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ISSUE Brief

Specialty Drugs: Issues and Challenges

Advancing Effective Strategies to Address Soaring Drug Costs While Ensuring Access to Effective Treatments and Promoting Continued Medical Innovation

TWEETS
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- Specialty drugs account for 1% of prescriptions but 32% of all Rx drug spending
- Issue brief explores the unsustainable cost trend of specialty drugs
- Learn about health plan strategies to promote access to specialty drugs while managing costs

KEY TAKEAWAYS

27 of 51

Specialty drug approvals by the FDA exceeded traditional drug approvals for the first time in 2010—a trend that has continued each year since. In 2014, 27 of the 51 drugs approved by the FDA were specialty drugs.

6%

The Centers for Medicare & Medicaid Services (CMS) projects sustained increases in drug spending of 6% or more annually from 2015 to 2022, as both drug prices and utilization increase.

Anti-competitive strategies used by some drug manufacturers, such as "evergreening" and "product hopping," restrict access to less costly, high-value generics and therapeutic alternatives.

Health plans have developed a number of innovative strategies to address unsustainable increases in the prices of specialty drugs.

Background

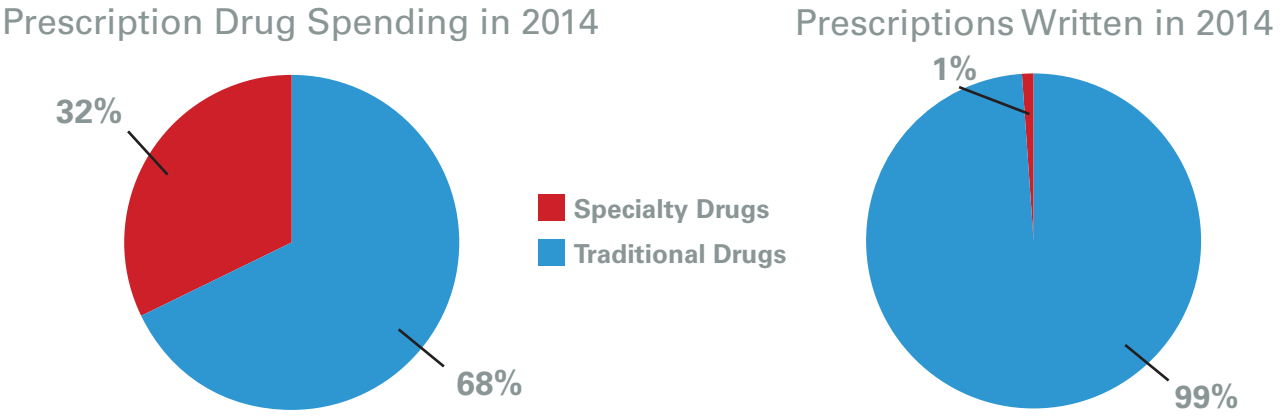
Spending on specialty drugs represents an increasing share of U.S. prescription drug spending and is growing at a rapid and unsustainable rate. Addressing these cost trends is critical to ensuring a sustainable health care system and achieving affordability for businesses and consumers. In 2014, U.S. spending on prescription drugs totaled nearly $379 billion—almost a third of which was spent on specialty drugs.[1]

Specialty drugs—which are generally understood to be drugs that are structurally complex and often require special handling or delivery mechanisms—are typically priced much higher than traditional drugs. While some of these drugs have been groundbreaking in the treatment of cancer, rheumatoid arthritis, multiple sclerosis, and other chronic conditions, the cost of treating a patient with specialty drugs can exceed tens of thousands of dollars a year. The treatment regimen for some of the most expensive specialty drugs can cost $750,000 per year.[2] Compounding the financial impact of these drugs is the changing demographics of those who use them. Historically these drugs have targeted diseases affecting very small populations—sometimes as few as a thousand individuals nationally. But over time and with breakthroughs in the understanding of disease and clinical pathways, these drugs are now used to treat chronic conditions affecting tens of millions of patients.

Although these drugs offer tremendous promise when medically necessary, their high costs and use for treatment of chronic conditions in large populations has upended traditional assumptions about prescription drugs and threatens the availability of affordable coverage options nationwide. Health plans, employers, and other stakeholders are searching for innovative, market-based strategies to restrain cost growth while simultaneously maintaining access to safe and effective drugs for patients.

This issue brief explores recent trends in the specialty drug market, highlights some of the innovative strategies health plans are adopting to provide patients with access to specialty drugs while managing costs, and recommends additional policy solutions to further promote high-value, high-quality care.

Figure 1: U.S. Spending on Prescription Drugs, 2014



Source: The Express Scripts 2014 Drug Trend Report. March 2015. Available at: http://lab.express-scripts.com/drug-trend-report/

Prescription Drug Cost Trends

Express Scripts and the IMS Institute for Healthcare Informatics estimate that overall spending on prescription drugs grew by 13.1% in 2014 to $373.9 billion—the largest year-over-year increase since 2001.[3]

Because of their extremely high cost, specialty drugs account for a disproportionate share of overall drug spending (Figure 1). For some specialty drugs, the monthly treatment cost can exceed tens of thousands of dollars (Figure 2).

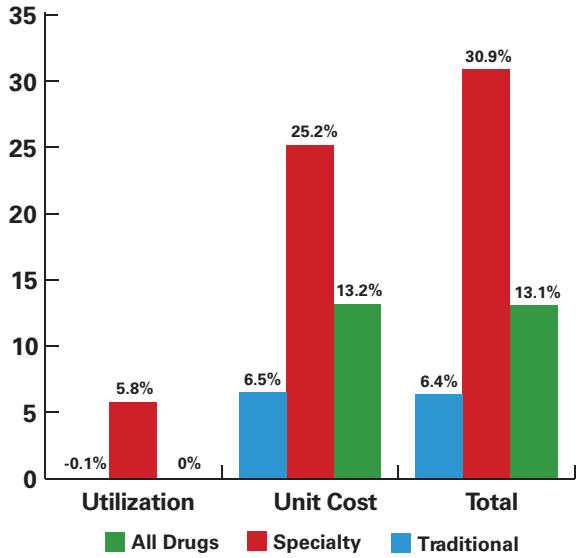
Figure 2: Approximate Monthly Cost of Commonly Used Specialty Medications, 2014

Medication	Sample indication for medication use	Monthly cost for sample indication
Provenge (sipuleucel-T)	Metastatic prostate cancer	$105,800
Sovaldi (sofosbuvir)	Hepatitis C	$29,900
Olysio (simeprevir)	Hepatitis C	$23,600
Rituxan (rituximab)	Non-Hodgkin's lymphoma	$21,900
Gleevec (imatinib)	Chronic myeloid leukemia	$11,900
Avastin (bevacizumab)	Metastatic colorectal cancer	$11,600
Revlimid (lenalidomide)	Multiple myeloma	$9,300
Neulasta (pegfilgrastim)	Neutropenia	$5,700

Source: Adapted from Specialty Medications: Traditional And Novel Tools Can Address Rising Spending On These Costly Drugs, Exhibit 1. Health Affairs, 33, no. 10 (2014).

In the area of oncology, the median price for new cancer drugs approved in the past 5 years now exceeds $10,000 per month (up from $4,500 a decade earlier), according to data from Memorial Sloan Kettering Cancer Center.[4] Moreover, prices for many existing brand-name and specialty drugs may not even fall when faced with competition from other drugs. Prices have been known to double for dozens of established drugs to treat serious chronic conditions such as diabetes, cancer, and multiple sclerosis, when a single manufacturer produces a number of drugs in a specific therapeutic area.[5]

Figure 3: Commercially Insured: Components of Trend, 2014



Source: The Express Scripts 2014 Drug Trend Report. March 2015. Available at: http://lab.express-scripts.com/drug-trend-report/

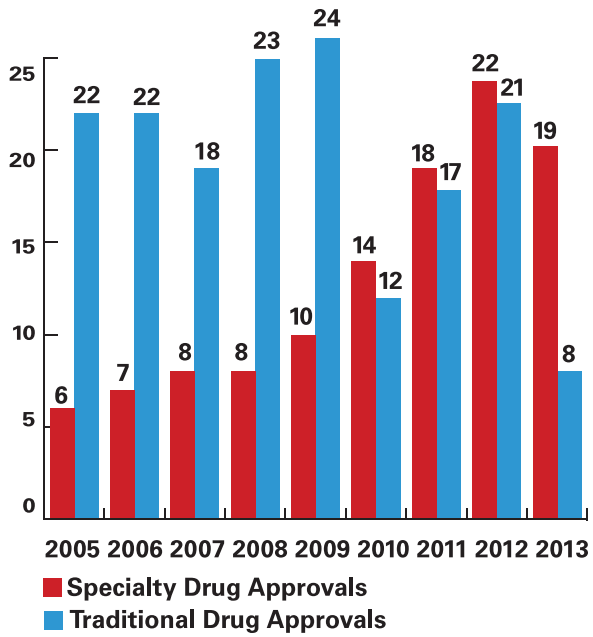
These prices drive the growth in prescription drug spending. While the growth rate in spending for traditional medications (non-specialty, small molecules) in 2014 was just 6.4%, spending on specialty drugs increased by more than 30% (Figure 3).

Many of the highest-cost specialty drugs are a unique subset of specialty drugs known as biologics. Unlike traditional medications made from chemical compounds, biologics are complex molecules derived from living or biological sources. Biologic medications can include vaccines, gene therapies, recombinant protein products, antibodies, and hormones. Advances in the understanding of how these medications work and their potential to help treat and cure disease have led to dramatic growth in the biologic market—eight of the 10 top-selling drugs are estimated to be biologics by 2016, while only one biologic was in the top 10 only a decade ago.[6] And these drugs come to market with a significant price tag. Some biologics can be 22 times more expensive than traditional medications.[7]

Unlike their traditional counterparts, spending on specialty drugs has shown no signs of moderation. An increase of 16% each year is forecast for the 2015–2018 period, with total spending comprising more than 50% ($235 billion) of total drug spending by 2018.[8]

Growing introduction, use, and price of specialty drugs in the pharmaceutical market further explain their position as the driver of drug spending. In 2010, specialty drug approvals by the Food and Drug Administration (FDA) exceeded traditional drug approvals for the first time (Figure 4), a trend that has continued each year since. And in 2014, 27 of the 51 drugs approved by the FDA—53%—were specialty drugs.[9] As of early 2015, 42% of drugs in the late stage of the FDA approval process were specialty medications.[10] A report by health care accrediting agency URAC noted that the marked increase of chronic illnesses in Americans (such as cancer, obesity, and diabetes) coupled with the pharmaceutical industry's ability to quickly identify and develop new and more personalized drugs has positioned the specialty drug market for continued growth.[11]

Figure 4: FDA Traditional and Specialty Drug Approvals, 2005-2013



Source: Adapted from Medical Cost Trend: Behind the Numbers 2015," PricewaterhouseCoopers Health Research Institute, Specialty Drug Infographic. June 2014. Slide 5.

The Broken Prescription Drug Market

Unsustainable growth of specialty drug spending is due to many complex factors but can be explained, in part, by the legal and regulatory treatment of these therapies. Under current law, brand-name biologic drugs are given a 12-year exclusivity period upon approval from the FDA—in effect a government-approved monopoly. This period of exclusivity is typically longer than the patent protection remaining for traditional drugs by the time they are brought to market. Although these exclusivity periods give pharmaceutical manufacturers the incentive to take on the risk of developing groundbreaking drugs, they also precipitate a number of negative policy consequences.

Granting lengthy exclusivity periods to specialty drugs removes the economic benefits of price competition, resulting in higher prices relative to what they would be in a perfectly competitive market. This phenomenon can be seen in Medicare spending for Part B drugs, which more often are biologics requiring physician administration and therefore covered through the medical, rather than pharmacy benefit.[12]

The Government Accountability Office released a report examining trends in Part B spending in 2010 with two notable findings: (1) only 10 drugs accounted for 44% of all Part B spending; and (2) none of these 10 drugs had a generic version also approved by the FDA.[13] The lack of adequate substitutes for these drugs constrains efforts by all payers' (health plans, public programs, employers) to implement effective policies to promote access and manage costs. Health plans have developed expertise in using value-based purchasing or cost-sharing designs that provide incentives for prescribers and patients to select high-quality, high-value treatments and care. But when generic or therapeutic alternatives do not exist, the options available for encouraging high-value are limited.

There is growing evidence that prescription drug manufacturers have gamed this regulatory process to artificially prolong the exclusivity period for some drugs and prevent less costly generic versions from reaching the market.[14] By making minor changes to a drug's chemical composition or delivery mechanism (e.g., an extended release version of a previously-patented drug that had to be taken twice a day), manufacturers can extend patents that would have otherwise expired. These so called "evergreening" schemes do not typically provide any enhanced clinical benefit for consumers—rather they are aimed at maintaining monopolistic pricing for products that are just as effective as their less expensive, generic counterparts. Other anti-competitive strategies such as

"product hopping"—when pharmaceutical manufacturers withdraw a certain drug from the market and introduce a new version with minor changes in an effort to delay the entry of a generic substitute—frustrate efforts to realize savings from generic drugs. Strategies like these have resulted in a market for insulin—a drug available for the last 90 years—with only brand-name versions costing hundreds of dollars per vial.[15]

Even when effective, less costly substitutes do exist, payment incentives are not necessarily aligned to encourage their use. Recently released data from CMS on Part B expenditures highlight this problem in the way two biologics from the same manufacturer—Avastin and Lucentis—are used to treat certain diseases of the eye. Although the two drugs have been found to be similarly effective at treating age-related macular degeneration, Lucentis costs more than $2,000 per dose, while Avastin (using off-label, intra-ocular injections) costs just $55. An analysis of Part B expenditures for these two drugs found that if providers only prescribed Avastin instead of Lucentis over the next decade, it would result in nearly $29 billion in savings to the health care system.[16]

In the United States, the ability for manufacturers to gain approval to create generic substitutes for expensive biologics is still relatively new. Until passage of the Biologics Price Competition and Innovation Act, the legal and regulatory pathways did not exist to bring generic versions of biologics to the market. These generic biologics, or "biosimilar medicines," are highly similar to previously approved brand-name biologics (known as the reference product) but are usually available at a much lower cost. Biosimilars must meet rigorous safety and efficacy requirements, and must also show no meaningful clinical difference from the reference product.

In March of 2015, the FDA approved the first biosimilar product for use in the United States.[17] The advent of biosimilars could have profound implications for our health care system and the affordability of coverage. A study conducted in 2013 found that the approval of 11 biosimilars already approved for sale in Europe and elsewhere would save approximately $250 billion in health care spending from 2014 to 2024.[18]

Health Plan Efforts to Manage Specialty Drug Spending While Ensuring Access to High-Quality Care

Health plans have developed a number of strategies in response to sustained cost increases that ensure access to critically important drugs while also holding down costs. These approaches include providing patients with tools and support to help them successfully manage their specialty medications, promoting collaborative arrangements with physicians and pharmacists, and focusing on the supply side through the use of specialty pharmacies.

Integration and Coordination of Pharmacy and Medical Benefits

Because of their complex nature and their delivery mechanism, some specialty drugs are often covered through the medical, rather than the pharmacy benefit. This distinction has made it difficult to get an accurate and complete picture of the prescribing and utilization patterns across the two benefits—undermining the use of medical evidence that determines the best type of treatments for patients.

Health plans have begun developing innovative benefit designs recognizing the unique nature of specialty drugs. These approaches encourage use of the most efficient site of care, including home or physician offices, if appropriate, and collaboration between treating providers and specialty pharmacists with expertise in medication management for specific conditions. More tightly integrating and coordinating the pharmacy and medical benefits also allows plans to better track the usage of specialty drugs across its enrollees and identify additional areas for alignment.

Policies to Maximize Treatment Adherence

Coverage of a specialty drug results in significant health care waste, poor outcomes, and higher costs when patients have poor adherence, or if they discontinue use after filling the prescription.

Health plans are helping to ensure that patients take their medications as indicated by engaging them about the disease and the therapeutic process. Health plans are also helping patients understand how to take their medications correctly by coordinating with providers and making sure that patients understand the guidelines for using the medication and any potential side effects. Condition-specific care management support teams help patients adhere to their treatment regimen and work with providers to coordinate care.

Growing Role of Specialty Pharmacies

Many health plans now contract with specialty pharmacies that supply enrollees with the specialty drugs they need and coordinate the often complex delivery and treatment processes associated with these drugs. These pharmacies have specialized capabilities to monitor and track the use of specialty drugs and have the necessary training and expertise to handle their distribution. Specialty pharmacies also employ dedicated teams of health care specialists that can help enrollees understand how to manage their medication and can help ensure that these drugs are administered at the most appropriate site of care.

Utilization and Pharmacy Management

By covering specialty drugs for their intended uses and monitoring the effectiveness and any side effects that occur during the therapy session, health plans can help to ensure that individuals receive safe, high-value care. For instance, drug formularies that are designed based on information regarding drug safety and efficacy help promote patient access to treatments while keeping health coverage affordable.

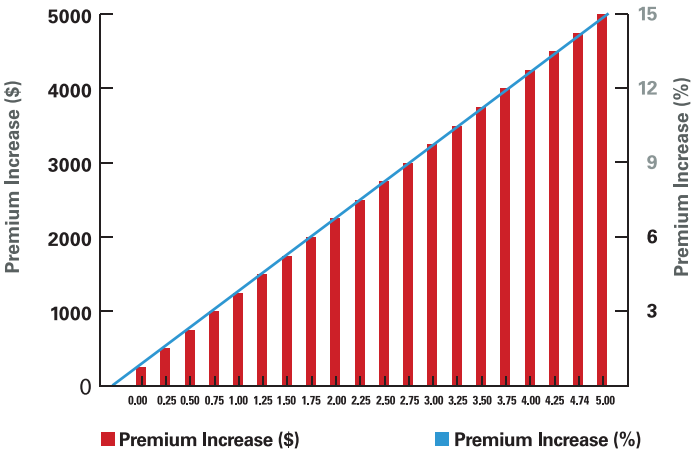
Clinical Pathway and Bundled Payment Arrangements

More health plans are exploring innovative approaches to managing specialty drugs, such as oncology drugs, for specific conditions. By encouraging treatment consistent with evidence-based, accepted clinical guidelines and reimbursing physicians for the treatment episode as a bundled service, plans are working to reduce treatment variability, improve outcomes, and promote value.

Policy Options to Promote High-Quality, Cost-Effective Drug Coverage

Although health plan efforts to promote access while lowering the growth of spending on specialty drugs have shown progress, substantial reforms are still needed at the state and federal levels to control specialty drug spending, promote patient safety, and encourage more competition. The problem facing policymakers is urgent—growth in specialty drug prices significantly outpaced growth in wages and the consumer price index between 2011 and 2013.[19] A recent analysis published in *Health Affairs* modeled the impact of a hypothetical specialty drug costing $100,000 per treated patient that would increase total health care costs by $250 for every 0.25% of the population using the drug.[20] Under this model, such a specialty drug used by just 5% of the population would lead to an almost 15% increase in premiums (Figure 5).

Figure 5: Rate and Percent Increase in Premiums For A New Specialty Drug Costing $100,000 Per Treated Patient, Depending on Disease Prevalence



Source: The Impact of Specialty Pharmaceuticals As Drivers of Health Care Costs. Health Affairs, October 2014. Exhibit 2.

Policymakers can leverage the experience of health plans and other payers to enact policies to meet the twin goals of affordability and patient access to effective treatments.

These policy options include:

- **Encouraging alternative payment and incentive structures—such as coverage with evidence development—for new drugs and technologies.** Such payment strategies can ensure access to new drugs while generating additional evidence on the value of these new medications to patients. As part of a broader value-based purchasing strategy, alternative arrangements—such as outcomes-based contracting or reimbursing providers a flat fee for obtaining drugs, rather than a percentage of the drug's total cost—provide enhanced financial incentives for manufacturers of new drugs and medical technologies that are contingent on agreed-upon standards for quality care, performance, and health outcomes. Greater use and availability of comparative effectiveness data is a key element in the future growth of these innovative payment arrangements.

- **Shortening the exclusivity period for biologics—to promote greater price competition and earlier access to lower-cost specialty drugs or biosimilars.** Congress should shorten the exclusivity period for biologics to allow for more competition from follow-on or generic biologics—similar to the patent protections afforded to traditional, small-molecule prescription drugs. By shortening the exclusivity period, this proposal would facilitate the entry of lower-cost, generic biologic drugs—reducing costs throughout the health care system. While specialty and other breakthrough drugs can offer lifesaving treatments to patients with serious medical conditions, there are opportunities to help reduce costs and improve efficiency in delivering high-quality, cost-effective treatments to patients. By shortening the exclusivity period, policymakers can ensure greater price competition in the specialty drug area and help alleviate cost pressures for payers and consumers.

  The U.S. Federal Trade Commission (FTC) has concluded that the current 12-year exclusivity period is "unnecessary to promote innovation by pioneer biologic drug manufacturers" and may harm consumers by "directing scarce research and development dollars toward developing low-risk clinical and safety data for drug products with proven mechanisms of action rather than toward new medical inventions to address unmet medical needs."[21]

- **Prohibiting abuse of the patent process by drug companies.** Congress should take meaningful steps to prohibit manipulation of the patent process in ways that artificially prolong patents on brand-name drugs. For example, Congress should bar certain anti-competitive settlements that prevent generics from entering the market in a timely manner, thereby expanding the availability of low-cost, but equally effective, generic drugs. Both the FTC and the Obama Administration have cited these arrangements as anti-competitive and the Administration has supported legislative efforts to remove these barriers to competition as a way to promote lower-cost generic drugs to patients and consumers. The Congressional Budget Office estimates that prohibiting these settlements would save $3.7 billion from 2015 to 2025.[22]

  Policymakers should also take steps to stop so-called "evergreening" strategies, where minor modifications are made to a drug to keep its patent from expiring while not providing any additional clinical benefit. Also, Congress should combat these efforts by preserving a robust Inter Partes Review (IPR) process for patent challenges, including challenges involving pharmaceutical patents.

- **Removing barriers at the state level that restrict the use of biosimilars.** While the Affordable Care Act authorized the FDA to develop an abbreviated licensure pathway for biosimilar drugs, it has yet to issue final standards that will determine when a biosimilar drug is truly interchangeable with an already approved biologic. Ahead of these standards, some states have already adopted legislation that may restrict the availability of biosimilars before they even reach the market. These proposals will limit

patient access to drugs that are not clinically different, yet cost substantially less than their brand-name counterparts.

- **Expanding agencies' authority to consider research on treatment effectiveness.** Consumers and providers should be empowered to know which treatments and drug regimens work and which are less effective. In the absence of a national process for measuring the cost-effectiveness of procedures and drugs, many providers are attempting to control costs by basing coverage decisions on the relative costs of similar treatments. Memorial Sloan Kettering Cancer Center announced in 2012 that it would not provide patients with Zaltrap—a drug used to treat advanced colorectal cancer—because it cost more than double the price of Avastin while offering no clinical advantages.[23]

  To expand this evidence base in America, Congress should provide new authorizing language for the Patient-Centered Outcomes Research Institute (PCORI) that explicitly allows it to consider research on cost-effectiveness as a valid component of patient outcomes research. PCORI and the Agency for Healthcare Research and Quality (AHRQ), in their funding of research on the effectiveness of treatments and technologies and their dissemination of the results of that research, should prioritize the establishment of a multi-stakeholder, deliberative process that can use such research to provide trustworthy recommendations on high-value and low-value care options to providers, payers, and patients.

- **Encouraging competition and innovation.** Congress and the FDA should seize opportunities to improve value to patients and reduce costs—such as targeted incentives for true breakthrough therapies or to serious or life-threatening diseases where no treatments are available, constructing a clear pathway for approval of biosimilars, and encouraging additional market entrants and greater market competition. These changes would help to restore balance to the prescription drug market and leverage market forces to promote greater efficiencies and savings.

- **Promoting transparency on prescription drug research, development, and pricing.** Greater transparency of clinical research and drug approval data would help physicians and patients select the optimal course of treatment. The timely availability and accessibility of clinical data from drug trials about efficacy, complications, and safety are critical to that decision-making process.

- **Reforming Medicaid drug manufacturer rebates to promote competition.** Under the current formula, drug manufacturers participating in Medicaid must provide a specific discount to states and the federal government for the drug they provide. This discount must equal the greater of either (1) 23.1% of the drug's average wholesale price; or (2) the difference between the average wholesale price and lowest price that the manufacturer receives for the drug from private purchasers (often referred to as the "best price"). This encourages drug manufacturers participating in Medicaid to raise prices higher than what they might be in a competitive market to avoid providing private market discounts to the Medicaid population. Congress should act to level the playing field so that market forces can work to lower the cost of drugs for both public and private payers.

- **Adopting a "least costly alternative" (LCA) standard for certain drugs covered under Medicare Part B**. CMS should be provided the flexibility to set a single payment rate for groups of clinically similar drugs based on the lowest-cost item. Similar to reference pricing strategies used successfully in many countries, these policies encourage cost-effective drug coverage and savings to consumers by setting a price ceiling for drugs within a category of drugs considered clinically equivalent and interchangeable.[24] Consumers and patients selecting a higher-cost drug would be responsible for any cost-differential between the drug selected and the lowest cost, clinically equivalent drug within a class. These policies work best in drug categories where there is sufficient competition and alternative drugs and treatments available to patients. In addition to reducing costs, this policy would also reduce incentives for physicians to prescribe more costly drugs when comparable lower-cost alternatives are available.

An analysis by the Office of the Inspector General (OIG) at The Department of Health and Human Services found that implementing a LCA policy with respect to Medicare Part B would have saved $33.3 million over the course of a year. Additionally, the OIG found that when LCA policies for Part B drugs were removed in 2010, utilization patterns shifted "dramatically" toward more expensive drugs with the same clinical purpose.[25]

Conclusion

The skyrocketing cost of specialty drugs remains a critical concern for policymakers and payers—given the current trajectory of pricing trends in this fast-growing and emerging area. These recommendations represent actionable steps that could be implemented to ensure the efficient and effective use of these high-cost treatments while—at the same time—promoting continued medical advances and innovations that offer promise and benefit patients and consumers.

End Notes

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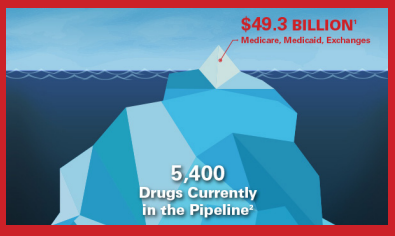

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