

In the Spotlight: Cost Trends of Prescription Drugs

In recent years, health care consumers nationwide- even those with health insurance coverage- have felt the effects of expensive prescription drugs. Nearly half of Americans take one or more prescription drugs,¹ so many consumers feel the impact of high drug prices. A recent report stated that drug spending reached \$373.9B in the U.S. in 2014, a 13.1% increase over previous spending and the largest spending growth since 2001.² Impacts of high drug prices are felt both directly, through increased out-of-pocket payments for consumers who take the drugs, and indirectly, through rising monthly premiums for all employers and consumers. Many factors contribute to the high cost of prescription drugs. This edition of *In the Spotlight* will consider some of the market and regulatory drivers of drug prices and the impact of drug prices on health insurers and consumers.

Influences on Drug Prices

Prescription drug costs are borne by pharmaceutical companies, health insurers, employers, taxpayers and consumers. Many issues factor in to how drug companies set prices and how those prices may be applied to consumers, including:

Regulatory Influences. There are several laws and regulations that limit consumer exposure to high drug prices, but few that regulate drug prices directly. In fact, some laws and regulations effectively cause drug prices to increase.

- **Patent Process:** When new drugs are created and approved by the FDA, they may receive a drug patent, which allows them to be made and sold exclusively by one drug manufacturer. Drug patents usually last about 20 years³ and allow manufacturers to set prices for the drug without the threat of competition. A recent study shows that price increases on patented drugs alone increased overall drug spending by 8.2% in 2014.⁴ Once a patent expires, other drug companies may enter the market to make and sell the formerly-patented drug in a competitive environment. It is believed that competitive environments assist in regulating drug prices. Indeed, in 2014, the drug market experienced lower spending of \$11.9B due to numerous drugs losing their patents.⁵
- **Affordable Care Act:** The Patient Protection and Affordable Care Act (ACA) includes several provisions that add consumer protections to drug coverage and limit consumers' costs for their drugs. Some of these regulations have the effect of increasing the cost of health care for all consumers, however.

¹ Kanavos, P., Ferrario, A., Vondoros, S. et al. "Higher US Branded Drug Prices and Spending Compared to Other Countries May Stem Partly from Quick Uptake of New Drugs." The Common Wealth Fund. April 8, 2013.

² "Medicines Use and Spending Shifts: A Review of the Use of Medicines in the U.S. in 2014." [IMS Institute for Healthcare Informatics](#). April 2015.

³ "Frequently Asked Questions on Patents and Exclusivity." [Food and Drug Administration](#). Updated July 2014.

⁴ "Medicines Use and Spending Shifts: A Review of the Use of Medicines in the U.S. in 2014."

⁵ "Medicines Use and Spending Shifts: A Review of the Use of Medicines in the U.S. in 2014."

- **Benefit Limitations:** The ACA sets limitations on the maximum level of cost-sharing that individuals must pay for health care costs, including pharmacy benefits. Once the consumer reaches their out-of-pocket maximum for prescription drugs and other health care, the insurer pays the remainder of the cost, which may be significant. In order to stay solvent, insurers must factor these costs into their premium rates for all consumers.
- **Benefit Non-Discrimination:** The ACA restricts insurers from discriminating with benefits based on factors such as a member's age or disability. State regulators have the ability to review plans for discriminatory design, and insurers that participate on the federal Marketplace may also be subject to federal review if the government has reason to suspect discriminatory practices. One example of a benefit design that may be deemed discriminatory is when an insurer places all drugs to treat a particular disease on the same, high-priced formulary benefit "tier", described later in the article. This requirement proves costly when specialty drug types that address similar, complex diseases are all very expensive in the market. These requirements restrict insurers' ability to use benefit tiering to steer users to lower cost drugs. As a result, more users may opt to take the higher cost drugs, which will ultimately lead to higher premiums for all consumers.
- **Price Transparency:** The ACA does take steps to create transparency about the amount and nature of payments from drug companies to physicians and teaching hospitals, through its [Open Payments system](#). Each year, applicable drug companies must submit financial information to the government for public reporting about payments they make for speaking engagements, gifts, entertainment, research activities and education. This requirement does not regulate drug prices, but may shed light on wasteful spending practices.
- **Absence of price regulation over drugs:** Part of the reason that the U.S. experiences such high drug prices is due to lack of direct regulation of drug costs or charges to payers like insurers or Medicare. Currently, commercial insurers or their pharmacy benefit managers must negotiate with pharmaceutical companies to arrive at a payment rate. Historically, the federal government has not had a role in this negotiation process. In fact, the Medicare Prescription Drug, Improvement and Modernization Act passed in 2003 explicitly restricts Medicare from negotiating drug prices.⁶ The ACA seeks to address drug prices in a small way by requiring that Medicare Part D members receive a discount (% off the plan's cost for the drug) on brand name and generic drugs when they fall within a federally-defined price range. Overall, however, drug prices remain largely unregulated.

Market Influences on Drug Prices. In addition to government regulation, drug prices are driven by market factors, which include industry research and development practices, demand for certain types of "specialty" drugs, and marketing and advertising costs.

- **Research and Development:** Drug manufacturers' expenses for research and development, including clinical trials, factor in to the price of drugs. One source estimates that developing a new prescription drug that is approved by the [Food and Drug Administration](#) to sell in the market costs \$1.4B per drug, and up to \$2.6B when opportunity cost over development period is considered.⁷ The same study finds that clinical

⁶ With exception of drugs covered under Part B.

⁷ "Costs to Develop and Win Marketing Approval for a New Drug is \$2.6 Billion." Press Release. [Tufts Center for the Study of Drug Development](#). November 2014.

costs to develop drugs have increased over time, due largely to clinical trial complexity, size of clinical trials, cost of input materials used to develop drugs and types of diseases targeted for treatment (currently chronic and degenerative diseases). Indeed, costs for protected brands increased by \$26.3B in 2014.⁸ Note that estimates of spending may vary significantly based on the assumptions used in calculating total expense.

- **Expansion of Specialty Drugs:** Specialty drugs are structurally complex drugs that may require special handling or other modes of delivery. They are designed to treat complex diseases and tend to be very expensive. Specialty drugs are expensive because they are costly to develop and demand is high among consumers with difficult-to-treat diseases. The highest cost specialty drugs over the past five years are designed to treat cancer, autoimmune diseases, HIV and multiple sclerosis.⁹ Over the past five years, national spending on specialty drugs has accounted for 73% of overall drug spending growth and in 2014, specialty drugs accounted for one-third of all drug costs nationwide. Recent trends suggest that the increase in specialty drugs will continue to grow. Development of these drugs accounts for 42% of all drugs in the late stages of development.¹⁰
- **Marketing and Advertising:** Drug companies spend a significant amount of money on marketing and advertising, according to a recent data. In 2014, the industry spent \$4.5B in marketing expenses directly to consumers, an increase of \$1B over 2013.¹¹ An even greater amount of money is spent on marketing to providers, who prescribe the drugs. Payments to providers as gifts, for research, entertainment and travel, for example, totaled \$3.7B during the last five months of 2013.¹² Remember that the costs of marketing and advertising are factored into the prices of drugs that consumers and insurers must bear.

Impacts of High-Priced Drugs

Insurer Impacts. As described above, health insurers are often responsible for a large portion the cost for expensive prescription drugs. Here are some tools that insurers may use to prevent high drug costs before they are incurred.

- **Benefit Design techniques:** Within the limitations of the law, insurers have flexibility to vary member responsibility for drugs in proportion with drug prices. This may create incentives for members to choose less expensive, clinically effective alternatives. Health insurers use tools including copays, coinsurance, deductibles and drug tiers within a formulary to vary member out-of-pocket costs.
- **Utilization Management tools:** A health insurer may employ tools to influence utilization of drugs that are covered in their formularies. These include:
 - **Prior Authorization:** Insurers may require health care providers to seek authorization from the health insurer prior to prescribing certain drugs. Once the insurer receives the request, its clinical staff reviews the medical history and drug prescribed to ensure clinical appropriateness. Health

⁸ "Medicines Use and Spending Shifts: A Review of the Use of Medicines in the U.S. in 2014."

⁹ "Medicines Use and Spending Shifts: A Review of the Use of Medicines in the U.S. in 2014."

¹⁰ "Medicines Use and Spending Shifts: A Review of the Use of Medicines in the U.S. in 2014."

¹¹ "It's Like Viagra for Pharma Ads: Pfizer's \$1.4Billion Marketing Blitz." [Bloomberg Business](#), March 2015 (citing data from Kantar Media).

¹² Centers for Medicare and Medicaid Services. "Annual Report to Congress on the Open Payments Program for Fiscal Year 2014." [U.S. Department of Health and Human Services](#), 2015.

insurers must adhere to standards set by the state and federal governments regarding how quickly this review takes place.

- **Step Therapy:** Insurers also may require that patients try an alternative, preferred drug regimen before fulfilling a request for certain less-preferable and costly drugs. If the preferred drug is clinically ineffective or the patient does not tolerate the drug under this approach, then the prescription may be filled for the drug that was originally sought by the consumer.

Consumer Impacts. Many consumers struggle to pay the cost-sharing necessary to cover the high cost of their prescribed drugs. For instance, a 2012 consumer report survey found that more than half of consumers who take one or more prescription drug must reduce other household expenditures to pay for their drugs. The survey suggests that the effects of high cost drugs are felt most severely by consumers under age 65 without a drug benefit, but consumers with drug benefits also experience financial challenges. Roughly 59% of consumers with a drug benefit had to reduce household expenditures to pay for their drugs.¹³

Consumers struggling with high drug costs may also alter their drug use to accommodate their budget. Medication “adherence,” or taking the right dosage of a prescribed drug at the right time, is currently an issue. Research found that overall, 20-30% of prescriptions are not filled, and about 50% of prescriptions are not continued as prescribed.¹⁴ Adherence rates depend on many factors including disease type, and patient and provider characteristics and cost of consumer out-of-pocket costs for drugs.

BCBSNC Views

BCBSNC is committed to ensuring that North Carolinians understand the drivers of health care costs. We encourage consumers to ask their providers about drug prices and whether generic, lower cost drug options are available. BCBSNC is working publicly, through our Let’s Talk Cost campaign and other advocacy work, to promote better public understanding of the impacts of state, federal and consumer actions on the cost of drug prices. BCBSNC supports and employs innovative utilization management and benefit design techniques to incentivize consumers and providers to make the most appropriate choices about their prescription drug options. We oppose efforts to strictly limit health insurers’ access to these types of tools to manage drug use and cost.

For More Information

BCBSNC Let’s Talk Cost Campaign:

<https://www.letstalkcost.com/>

This information has been prepared by Blue Cross and Blue Shield of North Carolina to assist our customers in understanding Health Care Reform. This publication is for informational purposes only. It is not legal or tax advice. Please consult with your attorney or tax advisor for information on your specific situation. As regulations and other interpretive guidance are published, this information may change. ®SM are registered marks of the Blue Cross and Blue Shield Association. ©, 2015 Blue Cross and Blue Shield of North Carolina is an independent licensee of the Blue Cross and Blue Shield Association. U#7259aaw

¹³ “Sluggish economy forces Americans to cut corners to pay for medications.” [Consumer Reports](#). Sept. 2012.

¹⁴ “Medication Adherence.” [Centers for Disease Control and Prevention](#). Presentation. March 2013.