As part of the Health Care Trends series, in this course you will learn about trends on current and projected prescription drug spending, Medicare Part D prescription drug coverage, projected drug spending, public opinion on drug costs and proposed controls, biologics and biosimilars, cancer drugs, and drug shortages. The course also posits projected impacts of these trends.

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**LEARN**

- **Introduction**
- **Prescription Drug Spending**
- **Biosimilars and Biologics**
- **Cancer Drug Costs**
After completing this course, you will be able to:

1. Identify current trends in drug spending, biologics, biosimilars, cancer drugs and drug shortages

2. Define causes of, and efforts taken, to mitigate the rising costs of prescription drugs and drug shortages

3. Explain predicted impacts of drug spending and drug shortage trends for patients, physicians, payers and policymakers
Growth in price and utilization of pharmaceuticals has varied over the past two decades. The cost of prescription drugs has become a hot-button issue with consumers and policymakers. One in four people taking prescriptions drugs report difficulty affording their medication. Polling results indicate bipartisan support for government action to lower prescription drug costs.
According to results of the 2017 Peterson–Kaiser Health System Tracker on prescription drugs:

- Prescription drugs will continue to represent a **larger portion** of overall health spending.

- Out-of-pocket costs for prescription drugs are expected to **increase** but will likely represent a small portion of overall drug spending.

- **Recent drug spending growth** has largely been due to new brands, high prices for existing drugs, and fewer patent expiration.

- Costly new specialty drugs were a major driver of a **recent spike** in health spending.

- **Diabetes** medicines topped traditional drug spending in 2016.

- Medications for **inflammatory conditions and multiple sclerosis** topped specialty drug spending in 2016.

- **Generic** drug prices have **declined** while **branded** drug prices have nearly **doubled**.

- The average price of specialty drugs in the United States is **significantly higher** than the price of these drugs in other developed countries, e.g., Tecfidera, prescribed to treat relapsing multiple sclerosis, is priced **174% higher** than in Switzerland, and **668% higher** than in the United Kingdom.


**Medicare Part D**

When Congress created Medicare Part D, it prohibited Medicare from negotiating with drug companies for lower drug prices. Congress also required eligible Medicare Part D plans to offer coverage for essentially all drugs in certain disease categories. Drug companies still face price pressure on drugs in the non-protected classes, though, because the private insurers that offer plans through Medicare Part D are able to negotiate.

**Medicaid**

The situation for Medicaid is different. The Federal government doesn’t negotiate Medicaid prices directly (though states can). Instead, by law it sets drug prices at the lowest amount others are paying, or sometimes even lower.

**U.S. Department of Veterans Affairs**
Projected Drug Spending

Spending on prescription medicines in the United States is projected to increase 4 to 7% through 2021, reaching $580 billion to $610 billion, according to a report released by QuintilesIMS Holding. QuintilesIMS, which compiles data for the pharmaceutical industry, had previously forecast average spending growth of 6 to 9% through 2021. It reduced its projections due to fewer new medicines approved in 2016 than prior years and as drug makers face increasing pricing pressure and competition.

Branded Medications

- Taking likely manufacturer discounts and rebates into account, spending would grow 2 to 5% to $375 billion to $450 billion in 2021, as net price increases for patent-protected branded drugs slows, the report said.

- Under pressure from politicians and insurers over the cost of many branded medicines, several drug makers have pledged to limit annual price hikes to less than 10%.
Some of the expense of new medicines will be offset by expanded use of cheap generics as several big-selling prescription drugs lose patent exclusivity and more biosimilars – less expensive versions of pricey biotech medicines – enter the market.

New Medications

The U.S. Food and Drug Administration (FDA) approved just 22 new medicines in 2016, down from 45 in 2015, which will also contribute to lower spending growth this year and next, the report said.

That is seen picking up in 2019 and beyond as QuintilesIMS estimates 40 to 45 new brand launches per year through 2021 based on a review of experimental medicines in drug maker pipelines.

The report found more than 2,300 novel products in later stage development, including more than 600 drugs for cancer, which remain able to command very high prices.

Prescription Medications

U.S. spending on prescription medicines in 2016 increased by 5.8% over 2015 levels to $450 billion based on list prices, and by 4.8% to $323 billion when adjusted for discounts and rebates.

The biggest drivers of prescription growth came from large chronic therapy areas, such as hypertension and mental health.

Overall use of pain medicines declined 1% with restrictions on prescribing and dispensing becoming more common as health care providers attempt to address the growing epidemic of addiction to opioid pain drugs.
Medicare Part D Prescription Drug Coverage

Medicare has become a major payer for prescription drugs.

On February 9, 2018 the President signed into law the Bipartisan Budget Act of 2018 (BBA of 2018), which included some provisions related to Medicare Part D prescription drug coverage. Just days later, on February 12, the Office of Management and Budget (OMB) released the President’s fiscal year (FY) 2019 budget, which also included several proposals related to Medicare Part D drug coverage and Part B drug reimbursement. Budget estimates reflect the 10-year (2018–2028) effects as estimated by the Congressional Budget Office (CBO).

Instructions: Click each plus sign below to learn more about budget estimates

Closing the Part D Coverage Gap

Closes the Part D coverage gap in 2019 instead of 2020 by accelerating a reduction in beneficiary coinsurance from 30% to 25% in 2019; also increases the discount provided by manufacturers of brand-name drugs in the coverage gap from 50% to 70%, beginning in 2019.

Estimated budget impact: not estimated separately by CBO; included in biosimilars provision below.
Proposed changes in the President’s FY2019 Budget would result in the following:

**Biosimilars**

Beginning in 2019, biosimilars will be treated the same as brand-name drugs in the Part D coverage gap, with manufacturer discounts of 70%; previously biosimilars were not included in the coverage gap discount program.

*Estimated budget impact: ~$10.05 billion.*

**Income-related Medicare Premiums**

Income-related Medicare premiums: Increases Medicare Part B and Part D premiums for beneficiaries with incomes of $500,000 (for individuals) and $750,000 (for married couples) or more, to 85% of program costs, up from 80%, beginning in 2019.

*Estimated budget impact: ~$1.63 billion*

Proposed changes in the President’s FY2019 Budget would result in the following:

- Requires Part D plans to pass on at least 30% of total rebates and price concessions to enrollees at the point of sale. *Estimated budget impact: +$42.16 billion*

- Add an out-of-pocket limit to Part D by phasing down beneficiary coinsurance in the catastrophic coverage phase from 5% to 0% over four years. Also, increase plans' share of costs from 15% to 80%, and decrease Medicare's reinsurance from 80% to 20%. *Estimated budget impact: +$7.36 billion*

- Exclude manufacturer discounts from the calculation of beneficiaries' true out-of-pocket (TrOOP) spending. *Estimated budget impact: ~$47.02 billion*
Loosen Part D plan **formulary standard** and expand plans’ ability to use **utilization management tools** for specialty drugs. *Estimated budget impact: -$5.52 billion*

**Eliminate cost sharing on generic drugs** for Part D enrollees receiving the low-income subsidy, including biosimilars and preferred multisource drugs. *Estimated budget impact: -$0.21 billion*

Permanently authorize CMS to contract with a single Part D plan to provide **coverage to low-income beneficiaries**. *Estimated budget impact: -$0.30 billion*

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**Public Opinion on Drug Costs & Proposed Controls**
Drug Importation

In an effort to curb drug costs, some states are advancing bills to prod the federal government on drug importation.

*Instructions: Flip each card to learn more about state efforts to curb drug costs*

Which states are pushing legislation that would seek permission from the Trump administration to launch

Utah, Vermont,

**Transparency Bills**

In 2017, state legislatures introduced 45 drug pricing transparency bills, compared to 38 in 2016.

**Instructions:** Flip each card to learn more about transparency bills
States approved how many laws targeting high drug prices through price transparency, compared to four in 2016?

14 laws

How many states introduced bills aimed at placing price controls on expensive drugs?

10 states

Biosimilars and Biologics

Defining Biologics and Biosimilars

Biologics account for the fastest-growing segment of prescription drug spending, but biosimilars have the potential to help slow some of the increase.

Instructions: Click each plus sign below to learn more about Biologics and Biosimilars

Biologic Products

A medication produced in living cells via a multistep process. Biologics encompass a number of broad categories, including vaccines, blood and blood components, somatic cells, gene therapy, tissues, and genetically engineered therapeutic proteins. Since their introduction, biologics have been used to treat many life-threatening and chronic conditions in areas such as nephrology, diabetes, cancer, inflammation, immunology, and respiratory, hematologic, gastrointestinal, lysosomal, and cardiovascular diseases.

Biosimilar Products

A biosimilar product is a biologic product that is approved based on demonstrating that it is highly similar to an FDA-approved biologic product, known as a reference product, and has no clinically meaningful differences in terms of safety and effectiveness from the reference product. Only minor differences in clinically inactive components are allowable in biosimilar products.
Differences between Products

A biosimilar is a biologic product and a generic is a small-molecule product. While identical generic versions of small molecules can be chemically synthesized, it is not possible to create identical versions of reference biologic medicines due to their complexity. Therefore, the processes used to develop generic medicines cannot be applied to development of biosimilar medicines.


Introduction to Biologics and Biosimilars

Costly new specialty drugs were a major driver of a recent spike in health spending.
Introducing “biosimilar” versions of complex biologic drugs used to treat illnesses such as cancer and rheumatoid arthritis could cut health care spending in the United States by $54 billion over the next decade, according to an analysis from the RAND Corporation.

“Biologics account for the fastest-growing segment of prescription drug spending, but biosimilars have the potential to help slow some of the increase,” said Andrew Mulcahy, lead author of the study and a policy researcher at RAND. “However, there remain many important industry, regulatory, and policy decisions to be made that will influence whether such savings are realized.”

While biologics are important treatments for many conditions, they often are expensive and patient copays for the treatments can be several thousand dollars per year. While 1 to 2% of the nation’s population is treated with a biologic each year, the drugs accounted for 38% of prescription drug spending in 2015. In addition, biologics accounted for 70% of the growth in prescription drug spending in the United States between 2010 and 2015.

The Biologics Price Competition and Innovation Act (BPCIA), enacted as part of the ACA, authorized the FDA to create a new approval pathway for biosimilars with the goal of promoting competition. This new pathway is faster and less costly for biosimilar developers.

RAND researchers estimated that biosimilars will cut spending on biologics by about 3% over the next decade. The range of the new savings estimate given reasonable ranges of key assumptions—like the price of biosimilars versus reference biologics and biosimilar market share—varied from $24 billion to $150 billion from 2018 through 2027.

Results of BPCIA

The BPCIA raised expectations that new competition would blunt price increases for biologic drugs; however, results to date are disappointing.

- The FDA has not yet finalized its guidance on demonstrating interchangeability.
- Medicare's reimbursement policies for these products are neutral with respect to choice of product on the basis of price, rather than promoting price competition.
- Product sponsors' secrecy about manufacturing processes adds an additional hurdle in bringing biosimilars to the marketplace.

Instructions: Flip each card to review more results of BPCIA

How many biosimilar products are on the U.S. market competing with originator brands?

Only 7 products
How much biologic spending is subject to competition from biosimilar products?

$3.2 billion (only 3%)
High out-of-pocket spending varies among cancer patients depending on their diagnosis and their health benefit plan.

"Lost in the ongoing debate surrounding health care is how Americans with cancer benefit from, and experience challenges with, a new and evolving health care system. This includes the impact on people covered through the Health Insurance Marketplaces, the unintended consequences of reform on those covered by Medicare, the short- and long-term effects of novel delivery of care models, and the impact of subsequent changes to employer-based plans."

Cancer is one of the leading causes of death and disease in the United States. The American Cancer Society (ACS) estimates that roughly 1.7 million new cases of cancer were diagnosed in the U.S. in 2017 and more than 15 million Americans living today have a cancer history. Not only does cancer take an enormous toll on the health of patients and survivors – it also has a tremendous financial impact.

With more than 200 different types of cancer, there is no “one size fits all” cancer treatment, but there are several consistent factors that contribute to patients’ overall costs for their care.

- Patients without health insurance are responsible for all of their treatment costs.
- Some uninsured patients may be able to negotiate discounts with providers, may qualify for “charity care” or may be able to participate in drug discount programs to reduce their costs.
- For patients with insurance, the kind of health insurance the patient has and the benefit structure are some of the most important factors in determining the ultimate costs for patients.


Cost of New Cancer Drug Development

The median cost to develop a new cancer drug was $648 million.
In an analysis of 10 cancer drugs approved between 2006 and 2015, researchers found that the median cost to develop a new cancer drug was $648 million when factoring a 7% per year opportunity cost, and the median time it took to develop the new drugs was 7.3 years.

- These 10 drugs represented 15% of all drug approval over that period.
- Some of these drugs made 10 times more money than had been spent during research and development (R&D).
- All of the 10 drugs in the analysis are still patent protected, with years left until they start to face competition from cheaper generic medications.
Economic Rules of Cancer Drug Prices

"Cancer drug prices in the United States follow their own economic rules that have little to do with what the market will bear." Oncology drugs have become synonymous with extremely high cost.

Instructions: Click each plus sign below to learn more about the economic rules of cancer drug prices

### Patented Cancer Drugs

The prices of patented cancer drugs in the United States have increased 5- to 10-fold from before 2000 and the cost of new drugs continue to grow far ahead of inflation.

### Cancer Drug Treatment Costs

The average cancer drug price for approximately 1 year of therapy or a total treatment duration was less than $10,000 before 2000, and had increased to $30,000 to $50,000 by 2005. In 2012, 12 of the 13 new drugs approved for cancer indications were priced above $100,000 per year of therapy.

### Cancer Drug Prescriptions
One-quarter of all cancer patients chose not to fill a prescription due to cost, according to a 2013 study in The Oncologist. And about 20% filled only part of a prescription or took less than the prescribed amount. Given that more than 1.6 million Americans are likely to be diagnosed with cancer this year, that suggests **168,000 to 405,000 ration their own prescription use.**


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**Policymakers' Role in Controlling Cancer Costs**

State and federal policymakers can address cancer patients’ costs by:

- **Ensuring cancer patients, survivors and those at risk for cancer have access to health insurance** that is adequate, available, affordable and easy to understand

- **Providing all Americans access to no cost prevention and early detection services** —preventing cancer and diagnosing it earlier can reduce patient costs

- **Passing public policies that prevent cancer** and its costs to patients and society by reducing tobacco use and exposure to secondhand smoke, promoting healthy eating and active living, and protecting Americans from increased skin cancer risk associated with exposure to UV radiation emitted by indoor tanning devices.

Predicted Impacts

AMA_Trends 2018-19 Health Economics MM3 Cancer Drug Costs.pdf
189.2 KB
Drug Shortages

The Food and Drug Administration (FDA) takes great efforts, within its legal authority, to address and prevent drug shortages.

These shortages can occur for many reasons, including manufacturing and quality problems, delays, and discontinuations. The agency works closely with manufacturers of drugs in short supply to communicate the issue and to help restore availability. The FDA also works with other firms who manufacturer the same drug, asking them to increase production, if possible, in order to prevent or reduce the impact of a shortage.
Communication between the FDA and the public is an essential component of preventing and mitigating drug shortages. Shortage notifications and updates may be reported to the FDA at drugshortages@fda.hhs.gov.

The FDA released Drug Shortages 2 mobile application for Android devices, through which these users are able to receive notifications when there is new or updated information about a shortage of a drug product or about a drug within selected therapeutic categories. The FDA is currently working on notifications for the iOS version of the Drug Shortage mobile app, which will be available soon.


American Society of Hospital Pharmacists

The American Society of Hospital Pharmacists (ASHP) and its partners keep the public informed of the most current drug shortages via the following website:

https://www.ashp.org/drug-shortages/current-shortages


Predicted Impacts

AMA_Trends 2018-19 Health Economics MM3 Drug
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Lesson 7 of 7

Additional Resources

Transcript

131.6 KB

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195.8 KB

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