UNLOCKING AN AFFORDABLE FUTURE

Building Toward a More Accessible and Affordable Health Care Future
Prescription drugs treat ailments and illnesses, great and small, and most adults take at least one prescription drug regularly. While most people have health insurance and say their drugs are affordable, a fair percentage still have trouble affording the drugs they need. Pharmacy Benefit Managers (PBMs) are hired by health plan sponsors including public and private employers, unions, retirees, and government programs, for their unique expertise in navigating the specialized field of prescription drug benefits. As pharmacy benefit experts, PBMs generate tremendous value (estimated at $145 billion annually) in large part by securing lower prescription drug costs. Still, the challenge some consumers have with affordability highlights the need for policymaker action.

PCMA’s vision for an Affordable Future focuses on solutions in three key areas, prioritizing patients and clinicians, and proposing actionable solutions to enhance the competitive market for drugs and biologics.

**KEY #1**
Ensure System Sustainability by Promoting Competition.

Enabling a robust private prescription drug marketplace that promotes competition is the best way to drive down prescription drug costs and make more affordable alternatives available for patients.

**KEY #2**
Support and Equip Clinicians with Tools and Data to Serve Patients Optimally.

Pharmacy benefit experts support efforts to help clinicians, including pharmacists and other health care practitioners, “practice at the top of their license” to optimize use of their clinical expertise and counseling abilities. Pharmacy benefit companies also work to increase clinicians’ administrative efficiency by offering information and tools to help serve patients.

**KEY #3**
Enhance Patient Outcomes and Improve the Patient Experience.

Pharmacy benefit companies use their prescription drug expertise to support better health outcomes and provide recommendations to meet each patient’s needs.

The Affordable Future platform calls on policymakers and all members of the prescription drug supply chain to work together toward a more functional, equitable, and affordable market for prescription drugs.
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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. Direct competition among products lowers prices, and competition in the prescription drug market has proven effective, with as few as six generic competitors lowering prices by 95%.³ The prescription drug market is unique, with patent and exclusivity protections designed to incent innovation by creating monopolies, granting manufacturers virtually unlimited pricing power for extended periods.

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. Strategies like “evergreening,” “patent thickets,” and “product hopping,” prevent less expensive competing products, like generics and biosimilars, from entering the marketplace. 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 Federal Trade Commission (FTC) Act to empower the FTC to challenge these actions as anticompetitive and seek remedies.

» Eliminate anticompetitive “reverse payment settlements” also known as “pay-for-delay” agreements. Defining settlements that prevent lower-cost alternatives from entering the market as antitrust violations—current and retrospective—under the FTC Act, would allow the FTC to challenge these actions and seek remedies.

» Apply stricter scrutiny to patent applications and thwart abuse by curbing “patent thickets,” including by capping (at 20) the patents assertable in infringement claims; requiring patentees to disclose all patents within 30 days of licensure and report any patents later granted, invalidated, or rendered unenforceable; and disallowing patentees from suing for infringement of a patent that was not disclosed to the U.S. Food and Drug Administration (FDA).

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. Addressing these and other abuses will create more competition and lead to lower overall drug costs for patients. To accelerate competition, PCMA recommends policymakers take the below actions.

» End Orphan Drug Exclusivity (ODE) abuses. Limit ODE to products with no reasonable expectation of recouping development costs with U.S. sales, regardless of patient population, and revoke ODEs granted otherwise.

» Reduce Biological Product Exclusivity to seven years and prohibit additional periods of exclusivity for reference biologics due to minor changes in product formulations. Seven years (reduced from 12 years under current law) of market exclusivity would provide sufficient return for manufacturers.
EVERGREENING IN ACTION

The products pharmaceutical companies bring to market save or improve the lives of people all over the world. When drug products are easily accessible and affordable, people benefit tremendously. However, high prices sometimes make these benefits unattainable. The best way to address high prices is through competition and big drug companies know that when they face substantial competition from either generic, biosimilar, or other brand products that treat the same condition, they will be forced to lower their prices. This concern motivates them to pursue processes they call “lifecycle management,” including creative patent and exclusivity extension strategies, product manipulation, and payments to keep competitors at bay.

Patent and exclusivity protections granted to drug companies allow them the advantage of not only knowing exactly when to anticipate competition but provide a foundation for plans and ideas about how to thwart it. Some common anticompetitive practices to extend a drug product’s lifecycle include evergreening, product hopping, patent thickets, secondary patents, and pay-for-delay agreements.

Product hopping is a common tactic used by drug companies to maintain market share. This strategy involves making incremental changes to a previously approved product (like changing a pill from a capsule to a tablet) and switching patients onto the new product, which has its own patent and/or exclusivity protections, by discontinuing or discouraging use of the old product.

Another common tactic is protecting a product with as many patents as a manufacturer can attain, known as a patent thicket. Patent thickets are made up of duplicate patents linked through terminal disclaimers, secondary patents, and/or patents on each component or feature of a drug. A terminal disclaimer is intended to support a patent continuation, but it can also be used to allow an inventor to make small changes to the invention (even as small as changing the wording in a label—“one week” as opposed to “seven consecutive days,” for example) and file a patent for the same invention. If the second patent is granted, competitors seeking to come to market will face additional challenges and expenses as they work to defeat each patent. A similar strategy, called “evergreening,” involves filing for new patents on secondary features of the product or on ancillary changes to the product formulation to extend the term of patent protection.

Sometimes, manufacturers simply strike deals with potential competitors, paying them to keep their products off the market for a specified period, a strategy known as “pay-for-delay” agreements. Such agreements are typically the result of a patent infringement litigation settlement and are also known as “reverse payment” settlements.

Aside from lifecycle management, another concerning practice is shadow pricing. Shadow pricing is a practice used to keep prices as high as possible for a group of competing products. In this arrangement, manufacturers closely monitor the pricing behaviors of competitors. As the price increases on related brands of competing products, companies adjust prices in a synchronized fashion.

» 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 to reduce product hopping and preserve the intent of NCE exclusivity to incentivize the development of certain fixed-combination products that improve patient outcomes.

» Ensure nonpatent exclusivities deliver on the promise of innovation—not higher prices. Direct the U.S. Office of Science and Technology Policy to measure innovative output, clinical outcomes, accessibility, price and spending trends, and other collateral effects associated with pharmaceutical innovation policy changes, including market and data exclusivities.

» Require significant clinical benefit for New Clinical Investigation Exclusivity. Limit New Clinical Investigation Exclusivity to products that demonstrate significant clinical benefit over therapies marketed during the prior five-year period.
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» Limit the scope of the 180-day First Generic Exclusivity. Allow certain non-first generic applicants (“me-too” generics) to obtain a court decision of patent invalidity or noninfringement to seek FDA approval or licensure.

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 common patent abuses described 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, including by allowing the FDA to deny a CP based on filer intent to delay competition and clarify the process for doing so; and allowing the FTC to initiate civil action against entities involved with submitting CPs to the FDA that are without merit, imposing civil monetary penalties, and making illegal CPs submitted to the FDA primarily to delay competition.

» 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. Proliferation of biosimilars can be achieved gradually by streamlining how new biosimilars come to market, educating physicians and patients on the efficacy of biosimilars, and protecting generic and biosimilar manufacturers from expensive lawsuits designed specifically to deter them. 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. The interchangeability designation is codified in the Biologics Price Competition and Innovation Act (BPCIA). To attain interchangeability, a biosimilar must meet additional requirements to demonstrate it will produce the same results as the reference product in all patients, and that switching between the biosimilar and the reference product will not produce any additional risks for patients. An interchangeable biosimilar product may be substituted without the intervention of the prescriber—the same way generic drugs are substituted for brand drugs—subject to state pharmacy laws.4 Removing the interchangeability designation requires a change to the BPCIA. Alternatively, policymakers could focus on streamlining the process to attain interchangeability.

» Encourage biosimilars through therapeutic substitution. Fully realize the potential savings and affordability of biosimilars by increasing biosimilar switching or therapeutic substitution, including by revisiting the FDA’s nonproprietary label name guidance for interchangeable biosimilars.

» Acknowledge that biosimilars for a single reference product are biosimilar to one another.


» Encourage the use of generics and other more cost-effective drugs in Medicare Part D, including by implementing differential cost sharing for preferred vs. non-preferred brand drugs for low-income subsidy (LIS) enrollees or eliminating cost sharing on generic drugs for LIS enrollees.

» Flip the burden of proof to the patentee. Flip the burden of proving patent validity from the generic manufacturer or biosimilar product sponsor to the brand/biological product sponsor, in part by presuming later-expiring patents expire unless the patentee proves otherwise.

» Enable biosimilars to launch without risk of treble damages.

» Provide the FDA with sufficient resources to speed competition—particularly for lifesaving drugs and drugs with limited or no therapeutic competition.

Click here to learn more about PCMA’s position on biosimilars.
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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 (IRA) 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. As policymakers begin to implement the IRA drug negotiation provisions, efforts should be taken to ensure other brand, generic, and biosimilar manufacturers remain incentivized to develop lower-cost products that reduce costs for all Americans. The Centers for Medicare & Medicaid Services (CMS) should broadly define “competition” at the therapeutic class level, and only calculate Maximum Fair Prices for drugs that truly leave prescribers and patients no alternative.

» Provide an offramp for drugs on the negotiated drug list. In addition to limiting Maximum Fair Price assessments to drugs without any real competition, CMS must identify a path to remove drugs from the selected drug list to ensure that lower-cost options can come to market and allow market forces to lower costs. New brand, generic, and biosimilar drugs can quickly drive down net prices in a therapeutic class. Additionally, decisions about selected drugs need to be made in accordance with the Medicare Part C and D program bid cycle to allow plans time to adjust and ensure compliance with the law.

Promote Pharmacy Networks

Maintaining a competitive market for prescription drugs requires participation from all members of the supply chain. Where a patient acquires a drug can impact its cost 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. Health plan sponsors may select—or in the case of Medicare Part D, prefer—specific networks of pharmacies to provide drugs to their enrollees at competitive prices. Nationally, 76% of employers report using a tailored pharmacy network and employees typically save about 38% out-of-pocket using in-network vs. out-of-network pharmacies. 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. Pharmacies large and small are important partners in delivering care to patients. Most pharmacy networks are designed to provide patients with a variety of options allowing them to get the drugs they need where they need them. Most independent pharmacies use large PSAOs to negotiate favorable contracts with pharmacy benefit companies. Data shows the independent pharmacy market is strong, and it is the only sector of retail pharmacy that has experienced growth over the last 10 years. By leveraging the power of large PSAOs to negotiate with pharmacy benefit companies on their behalf, independent pharmacies can secure favorable contract terms and, on average, higher reimbursements than chain drugstores.

» Protect pharmacies’ ability to operate optimally within their area of expertise. Health plans with a variety of sites of care in their networks are able to promote access, affordability, and value. The right mix of brick-and-mortar, mail, and specialty pharmacies improves adherence to therapy and patient safety. Not all pharmacies can or should do all things because they offer differing levels of expertise and services to ensure patients are getting what they need to secure the best health outcomes.

» Protect employers’ and health plan sponsors’ ability to make choices that allow them to effectively serve plan participants. Health plan sponsors need the ability to design plans without government interference to make affordable choices for their participants. As health plan sponsors strive to create accessible, affordable benefits that meet the needs of the populations they cover, policymakers should avoid mandates that could increase costs and decrease quality.

Click here to learn more about independent pharmacies.
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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 companies 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. Patient eligibility and benefit verification and claim submissions have been streamlined as health care providers and pharmacies have fully integrated pharmacy benefit companies’ “real-time” tools. Pharmacy benefit companies conduct 94% of eligibility and benefit verifications electronically, in real-time. Eligibility is verified during the real-time adjudication process for pharmacy claims, and pharmacy benefit companies lead the way in adjudicating claims at the point of service with nearly 100% of pharmacy benefit companies (99%) and health plans (96%) processing claims fully electronically. Full adoption of RTBT, ePA, and eRx offers similar promise. Pharmacy benefit companies, 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. Pharmacy benefit companies strongly support the use of RTBT to increase transparency by giving prescribers and patients the exact information they need to determine the most appropriate and cost-effective prescription drugs to prescribe and use for each patient. RTBT recommendations lead to lower patient out-of-pocket costs, with the largest savings—typically around 40%—occurring for high-cost medications, especially when therapeutically appropriate lower-cost alternatives exist. A recent study revealed RTBT recommendations were made for only a small percentage of prescriptions, presenting a key opportunity for improving access to affordable prescription drugs. RTBT tools are the most promising vehicle to increase medication adherence and reduce medication abandonment.

» Require the use of electronic prescribing and prior authorization. Seventy-five percent (75%) of pharmacy prior authorizations are fully electronic and use the National Council for Prescription Drug Programs (NCPDPs) SCRIPT electronic standard for prior authorizations. Prior authorization is a critical tool for helping patients access safer and lower cost drugs and reflects the most recent clinical standards. Public policies should focus on establishing and adopting technical standards and resources for everyone to facilitate adoption and uptake of electronic prior authorization. Requiring the use of electronic prior authorization will streamline the process for patients and health care providers. Pharmacy benefit companies stand ready to support our partners in health care to implement ePA and urge other stakeholders to join us.
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» Add ePA to Medicare quality measures. In Medicare Part D, eRx adoption has not fully actualized for all providers, limiting ePA capabilities. Rulemaking has added the use of eRx to Medicare quality measures for physicians. CMS should propose to add ePA to quality measures as well.

» Pave the way for interoperability. For the commercial market, the U.S. Department of Health and Human Services (HHS) Office of the National Coordinator for Health Information Technology (ONC) should propose and finalize NCPDP SCRIPT 20170701 for prescription drugs, American National Standards Institute (ANSI) X12 for medical, and work through issues related to electronic health record (EHR) and eRx interoperability to prepare the way for eRx and ePA 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.” Pharmacists are skilled accessible health care providers. Policymakers and regulators should enact legislation enabling pharmacists, where appropriate, to perform diagnostic testing, prescribe indicated medication, and administer vaccines to expand access to care.

» Provide biosimilars education for providers and resources they can share with patients. Reliable sources, including government entities, academia, and clinician groups, can increase health literacy and promote uptake of biosimilars, which will generate savings for patients.

» Provide incentives for using RTBT. To support the use of economical treatment options, the Center for Medicare and Medicaid Innovation (CMMI) should conduct a demonstration that incentivizes providers who use RTBT and choose therapeutically appropriate, lower cost alternatives. CMMI could later expand the demo in an alternative payment model to include prescribers eligible to share in any potential plan-level savings if they select lower-cost alternatives at the list price level, such as demonstrating a shift toward generic drugs over brands.

- To evaluate patient behavior in the demo, CMMI should expand its limited “rewards and incentives” (R&I) reach for beneficiaries (R&I is currently only available in one Medicare Advantage model). CMMI should then evaluate improvements in medication adherence resulting from the use of lower-cost drugs, as well as improvements in total spend resulting from guiding and incentivizing prescriber choices.

» Sponsor a Senior Savings Model focused on areas of known health inequities. For purposes of reducing risk selection and with the intention of promoting health equity, the next Senior Savings Model demo should take the form of targeted therapeutic class-specific plan offerings focused on at least one disease state in which health inequities are particularly significant, such as asthma, chronic obstructive pulmonary disease (COPD), or heart disease. The Senior Savings Model demo should operate in a manner nearly identical to the Medicare Part D Senior Savings Model implemented for insulins in 2021 and 2022—recognizing the use of manufacturer-side agreements related to the Coverage Gap Discount Program may be less feasible in crowded classes, especially as the Coverage Gap Discount Program transitions into the new, but lower-discounted Manufacturer Discount Program (MDP) in 2025 (10% and 20% dependent on the benefit phase). MDP discounts could serve a similar purpose, to reduce cost-sharing for model drugs, as could existing manufacturer rebates paid to Part D plan sponsors. Additionally, CMS currently limits sponsors to offering no more than three Part D plans in a region. To facilitate robust participation, CMMI should allow sponsors to offer a fourth Part D plan in a region if at least one of their plans was a Part D Senior Savings plan.
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Accelerate Value-Based Care
Pharmacy benefit companies and drug 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. Greater adoption of value-based purchasing (VBP) and accelerating patient-focused pharmacy care can improve health outcomes. Providing Medicare Part D Prescription Drug Plans with access to Medicare Parts A and B claims data, expanding safe harbors for VBP contracting, and allowing Part D and state Medicaid plans greater flexibility to adopt private-sector formulary management techniques will provide a boost to these payment models. 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. Part D plans can utilize medical data in combination with prescription data to improve health outcomes. Legislative changes allowing use of these data for this purpose also would advance indication-based formularies and decrease prescriber burden.

» Permit states the same tools available to employers and Medicare Part D plans to limit coverage of drugs in their Medicaid programs for which there is inadequate evidence of clinical effectiveness or ample competition of therapeutic alternatives. New legislation should provide states flexibility to adopt private-sector formulary management techniques to drive value and lower costs in their Medicaid programs, including:

- Allowing states to exclude covered outpatient drugs with insufficient clinical evidence,
- Setting their own formularies for Medicaid drug coverage,
- Creating a state option to include drugs provided as part of a bundled service in the Medicaid Drug Rebate Program, and
- Allowing states to exclude or otherwise restrict coverage of a covered outpatient drug for 180 days after a new drug or new formulation of a drug has been approved by the FDA and entered the market.

» 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. While CMS took a necessary first step with respect to the treatment of VBP arrangements under Medicaid Best Price, there are additional improvements that would foster greater innovation and expansion in the use of VBP for prescription drugs. Regulatory amendments creating a safe harbor for VBP of prescription drugs would enable innovation in design and encourage participation, specifically by:

- Creating additional safe harbors for drug related VBP at 42 C.F.R. § 1001.952,
- Expanding the “value-based purpose” definition to include “reducing total cost of care of a target patient population as a value-based purpose at 42 C.F.R. § 1001.952 and 42 C.F.R. § 411.351, and
- Expanding the “value-based entity participant” definition to include pharmacy benefit companies and, to the extent that such parties are participating in VBPs with pharmacy benefit companies and health plans, drug manufacturers, manufacturers of durable medical equipment, wholesalers, and distributors at 42 C.F.R. § 1001.952 and 42 C.F.R. § 411.351.

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. Clinicians need accurate, scientifically reliable information on prescription drugs throughout their lifecycles, from pre-approval for timely coverage decisions to post-market surveillance, and research into side effects and long-term efficacy for expedited approvals. These efforts should include rigorous evidence of performance under real-world conditions and capture demographics, including race and ethnicity, which can be used to determine whether a drug functions better or worse than anticipated for specific populations. To help the health care industry realize the promise of real-world evidence, PCMA recommends policymakers take the below actions.
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» Require manufacturers to provide comparative effectiveness research (CER) studies as part of their application for new drug approval or new indications.

» 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). If a drug is deemed by the FDA to be conditional or low additional value, such information should be used by payers as a criterion for negotiating down net prices and/or negotiating outcomes-based contracting.

» Increase funding of efforts focused on producing objective information and research on the evidence of prescription drug value and comparative effectiveness.

» Accelerate efforts to build a robust real-world evidence (RWE) program and rigorous, science-based criteria for how RWE can be used to inform payment and coverage decisions (e.g., for use in VBP strategies).

» Enforce and strengthen existing post-market surveillance requirements, particularly for accelerated approvals, and require the FDA to share findings publicly to inform coverage decisions and value-based payment of prescription drugs.

» Require manufacturers to continue research into the long-term efficacy and side effects of drugs under accelerated approval (after they come to market) with specific timelines and reporting requirements.

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. Following the science, pharmacy benefit companies use clinical data to support decision-making and help patients stay on course with their prescription therapy through evidence-based medication adherence and health coaching programs. Pharmacy benefit companies also help pharmacies enhance patient safety, prevent potentially harmful drug interactions, and reduce unnecessary medication. 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.
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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. Greater flexibility allows for person-centered care, care coordination, integrated pharmacy, and patient choice, all of which can improve health and help address existing health care inequities. 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. Pharmacy benefit companies seek to provide patients and providers with actionable transparency in the form of data and tools that allow for better decision-making and improve health literacy. RTBT identifies therapeutic alternatives that meet a patient’s medical needs and provides options that are often more affordable based on the patient’s prescription drug coverage. Today, well over half a million healthcare providers are using RTBT to determine what patients should expect to pay at the pharmacy counter or when they receive their home delivery drugs. According to recent data, when RTBT identifies a lower cost, yet still therapeutically appropriate treatment option, patients typically save about $37 for their prescription drug therapy. Onerous transparency requirements that create extensive administrative burdens, generate unnecessary operational costs, and expose proprietary information, which enables drug manufacturers to keep prices higher, do nothing to help patients and providers. Future transparency policies should be focused on enhancing and refining information available to support patient health and affordability needs.

» Support the use of specialty pharmacies. Many pharmacy benefit companies own or partner with specialty pharmacies to dispense drugs with complex handling requirements. Permitting use of specialty pharmacies in all appropriate circumstances typically saves between 11% and 45% on specialty drugs.


2. Seamless for Patients: Specialty pharmacies support patients by proactively confirming appointments, providing pre-testing requirements and safety reminders, and delivering drugs directly to the most convenient location for the patient, such as their home, place of work, or site of care.

3. More Affordable: Specialty pharmacies buy “in bulk,” which enables them to avoid additional price markups and pass on savings to patients, employers and other plans sponsors, and government programs.

» Enable home delivery. Home delivery, sometimes referred to as mail order pharmacy, is a service pharmacy benefit companies provide that allows patients to have their prescription drugs shipped to their preferred location and pay lower out-of-pocket costs. Additionally, home delivery removes certain barriers connected to social determinants of health, such as lack of transportation, which enables access and aligns with pharmacy benefit companies’ commitment to addressing health inequities.

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. Most FDA-approved drugs available to patients have demonstrated durable clinical benefits that outweigh the risks associated with their use. When new drugs come to market with limited clinical
trials, a lot of questions remain related to the long-term risks and benefits. Accelerated Approval, along with other hastened review processes like Fast Track, Breakthrough Therapy, and Priority Review, can be helpful approaches to speeding patient access to drugs in rare situations of high unmet need. While pharmacy benefit companies support expeditious access to innovation, patient safety is paramount. Medicare and Medicaid spent more than $18 billion from 2018 to 2021 for 18 drugs that did not complete required confirmatory trials on which their FDA approval hinged, leaving many unanswered questions about clinical benefits for patients, health care providers, and insurers like Medicare and Medicaid. To optimize patient care PCMA recommends policymakers take the below actions.

» **Start phase 4 trials early.** Require manufacturers to initiate phase 4 confirmatory trials prior to granting approval under the Accelerated Approval review process.

» **Enforce research schedules.** Ensure that research schedules are closely adhered to with predetermined monitoring checkpoints and swift penalties for delays.

» **Enable VBP in all markets.** Enable payers to explore outcomes-based payment arrangements in both the public and private markets.

» **Empower the FDA to pull unhelpful drugs.** Ensure the FDA is fully empowered to exercise its authority to protect patients from ineffective drugs.

» **Increase clinical trial diversity.** Diversify clinical trials including through expanding eligibility criteria and reducing the burden on trial participants, as well as community-based collaboration.

» **Improve data collection and stratification.** Standardize and incentivize racial and ethnic data collection to allow stratification. Stratifying data collected from clinical trials will help payers optimize outcomes-based agreements.

» **Improve interagency collaboration.** Align CMS processes like coverage determinations with the FDA’s approval processes.

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**CLICK THE IMAGES TO LEARN HOW PBM CLINICAL PROGRAMS SUPPORT PATIENTS WITH ASTHMA AND DIABETES**

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Conclusion

Even with pharmacy benefit companies generating $145 billion in value annually,17 just over a quarter of adults say it is difficult to afford their prescription drugs—with those age 30 to 49 facing the greatest affordability challenges18—highlighting the need for policymaker action. Advocating for a better-functioning, equitable, and more affordable health care future for patients is fundamental to the role and mission of the pharmacy benefit industry. On behalf of the more than 275 million people pharmacy benefit companies serve, PCMA has proposed three keys to unlocking an affordable future:

**KEY #1**
Ensure System Sustainability by Promoting Competition.

**KEY #2**
Support and Equip Clinicians with Tools and Data to Serve Patients Optimally.

**KEY #3**
Enhance Patient Outcomes and Improve the Patient Experience.

This set of comprehensive policies, if adopted, would result in a future that is more affordable and desirable for patients, clinicians, and those paying for health care.

Competition reduces costs and spurs innovation. To ensure patients can reap the benefits of a competitive market, policymakers should focus on ending patent abuse, encouraging regulators to reserve market exclusivity for true innovation, and stop other anticompetitive behaviors like misuses of the FDA citizen petition process and shadow pricing. When generic and biosimilar drugs are introduced to the market, patients pay less, and pharmacy benefit companies have the leverage needed to further reduce drug prices. Generic drugs have significantly reduced the cost of small molecule drugs and biosimilars can do the same for large molecule drugs. To speed uptake of biosimilars, policymakers should focus on reducing the hurdles biosimilar manufacturers face to bring them to market, encouraging substitution, and proliferating reliable educational resources. While generic and biosimilar drugs are vital to reducing drug costs, bringing new brand drugs to market in classes with established drugs provides patients and providers with more chances to find the best treatment to meet a patient’s unique needs. For this reason, it is important to hasten access to “me too” drugs as well.

Supporting and partnering with clinicians is the best way to ensure patients’ needs are met. The tools and data pharmacy benefit companies provide give clinicians information to save patients money. Beyond saving money, the opportunity to increase value and improve patient care using real-world evidence can lead to improved outcomes for not just individual patients, but entire patient populations.
While market competition and clinician support ultimately benefit patients, there are additional actions policymakers can take to preserve and enhance patients’ outcomes and experiences. Patients benefit when the information shared about their drugs is actionable. When patients and providers can see how a particular plan covers drugs and what the patients’ cost sharing would be, as well as what other treatment options exist, they are able to make informed decisions. Pharmacy benefit companies need the flexibility to continue to enhance and improve the information available to patients and their care teams, while protecting information that could, if shared with the wrong parties, result in higher drug prices. Patients also save money and receive additional clinical support by using specialty pharmacies to access their drugs in a safe, secure, and seamless manner. Like specialty pharmacy, home delivery pharmacy can save patients money, and offers the additional benefit of helping to address health inequities by removing challenges presented by certain social determinants of health.

Finally, protecting patients must always be paramount. Accelerated Approval offers the opportunity to bring new drugs that treat serious conditions to market where no other similar drug exists; however, because the associated clinical trials are not designed to demonstrate the full effect of the drug, patients, providers, and payers are often left with questions when these drugs are approved. To quell concerns, drug manufacturers need to be held accountable for completing phase 4 trials on time. Barriers to value-based payments must be removed, harmful or unhelpful drugs must be taken off the market quickly, clinical trials should be appropriately diversified, and data collection and stratification must be enhanced.

PCMA looks forward to working with policymakers at the state and federal level to promote these policies and build toward a more accessible and affordable health care future.

ENDNOTES

   public-opinion-on-prescription-drugs-and-their-prices/
15 FDA. 2022. https://www.fda.gov/media/127712/download
16 PhRMA. 2022. https://phrma.org/-/media/Project/PhRMA/PhRMA-Refresh/Campaign-Pages/Clinical-Trial-Diversity/PDF/CTD-Press-Release-FINAL.pdf

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.