



Joint Recommendations of the American Academy of Family Physicians, American Academy of Pediatrics, American College of Obstetricians and Gynecologists, American College of Physicians, American Osteopathic Association, and American Psychiatric Association
on
Rising Costs and Growing Shortages of Prescription Drugs

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Introduction

The rising cost of prescription drugs, combined with shortages of many vital drugs, are creating barriers to patients getting the medications they need to maintain and improve their health.

- Rising drug prices, combined with high deductible health plans, are making medications unaffordable for many patients.
- Prescription drug price increases are contributing to higher premiums charged to both employers and employees, and greater outlays from public programs like Medicare and Medicaid.
- The problem is affecting all types of medications. Not only are many newly-approved drugs being priced at a level that few can afford, many medications that have been on the market for many years, even decades, are experiencing unprecedented price increases—including for both brand-name and generic drugs.
- In many cases, payers are reacting to the higher costs of covering prescription drugs by removing beneficial drugs from their approved formularies, requiring that patients and their physicians get pre-authorization before the medication that best treats their medical condition will be covered, or requiring that they try other drugs (step therapy) before the preferred medication will be authorized.
- In addition, many patients and their physicians are finding that life-saving medications, like epinephrine autoinjectors, Naloxone, and insulin, are in short supply or unaffordable.
- For older off-patent drugs, especially for those prescribed for small patient populations or to treat rare infectious diseases, high drug prices can be life-threatening.

Our organizations, which represent more than 560,000 physicians and medical students, believe that it's imperative that policymakers come up with solutions to rising drug prices and shortages of vital medications. Our members are the nation's frontline physicians, providing care to individuals and families in communities large and small, urban and rural. They see first-hand how devastating it can be to their ability to help their patients maintain and improve their health, when needed and often life-saving medications are simply unaffordable or unavailable to them. The barriers to care created by rising drug prices also are undermining the patient-physician relationship, as physicians are sometimes forced to prescribe less effective medication to their patients because the preferred and most effective drug is unaffordable, unavailable, or not covered by the patient's insurer. In addition, insurers are implementing cost-containment measures, like prior authorizations or step therapy, that create unnecessary burdens on both physicians and patients.

Key facts

- A recent study found that between 2002 and 2013, the price of insulin increased dramatically, with the typical cost for patients increasing from approximately \$40 a vial to \$130. As a result, according to a published report on the new study “a surprisingly large number of people with diabetes are using less insulin than prescribed because of the rising cost of the drug, putting themselves in danger of serious complications. Those are the findings of a small new study by researchers at Yale University, who found that at one clinic in New Haven, Conn., one in four patients admitted to cutting back on insulin use because of cost.”ⁱ
- A new study found that “Prescription drug shortages may result in substitution of less effective drugs, delays in necessary treatments, and omission of or reductions in doses. These shortages cause an estimated \$230 million in additional costs each year because of the rising prices of drugs under shortage and the higher costs of substitute drugs.”ⁱⁱ
- A report by the Senate's Homeland Security and Governmental Affairs Committee found that “The prices of many of the most popular brand-name drugs increased at nearly ten times the cost of inflation from 2012 to 2017. . . Prices increased for every brand-name drug of the top 20 most-prescribed brand-name drugs for seniors in the last five years. On average, prices for these drugs increased 12 percent every year for the last five years—approximately ten times higher than the average annual rate of inflation. Twelve out of the 20 most commonly prescribed brand-name drugs for seniors had their prices increased by over 50 percent in the five-year period. Six of the 20 had prices increases of over 100 percent. In one case, the weighted average wholesale acquisition cost for a single drug increased by 477 percent over a five-year period.”ⁱⁱⁱ
- Generic drugs, which usually are expected to offer a lower-priced competitive alternative to bioequivalent brand name drugs, are also experiencing major price increases. A study in the October issue of Health Affairs shows that the portion of generic drugs that at least doubled in price, year-over-year, represents a small but growing share of the market: from one percent of all generic drugs in 2007 to 4.39 percent in 2013. “For consumers, this can mean soaring costs to purchase some drugs that are life-savers, sparking public outrage and leading many to question whether the market — which has historically functioned well — is still working.”^{iv}

- According to an article published in the Journal of General Internal Medicine, between 2010 and 2015 300 off-patent drugs experienced price increases of 100 percent or more, and some drugs were sold at 5500 percent higher than in previous years.^v

The solutions to rising drug prices, higher out-of-pocket expenses, limits on coverage, and shortages of vital medications are complicated. Yet there is a growing consensus that systematic problems in the marketplace for drugs are contributors; including a lack of transparency in the pricing and in the research and development costs for new and existing drugs, inadequate competition, lack of price negotiation, and insufficient numbers of suppliers and manufacturers. In addition, there is a lack of transparency regarding the causes of drug shortages and, in some cases, insufficient financial incentives to maintain adequate drug supply.

Principles

Our organizations offer the following principles to address the problems of high drug prices and shortages of needed medications:

1. *Policymakers and stakeholders should commit to the shared objective of ensuring that every patient has access to the medications that are most effective for their medical conditions, at a cost that they, and the overall health care system, can afford; including developing solutions to ensure a sufficient supply of drugs to treat patient populations.*
2. *Specific characteristics of the market for prescriptions that the evidence suggests are contributing to excessive pricing and lack of affordability should be examined, and policy solutions implemented to address such characteristics, including:*
 - A. *For new drugs, manufacturers typically are not transparent on why the medication is priced at a particular level and the research, development, and marketing costs that contribute to the price, or for drugs already on the market, why the price for an existing drug is being increased. In particular, the prices of numerous drugs have increased years after coming to market, without transparency on why prices are being raised and the justification for them.*
 - B. *Lack of competition in the marketplace among brand name manufacturers, and from and among generic manufacturers, especially for brand-name and generic sole-source drugs. Industry practices that may inappropriately limit competition should be examined. While providing for intellectual property protection is important to encourage innovation and introduction of medical advancements, industry practices that may inappropriately extend exclusivity to limit competition should be examined and addressed.*
 - C. *The roles of regulatory agencies, payers, and pharmacy benefit managers (PBMs) in encouraging or discouraging competition, value and fair pricing of medications should be examined.*
 - D. *In determining which drugs will be covered and included on approved formularies, and the requirements that patients and their physicians must comply with in order to*

secure authorization for needed drugs, PBMs and payers should avoid imposing unnecessary administrative burdens that interfere with the patient-physician relationship and impede patients' access to needed medications.

3. *Current law essential benefit requirements, which require that qualified health plans include coverage of prescription drugs, should be maintained; sales of plans that do not include such coverage should not be allowed.*
4. *Solutions to the problems of high drug prices, lack of affordability, and shortages of vital medications should consider the United States' acknowledged global leadership in investing in research, development, and innovation to bring forward new and life-saving medications to market, while recognizing that the benefits of such research and development are undermined if the medications brought to market are unaffordable to those who need them and to the overall health care system, if prices do not moderate through the life-cycle of the drug, and if there are shortages of such drugs.*

Our organizations are committed to working on a non-partisan basis with Congress, the Administration, and with public and private payers, PBMs, researchers, and manufacturers to develop and implement solutions to ensure that every patient has access to the medications that are most effective for their medical conditions, at a cost that they, and the overall health care system, can afford.

ⁱ <https://www.nytimes.com/2018/06/22/well/diabetes-patients-at-risk-from-rising-insulin-prices.html>

ⁱⁱ Hernandez I, Sampathkumar S, Good CB, Kesselheim AS, Shrank WH. Changes in Drug Pricing After Drug Shortages in the United States. *Ann Intern Med.* [Epub ahead of print] doi: 10.7326/M18-1137

ⁱⁱⁱ <https://www.hsgac.senate.gov/media/minority-media/breaking-brand-name-drugs-increasing-at-10x-cost-of-inflation-mccaskill-report-finds>

^{iv} <https://news.usc.edu/149667/do-price-spikes-on-some-generic-drugs-indicate-problems-in-the-market/>

^v <https://link.springer.com/article/10.1007/s11606-018-4372-3>