

# ENSURING PATIENT ACCESS

to Safe, Effective and Affordable  
Prescription Medicines

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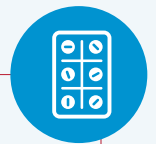
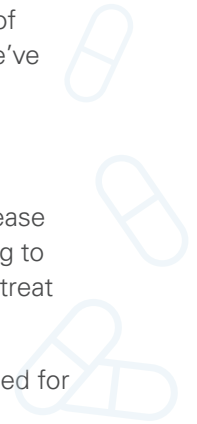


# EXECUTIVE SUMMARY

Prescription drugs play a critical role in helping to prevent, manage and cure various conditions and diseases. Today, ground-breaking medicines are profoundly improving the conditions of millions of patients who are able to enjoy longer, healthier lives. Yet for all the progress we've achieved through pharmaceutical breakthroughs—and the great promise that new drugs hold—the cost of prescription drugs is straining the budgets of families, businesses and taxpayers alike.

It's estimated that almost \$450 billion was spent on prescription drugs in 2016, a 5.8% increase from the previous year.<sup>1</sup> Among the biggest drivers of prescription medicine costs, according to the Centers for Medicare & Medicaid Services (CMS), are new and specialty drugs used to treat serious conditions.<sup>2</sup>

In 2015, only 1 to 2 percent of the American public used specialty drugs, yet they accounted for approximately 38 percent of total of total drug expenditures.<sup>3</sup>



**Almost \$450 BILLION** was spent on prescription drugs in 2016.

**Source:** American Journal of Health-System Pharmacy. "National trends in prescription drug expenditures and projections for 2017". Aug. 2017. Web. <http://www.ajhp.org/content/early/2017/05/17/ajhp170164?sso-checked=true>

The Blue Cross Blue Shield Association (BCBSA) and its 36 independent, locally based Blue Cross and Blue Shield (BCBS) companies are committed to ensuring that people have timely access to safe, effective and affordable cutting-edge prescription medicines when they need them, whether the drugs cost pennies or thousands of dollars. In fact, health insurance benefits cover more than 98 percent of prescription drug costs for people who need more than \$100,000 in medicines per year.<sup>4</sup> The average out of pocket cost for a person who purchases prescription drugs is \$12 each month.<sup>5</sup>

<sup>1</sup>American Journal of Health-System Pharmacy. "National trends in prescription drug expenditures and projections for 2017". Aug. 2017. Web. <http://www.ajhp.org/content/early/2017/05/17/ajhp170164?sso-checked=true>

<sup>2</sup>Centers for Medicare & Medicaid Services. "National Health Expenditure Data." May 2014. Web. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/index.html?redirect=/nationalhealthexpenddata/>

<sup>3</sup>The Pew Charitable Trust. "Specialty Drugs and Health Care Costs" Nov. 2015. Web. <http://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2015/11/specialty-drugs-and-health-care-costs>

<sup>4</sup>Express Scripts. "Super Spending: U.S. Trends in High-Cost Medication Use." 13 May 2015. <http://lab.express-scripts.com/lab/insights/drug-options/super-spending-us-trends-in-high-cost-medication-use>

<sup>5</sup>The Henry J. Kaiser Family Foundation. "New Analysis Finds Out-of-Pocket Prescription Drug Spending Decreasing on Average, But More People Spending in Excess of \$1,000 a Year." Oct 2016. Web. <http://www.kff.org/health-costs/press-release/new-analysis-finds-out-of-pocket-prescription-drug-spending-decreasing-on-average-but-more-people-spending-in-excess-of-1000-a-year/>

After insurance coverage, the average out-of-pocket cost for a person who purchases prescription drugs is **\$12 A MONTH.**



Insurance benefits cover more than **98 percent** of prescription drug costs for people who need more than **\$100,000 IN MEDICINES PER YEAR.**

**Source:** Express Scripts. "Super Spending: U.S. Trends in High-Cost Medication Use." 13 May 2015.

**Source:** The Henry J. Kaiser Family Foundation. "New Analysis Finds Out-of-Pocket Prescription Drug Spending Decreasing on Average, But More People Spending in Excess of \$1,000 a Year." Oct 2016. Web.

Collectively, the Blue Cross and Blue Shield System covers one in three Americans, and provides members with access to the prescription medicines they need while proposing constructive policy solutions to the underlying marketplace challenges that have made drug prices a top national concern.

For example, BCBS companies help customers understand how to maximize their health benefits to get the right prescription medicine for them at the most affordable price. Patients are encouraged to speak with their physicians about taking generic prescription medicines, because they are just as effective and contain the same active ingredient, strength and dosage as brand-name drugs, yet are more affordable. On average, the cost of a generic drug is 80 to 85 percent lower than the brand-name product, according to the Food and Drug Administration (FDA).<sup>6</sup> Obtaining prescriptions by mail is another cost-saving option.

## GENERIC DRUGS COST



**80 TO 85% LESS THAN**

**brand name drugs**

**Source:** Food and Drug Administration. "Facts About Generic Drugs." June 2015.

<sup>6</sup> Food and Drug Administration. "Facts about Generic Drugs." June 2015. Web. <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm>

Importantly, BCBS companies help people adhere to their medication plans as prescribed by their physicians to help them maximize the health benefit from their medicine and avoid adverse side effects. Unfortunately, nearly three out of four people report that they do not always take their prescription medicine as directed.<sup>7</sup> Following a doctor's instructions could reduce more than one-third of medicine-related hospitalizations and save as much as \$337 billion in avoidable costs to the healthcare system annually.<sup>8</sup>

Yet even when patients follow every one of these strategies, none provides an antidote to the impact of rising pharmaceutical prices and to legitimate concerns about a pattern of unsustainable growth in drug costs.

Based on BCBS companies' generations of experience in healthcare, and their commitment to ensuring that their customers' health needs are met, BCBS has identified four key strategies that are critical to addressing escalating prescription drug costs and ensuring that people have timely access to safe, effective, cutting-edge prescription medicines and their generic equivalents at the most affordable price, and in the right setting.

- 1 Reduce barriers that limit competition and consumer choice, particularly those that limit patient access to new, lower-cost drugs;**
- 2 Promote greater transparency and sharing of information regarding the pricing of prescription medicines;**
- 3 Provide medical and healthcare professionals with the tools they need to support patient education and adherence; and**
- 4 Promote additional regulatory changes that help patients get the right medicines for them, at the most affordable prices.**

It is critical that everyone in the healthcare system works together to ensure the affordability of prescription medicines for Americans. Achieving this important goal will require the public and private sectors to collaborate to develop solutions that benefit patients and the entire health system.

This paper details a four-part, patient-focused strategy that will lead to high-quality, more affordable healthcare, specifically by improving access to prescription medicines.

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<sup>7</sup>National Community Pharmacists Association. "Take As Directed: A Prescription Not Followed." Dec. 2006. Web. <http://www.ncpanet.org/pdf/adherence/patientadherence-pr1206.pdf>

<sup>8</sup>Express Scripts. "The High Price of Low Adherence to Medication." Jul. 2015. Web. <http://lab.express-scripts.com/lab/insights/adherence/the-high-price-of-low-adherence-to-medication>

# ENSURING PATIENT ACCESS TO SAFE, EFFECTIVE AND AFFORDABLE PRESCRIPTION MEDICINES

The rising cost of prescription drugs is a growing concern for everyone—the public, medical professionals, healthcare companies, employers of all sizes and taxpayers who bear the cost of prescription drugs provided by government programs such as Medicare and Medicaid.

It's estimated that almost \$450 billion was spent on prescription drugs in 2016, a 5.8% increase from the previous year.<sup>1</sup> Among the biggest drivers of prescription medicine costs, according to the Centers for Medicare & Medicaid Services (CMS), are new and specialty drugs used to treat serious conditions.<sup>2</sup> In 2015, only 1 to 2 percent of the American public used specialty drugs, yet they accounted for approximately 38 percent of total of total drug expenditures.<sup>3</sup> BCBS companies are committed not only to ensuring that their members can access the medicines they need, but also to addressing some of the underlying market challenges that are driving costs up for everyone.

BCBSA proposes a four-part, patient-focused strategy to address barriers that are hindering access to safe, effective and affordable prescription medicines.

## **1** Reduce barriers that limit competition and consumer choice, particularly those that limit patient access to new, lower-cost drugs

Currently, significant barriers hinder patients' timely access to affordable, safe, effective and cutting-edge prescription medicines and their generic equivalents. Promoting competition and consumer choice will make prescription medicines more affordable, and BCBSA recommends the following steps to allow market forces to work more effectively and efficiently:

### **Speed up the approval process for generic prescription drugs**

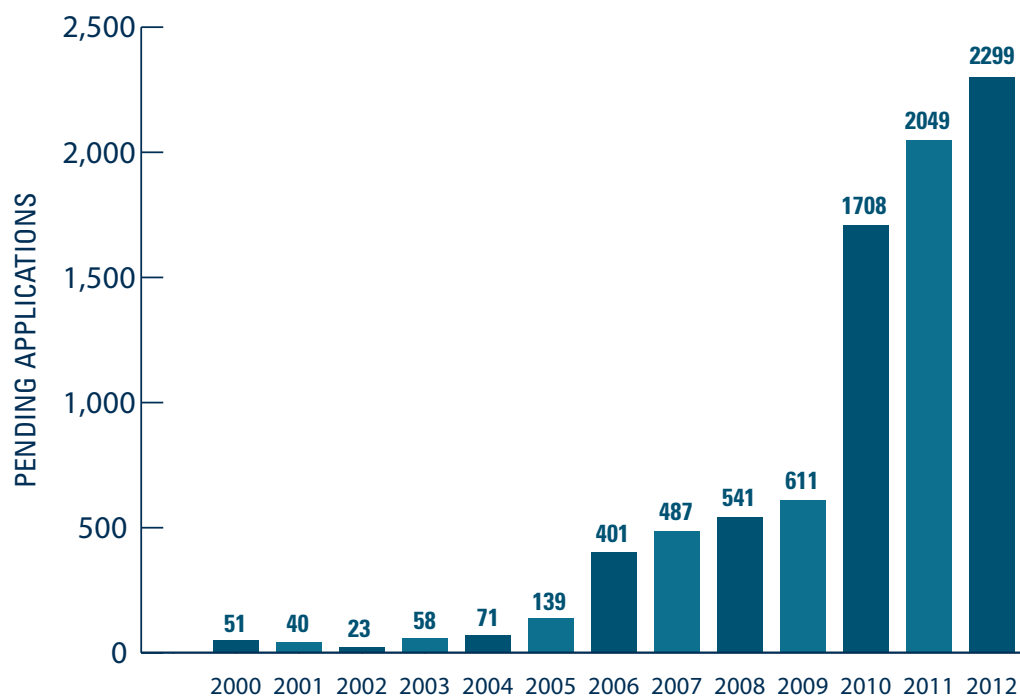
There is currently a backlog of generic prescription drug approval applications at the FDA. While the agency estimated in 2012 that about 750 generic prescription drug applications would be filed each year, in fact, more than 1,000 were filed each year since 2012. The FDA now has a generic drug application backlog of about 4,000 applications.<sup>9</sup>

The review process should be improved to ensure speedier approval of generics and in turn, promote competition and consumer choice in the marketplace. We are pleased that steps have been taken to speed generic approvals in many instances. The review process should also be sped up in cases where branded products have fewer than three competitors in a class.

BCBSA recommends that an independent analysis be conducted that evaluates the review and approval processes for competing prescription medicines. This will help determine whether the creation of new processes will bring some lower-cost prescription medicines to the market more quickly.

<sup>9</sup> Food and Drug Administration. "The Generic Drug Review Dashboard." Apr. 2017. Web. <https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM556596.pdf>

## FDA GENERIC DRUG APPLICATIONS PENDING MORE THAN 180 DAYS



Source: Janet Woodcock, M.D. "Implementation of the Generic Drug User Fee Amendments of 2012 (GDUFA)." Food and Drug Administration. Jan. 2016.

### Eliminate additional exclusivity periods for new indications or dormant therapies to improve access to affordable treatments

Prescription medicines and biologicals should not be exempt from the inter parties review (IPR) process, which provides a pathway for resolving patent-related issues when a manufacturer develops a biosimilar or biologic equivalent for brand-name drugs. When drug makers bypass this process, it can facilitate extended patent protections—in some cases up to 15 years—hindering the entry of lower-cost brand-name or generic equivalents to the marketplace.

Today, drug companies can practice "evergreening," a process through which manufacturers seek patents for "new inventions," which are, in fact, only slight modifications of existing prescription drugs. This has the effect of extending a drug's patent exclusivity and blocking competition. In some cases, it can add decades to the exclusivity of the drug patent.<sup>10</sup> It also leads to increased spending on prescription medicines without measurable improvements in quality and better health outcomes for patients. One study estimated that eliminating "evergreening" and replacing a set of eight follow-on drugs with generics would have reduced drug costs by 8.4 percent.<sup>11</sup>

<sup>10</sup> Health Affairs. "Secondary Patenting Of Branded Pharmaceuticals: A Case Study Of How Patents On Two HIV Drugs Could Be Extended For Decades." Tahir Amin and Aaron S. Kesselheim, October 2012. Web. <http://content.healthaffairs.org/content/31/10/2286.full>

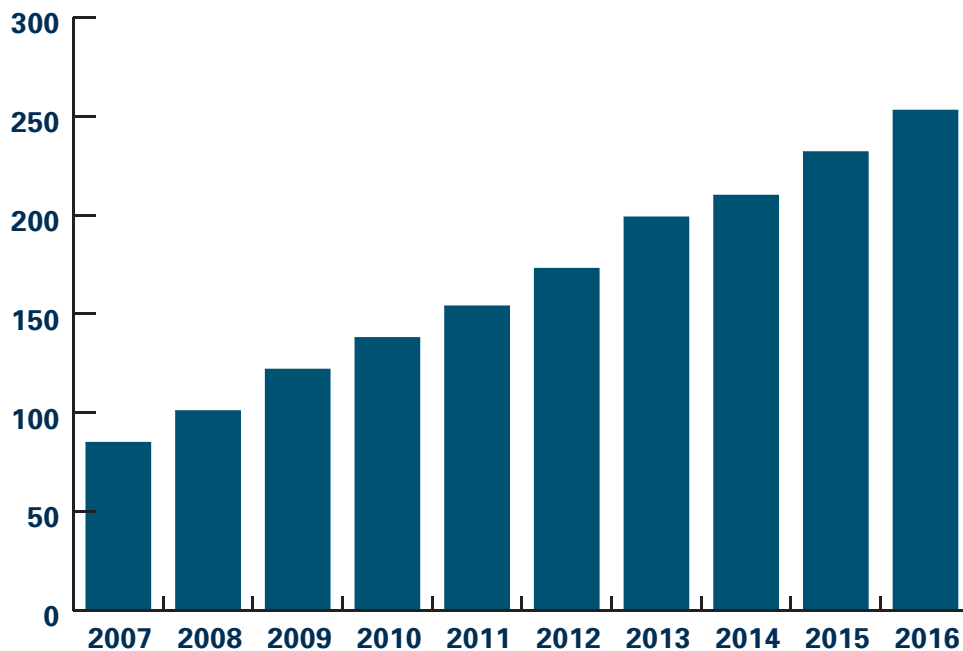
<sup>11</sup> PLOS Medicine. "Patented Drug Extension Strategies on Healthcare Spending: A Cost-Evaluation Analysis." Nathalie Vernaz, et al., June 2013. Web. <http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001460>

## Disallow “pay-for-delay” agreements that limit access to generic drugs

Brand-name prescription drug manufacturers are currently permitted to pay generic drug manufacturers to delay bringing lower-cost, generic drugs to the market. This directly limits patient access to affordable prescription medicines and increases costs. The Federal Trade Commission (FTC) estimates these anticompetitive arrangements cost taxpayers and patients \$3.5 billion in higher prescription drug costs every year.<sup>12</sup>

This practice should be prohibited to ensure that generic drugs can enter the market quickly, encourage competition and promote patient choice.

## SAVINGS FROM GENERICS TOTALED \$1.67 TRILLION, 2007-2016



Source: Association for Accessible Medicines. "Generic Drug Access & Savings in the U.S." 2017.

<sup>12</sup> Federal Trade Commission. "Pay-For-Delay: How Drug Company Pay-Offs Cost Consumers Billions: A Federal Trade Commission Staff Study," Jan. 2010. Web. <https://www.ftc.gov/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff>

## 2 Promote greater transparency and sharing of information regarding the pricing of prescription medicines

Understanding how drug prices are currently established is a necessary step in discussing any policy options that are meant to address the unsustainable rate of rising prices. There should be transparency regarding the pricing of prescription medicines. Specifically, information about a drug's price and its effectiveness should be widely available to the public. It is also important that health insurers know which new drugs are coming into the pipeline. This allows health insurers to work with doctors and pharmacists in planning and in working to ensure there are ways to get prescription medicines to patients at the most affordable cost. Specific recommendations include:

### Collect additional information during the FDA's prescription drug application process to better understand the price and therapeutic value of each medicine

Collecting additional information during the FDA's prescription drug application process enables payers and pharmacy benefit managers (PBMs) to design coverage options, anticipate changes to drug lists or formularies, and establish appropriate health insurance premium rates while working with manufacturers to develop value-based purchasing arrangements. It also ensures that healthcare professionals and medical societies have enough time to develop new guidelines for emerging treatment options.

The initial prescription drug application should include a valuation model for the prescription drug, an accompanying assessment of the therapeutic value of the product to justify the price, and a draft label. Manufacturers should be required to provide information during the application process that identifies how public funds, such as taxpayer-funded research by the National Institutes of Health (NIH), may have been allocated toward the research and development process of a specific prescription drug.



**86% OF AMERICANS** favor requiring prescription drug companies to release information to the public on how they set their drug prices

**Source:** The Henry J. Kaiser Family Foundation. "New Analysis Finds Out-of-Pocket Prescription Drug Spending Decreasing on Average, But More People Spending in Excess of \$1,000 a Year." Oct 2016.



## **Provide more comprehensive information on prescription drug pricing and effectiveness that allows for better decision making**

Providing patients and medical professionals with information on a prescription drug's safety, effectiveness and therapeutic value in comparison to other treatment options is critical to ensuring that physicians follow safe and effective prescribing practices. In order to achieve this, BCBSA believes policymakers should:

- Redirect a portion of funding now supporting the Patient Centered Outcomes Research Institute (PCORI) to the Institute for Clinical and Economic Review (ICER) or other private sector entities that engage in prescription drug value assessments;
- Require manufacturers, during the FDA approval process, to provide information on how NIH helped fund research and development of a drug; and
- Require drug manufacturers to provide more comprehensive information on drug pricing and effectiveness relative to other treatments, to ensure safe and effective prescribing practices.

## **Commission Government Accountability Office (GAO) studies on prescription drug pricing practices to increase publicly available information**

BCBSA recommends that policymakers ask the GAO to conduct studies that address this critical issue. The studies should include an assessment of:

- The amount of taxpayer-funded drug research that has been used in developing certain prescription medications, specifically through research funded by NIH;
- Cost to taxpayers of certain new prescription medicines that are provided through various government programs such as Medicare and Medicaid;
- Trends in the generic market that may be reducing competition and choice for patients; and
- An assessment of the actual research and development costs for a sample of prescription drugs, including how prescription drug cost estimates are calculated.

## **3 Provide medical and healthcare professionals with the tools they need to support patient education and adherence**

BCBS companies support policies that give medical professionals the tools they need to educate and support patients in taking their prescription medications as directed. Unfortunately, nearly three out of four people report that they do not always take their prescription medicine as directed.<sup>13</sup> Addressing this problem would improve patients' health and safety, prevent adverse side effects and unnecessary hospitalizations, and, as a result, help to rein in costs.

## **Encourage prescribers to consider lower-cost but equally-effective alternatives**

Policymakers should find ways to encourage physicians to prescribe equally effective, but less expensive medications whenever they are available. The government can be an effective partner in ensuring that proper incentives are in place to discourage systems that promote higher cost medications in certain settings.

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<sup>13</sup> National Community Pharmacists Association. "Take As Directed: A Prescription Not Followed." Dec. 2006. Web. <http://www.ncpanet.org/pdf/adherence/patientadherence-pr1206.pdf>

## **Provide seniors with greater access to generic drugs**

Medicare provides support to beneficiaries eligible for both Medicare and Medicaid (dual-eligibles) and low-income subsidy (LIS) Medicare enrollees to ensure access to needed prescription medications. However, the program's current co-pay structure for these beneficiaries does not do enough to encourage substitution of generics for expensive, brand-name prescription medicines.

BCBSA recommends that Medicare Part D co-pay amounts be adjusted for generic and brand-name prescription medicines, in order to promote greater use of lower-cost but equally-effective alternatives. In instances where there are AB-rated generics at a significantly lower cost, the patient would pay the difference for the brand-name equivalent.

## **Prevent prescription drug fraud and abuse**

Programs must be put in place that provide patients with affordable, accessible and appropriate pain care, but also decrease the risk of addiction and the unauthorized transfer of opioid or painkiller prescriptions. This includes requiring certain patients identified as high-risk for opioid abuse to choose a single pharmacy or pharmacy chain to be used for all opioid prescriptions. This would prevent patients from filling prescriptions at an excessive rate by going to multiple doctors and pharmacies, a tell-tale sign of potential fraud and abuse. The Comprehensive Addiction and Recovery Act enacted in 2016 applies this type of program to Medicare beneficiaries.

In addition, independent reviews should be conducted regarding the effectiveness of products labeled as abuse-deterrent opioids so that prescribers can be sure the evidence shows they are truly safe and effective at preventing addiction.

BCBSA is pleased that the White House and Congress have been allocating funding to support additional prescriber education and training to encourage best prescribing practices and access to treatment. Additionally, more funding is needed to properly address treatment gaps and support services for patients and their families.

## **Address misuse of co-pay coupons that increase the cost of prescription drugs**

Co-pay coupons are banned in federal health insurance programs such as Medicare, Medicaid and the veterans' healthcare system, but enforcement is inconsistent. Drug manufacturers often provide patients with discount coupons to help offset the patients' out-of-pocket costs for medication. While these discounts help individual patients, they are in fact also helping to promote the use of higher-cost drugs even when less expensive, equally-effective drugs are available. This raises costs for everyone.

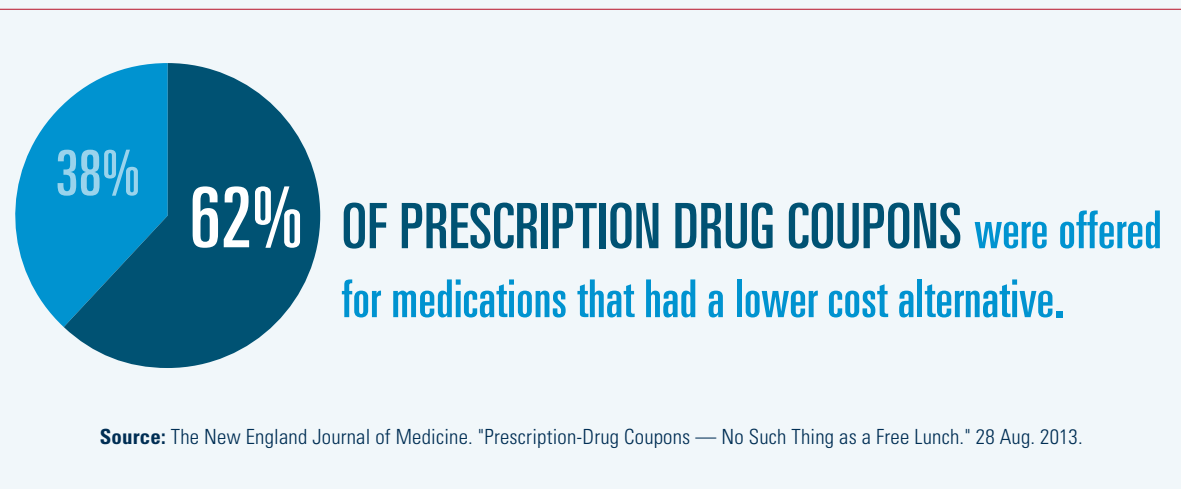
One recent study estimates that coupon use increased the percentage of prescriptions filled with brand-name formulations by more than 60 percent. As a result, the study estimated that national spending on drugs, on average, grew by \$30 million to \$120 million for each co-payment coupon over a 5-year period following the entry of generic competitor drugs.<sup>14</sup>

Where there is a lower-cost, equally-effective medication available to enrollees, the use of co-pay coupons should not be permitted in any program partially funded by the government, including the health insurance marketplaces established by the Affordable Care Act, the Federal Employee Health Benefit Program (FEHBP) and military health programs. To better enforce this policy, private insurers need additional information on the use of co-pay coupons (as part of the claim transaction, for example) to better understand their financial impact on the healthcare system and patients as a whole

<sup>14</sup> The New England Journal of Medicine. "Undermining Value-Based Purchasing — Lessons from the Pharmaceutical Industry." Nov. 2016. Web. [http://www.nejm.org/doi/full/10.1056/NEJMp1607378?query=featured\\_home&](http://www.nejm.org/doi/full/10.1056/NEJMp1607378?query=featured_home&)

Dollars that patients receive via coupons should not count toward the deductible or out-of-pocket maximums (MOOP), and drug makers should not be able to deduct from their taxes contributions to drug assistance programs that are used to support the use of their own branded drugs.

Furthermore, coupons should not just be limited to patients who are covered by insurance. They should be an option for those who are uninsured, as they are most in need of discounts and are at risk of being denied access to the medicines they need.



### **Encourage innovation and flexibility in health plan design to increase access to safe, effective and affordable prescription drugs**

Insurers design healthcare benefits so people can choose the health plan that best fits their needs. Payers can design plans to increase customer access to safe, effective and affordable prescription drugs—for both new and existing medicines. Limiting how benefits are designed hinders the ability of health insurers to offer benefits that meet everyone’s needs and help people access affordable, high-quality care. Specifically, BCBSA recommends:

- Allowing additional generic and specialty drug tiers in Medicare;
- Eliminating Medicare Part D’s six protected classes over time;
- Providing greater flexibility to create equivalent formularies to the Medicare Part D benchmark for the health insurance exchange plans;
- Providing flexibility in length of supply and use of mail order services as well as the use of specialty pharmacies, in Medicare Part D; and
- Removing barriers to the access and adoption of biosimilars, including onerous pharmacy substitution requirements.

## **Oppose efforts to cap co-pay amounts, which would result in higher premiums for all**

Drug companies set the price of drugs, and co-pays represent only a fraction of the cost. Insurers design benefits to provide a wide range of options so people can choose the health plan that best fits their needs. Co-pays are one tool that is used to keep monthly premiums down for everyone. Capping these would not eliminate the costs, but simply shift them around to others covered by insurance.

## **4 Promote additional regulatory changes that help patients get the right medicines for them, at the most affordable prices**

BCBS companies believe that a number of regulatory adjustments can be made to increase competition and improve patient access to affordable prescription medicines.

### **Ensure the off-label use of prescription drugs is regulated by the FDA**

Currently, prescription drug manufacturers are prohibited from promoting a drug's use that has not been approved by the FDA (e.g., off-label use). These restrictions safeguard patients and reduce wasteful spending, while still allowing manufacturers to communicate effectively with payers and PBMs regarding FDA-approved uses. In order to protect patients and help support doctors' practice of evidence-based medicine, the FDA must apply clearer evidence standards and stricter oversight of messages for off-label uses of drugs.

Expanding off-label promotion reduces incentives for manufacturers to seek approval for new uses—and thereby reduces the amount of data on clinical effectiveness of new uses that are submitted to and reviewed by the FDA. To remedy this, the FDA should require manufacturers to receive explicit authority for new uses of their drugs based on proven effectiveness in treating any additional conditions.

### **Prescription drug marketing guidelines should be modified to improve transparency around pricing and effectiveness**

The U.S. is one of just two countries in the world—the other is New Zealand<sup>15</sup>—that allows prescription drug advertising aimed directly at the general public. There is concern that this advertising may lead to the overuse of high-cost prescription medicines, even when highly effective, lower-cost alternatives are available.

The FDA should revisit its rules on direct-to-consumer (DTC) advertising and require that manufacturers include information such as price and clinical effectiveness in any advertising. Furthermore, manufacturers who advertise directly to consumers should be required to discount the drug's list price, at a minimum, by the amount spent on this advertising.

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<sup>15</sup> World Health Organization. "Direct-to-consumer advertising under fire." Aug. 2009. Web. <http://www.who.int/bulletin/volumes/87/8/09-040809/en/>

## **Increase patient access to more affordable prescription medicines by allowing generic drug manufacturers' access to brand-name products**

Some generic drug manufacturers are unable to access brand-name prescription medicines through regular distribution channels, because the drug is subject to restrictions imposed by a Risk Evaluation and Mitigation Strategies (REMS) program. The goal of REMS is to enhance drug safety, specifically to ensure REMS programs that a drug or biological product's benefits outweigh its risks.

REMS programs may be required for the approval of a new product or when new safety information is released. Some brand-name prescription drug companies claim that providing supplies of their drug to prospective generic manufacturers violates their REMS. This often prevents generic drug manufacturers from developing generic equivalents and submitting them for FDA approval. Currently, the FDA does not have the authority to force brand-name prescription drug manufacturers to make their products available to generic manufacturers.

BCBSA recommends that policymakers support the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2017 or the Fair Access for Safe and Timely (FAST) Generics Act. These bills address the use of restricted access programs that undermine generic competition by providing a pathway to end these abusive, anti-competitive practices. This change is estimated to save \$2.4<sup>16</sup> to \$3.3 billion<sup>17</sup> over 10 years.

## **Pass appropriate legislation to give CMS the authority to pay for drugs based on the "Least Costly Alternative" for clinically comparable drugs**

Until 2010, CMS allowed Medicare to base payment for prescription drugs administered in a hospital or clinical settings (Part B drugs) on their proven effectiveness, providing the "Least Costly Alternative" (LCA) when treatments were clinically comparable. Beneficiaries could sign an Advance Beneficiary Notice of Noncoverage (ABN), which required them to assume the additional financial responsibility if they wanted to receive the more expensive drug.

In 2010, CMS discontinued LCA policies after the U.S. Court of Appeals, District of Columbia Circuit ruled that LCA was not authorized under Medicare law. However, in 2012 a report by the Office of the Inspector General (OIG) showed that in one example, Medicare expenditures would have been reduced by \$33.3 million in one year had the least costly alternative drug been used. The OIG recommended that CMS seek legislative authority to implement LCA policies for Part B drugs under appropriate circumstances.<sup>18</sup> In March 2016, The Pew Charitable Trusts examined this issue and concluded that a LCA policy for some medications would significantly reduce Part B drug costs.<sup>19</sup>

Congress should give Medicare the authority to use clinically effective drugs that are the least costly, and CMS should continue to safeguard patient access to medically appropriate therapies.

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<sup>16</sup> Patrick Leahy. "Leaders Of Senate and House Judiciary Committees Reintroduce Bipartisan Legislation To Counter Rising Prescription Drug Prices." Apr. 2017. Web. <https://www.leahy.senate.gov/press/leaders-of-senate-and-house-judiciary-committees-reintroduce-bipartisan-legislation-to-counter-rising-prescription-drug-prices>

<sup>17</sup> Generic Pharmaceutical Association. "Lost Prescription Drug Savings from Use of REMS Programs to Delay Generic Market Entry." July 2014. Web. [http://www.gphaonline.org/media/cms/REMS\\_Studyfinal\\_July2014.pdf](http://www.gphaonline.org/media/cms/REMS_Studyfinal_July2014.pdf)

<sup>18</sup> Department of Health and Human Services Office of the Inspector General. "Least Costly Alternative Policies: Impact on Prostate Cancer Drugs Covered Under Medicare Part B." Nov. 2012. Web. <http://oig.hhs.gov/oei/reports/oei-12-12-00210.pdf>

<sup>19</sup> The Pew Charitable Trusts. "The 'Least Costly Alternative' Approach for Payment of Medicare Part B Drugs." March 2016. Web. <http://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2016/03/the-least-costly-alternative-approach-for-payment-of-medicare-part-b-drugs>

## **Allow for greater prescription drug discounts by reforming best price rules in Medicaid**

The Medicaid Drug Rebate Program helps to offset the federal and state costs of most outpatient prescription drugs dispensed to Medicaid beneficiaries. The program requires a prescription drug manufacturer to enter into, and have in effect, a national rebate agreement with the Department of Health and Human Services in exchange for state Medicaid coverage of most of the manufacturer's drugs. While these arrangements reduce prescription drug costs incurred by Medicaid beneficiaries, Medicaid best price rules can act as a ceiling for prescription drug discounts in other lines of business within the healthcare industry.

In order to allow manufacturers and payers to negotiate deeper discounts without affecting discounts owed to Medicaid, BCBSA recommends that a new policy be created to eliminate Medicaid best price. In an effort to make Medicaid programs "whole," the base Medicaid discount should be increased. A review of existing regulations and policies that could inhibit value-based contracting should be undertaken to ensure that no improper barriers exist to these types of contracts.

## **CONCLUSION**

As spending on prescription drugs continues to increase at an unsustainable pace, the broad and collective BCBS experience demonstrates that ensuring access to safe, effective, affordable, and timely prescription medicines while extraordinarily complex is possible when insurers, doctors, prescription drug manufacturers and the government work together.

BCBSA and the 36 BCBS companies look forward to partnering with government and others in the private sector to provide Americans with access to the medicines they need, in the right settings, at a price they can afford.