference biologic and its biosimilars.
- » Encourage the use of generics and other more cost-effective drugs in Medicare Part D.
- » Flip the burden of proof to the patentee when patent infringement is alleged.
- » Enable biosimilars to launch without risk of treble damages.
- » Provide the FDA with sufficient resources to speed competition.



Learn more about PCMA's position on biosimilars.

Ensure a Competitive Medicare Part D Prescription Drug Market

Pharmacy benefit companies—with their scale, deep pharmacy and prescription drug benefit expertise and proven strategies to secure cost savings for Medicare Part D plans and beneficiaries, employers, and ultimately, patients and taxpayers—are best equipped to harness competition to lower prescription drug costs. The Inflation Reduction Act’s requirement for Part D plans to include all selected drugs on their formularies may have the unintended consequence of disincentivizing generic and biosimilar manufacturers who might otherwise seek to compete. To incentivize production of competing products and improve the functionality of the prescription drug market, PCMA recommends policymakers take the below actions.

- » Limit CMS’s Maximum Fair Prices to drugs without any competition.
- » Provide an offramp for drugs on the negotiated drug list.

Promote Pharmacy Networks

Where a patient acquires a drug can impact costs significantly. Policies that restrict pharmacy benefit companies’ ability to develop pharmacy networks drive costs up, while well-managed pharmacy networks offer savings to both plan sponsors and enrollees.

To preserve the benefits of pharmacy networks, PCMA recommends policymakers take the below actions.

- » Seek to better understand the critical role of pharmacy services administrative organizations (PSAOs) in supporting pharmacies.
- » Protect pharmacies’ ability to operate optimally within their area of expertise.
- » Protect employers’ and health plan sponsors’ ability to make choices that allow them to effectively serve plan participants.



Learn more about independent pharmacies.

**KEY #2**

Support and Equip Clinicians with Tools and Data to Serve Patients Optimally

Physicians, pharmacists, and other health care providers are both valued employees within pharmacy benefit companies and indispensable external partners as we work together to provide patients and caregivers with care and support. Pharmacy benefit specialists are making it a priority to reduce any existing administrative strains, enabling clinicians to maximize their ability to improve patient care.

Support and Partner with Clinicians on Prescription Drug Affordability

Electronic pharmacy benefit tools like Real Time Benefit Tools (RTBT), electronic prior authorization (ePA), and electronic prescribing (eRx), reduce administrative burden and speed access, enabling clinicians to allocate more time to direct patient care.

Pharmacy benefit specialists, electronic health record providers, and pharmacies are equipped to facilitate RTBT, ePA, and eRx. To incentivize prescribers to use these services, which support increased medication adherence and reduce medication abandonment, PCMA recommends policymakers take the below actions.

- » Expand the use of RTBT.
- » Require the use of electronic prescribing and prior authorization.
- » Add ePA to Medicare quality measures.
- » Pave the way for interoperability.

Encourage Use of Lower Cost Care Options

Decisions made about sites of care and drug products selected have cost implications. To enable pharmacy benefit companies to more effectively partner with clinicians to help contain drug costs, PCMA recommends policymakers take the below actions.

- » Allow pharmacists to “practice at the top of their license.”
- » Provide biosimilars education for providers and resources they can share with patients.
- » Provide incentives for using RTBT.
- » Sponsor a Senior Savings Model focused on areas of known health inequities.



Accelerate Value-based Care

Pharmacy benefit companies and manufacturers negotiate value- and outcomes-based contracts for drugs that have proven clinical value for patients. Data collected to inform these contracts continue to provide physicians and payers with insights that enhance clinical decision-making, improve patient health, and increase competition in the marketplace. To accelerate value-based care, PCMA recommends policymakers take the below actions.

- » Give Medicare Part D plans meaningful access to Medicare Part A and B claims data to coordinate care and make the best coverage decisions for beneficiaries.
- » Provide states with the flexibility to adopt private-sector formulary management techniques to drive value and lower costs in their Medicaid programs.
- » Remove remaining barriers to the uptake of innovative payment and incentive structures that promote pharmaceutical value and ensure flexibility that allows for other innovative contract models.

Advance Use of Real-World Evidence to Protect Patient Safety

In a world where the cost of a drug can exceed an individual's lifetime earnings, drug manufacturers should be expected to undertake ongoing research to ensure effectiveness and durability of effectiveness, even after their products are approved. To help the health care industry realize the promise of real-world evidence, PCMA recommends policymakers take the below actions.

Unlocking an Affordable Future

- » Require manufacturers to provide comparative effectiveness research (CER) studies.
- » Authorize the FDA to assess value at the time of a drug's approval or authorization (e.g., low additional value, high additional value, innovative and high value).
- » Increase funding of efforts focused on producing objective information on drug value.
- » Accelerate efforts to build a robust real-world evidence (RWE) program.
- » Enforce and strengthen existing post-market surveillance requirements.
- » Require manufacturers to continue research into the long-term efficacy and side effects of drugs under Accelerated Approval.



KEY #3

Enhance Patient Outcomes and Improve the Patient Experience

At the core of the pharmacy benefit specialty function lies expertise used to ensure the right patient gets the right drug in a timely manner. Pharmacy benefit companies bring together pharmacists, physicians, and other clinicians who use their specialized knowledge to evaluate prescription drugs and make recommendations to help provide people access to the safest, most effective drug to meet their needs at the best price available to them. Beyond clinical expertise, patients benefit from offerings like home delivery—saving time and money while increasing access and care coordination, and medication management programs designed to provide support, promote health literacy, and improve patient outcomes.

Enable Flexibility

Pharmacy benefit companies serve people along the full spectrum of life circumstances and are best able to meet patients' needs when pharmacy benefit tools and offerings are fully available. To further enhance the ability of pharmacy benefit companies to support better health outcomes, PCMA recommends policymakers take the below actions.

- » Encourage transparency that gives patients and providers actionable information.
- » Support the use of specialty pharmacies.
- » Enable home delivery.

Cover What Works for Patients

Accelerated Approval is a faster review process for certain drugs with approval criteria based on clinical trials not designed to demonstrate the full effect of the drug and, as such, should be granted extremely rarely. To optimize patient care PCMA recommends policymakers take the below actions.

- » Start phase 4 trials early.
- » Enforce research schedules.
- » Enable value-based purchasing in all markets.
- » Empower the FDA to pull unhelpful drugs.
- » Increase clinical trial diversity.
- » Improve data collection and stratification.
- » Improve interagency collaboration.



Scan the QR code to view the entire Affordable Future platform.

ABOUT PCMA

PCMA is the national association representing America's pharmacy benefit managers (PBMs). PBMs administer prescription drug plans for more than 266 million Americans who have health insurance from a variety of sponsors including: commercial health plans, self-insured employer plans, union plans, Medicare Part D plans, the Federal Employees Health Benefits Program (FEHBP), state government employee plans, Medicaid plans, and others.