High-priced specialty drugs: Exposing the flaws in the system

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Credit: Eva Bronzini from Pexels

My husband, Andy, has Parkinson's disease. A year ago, his neurologist recommended a new pill that he was to take at bedtime. We quickly learned that the medication would cost US$1,300 for a one-month

supply of 30 pills. In addition, Andy could obtain the drug from only one specialty pharmacy and would have to use mail order.

This was our introduction to specialty drugs.

These medications are becoming increasingly common, though many Americans are unfamiliar with the term. In 2018, the Food and Drug Administration approved 59 new medications, of which 39 are considered specialty drugs.

Specialty drugs are generally high-cost drugs requiring special handling such as refrigeration or injection, though Andy's did not. They treat complex conditions such as cancer and multiple sclerosis.

Specialty drugs are often available only through specialty pharmacies. In addition to filling prescriptions, these outlets provide educational and support services to patients. For example, they provide refill reminders and help patients learn how to inject their drugs.

In a forthcoming article, professor Isaac Buck and I argue that specialty drugs raise significant legal and ethical questions. These merit attention from the public and policymakers.

Specialty drug concerns

First, the term "specialty drug" is somewhat elusive and has no clear definition. In addition, government authorities and medical experts are not the ones who decide whether a medication is designated a specialty drug. Rather, the decision is entirely up to pharmacy benefit managers, or PBMs.

PBMs administer health plans' drug benefit programs and thereby serve insurers. PBMs have been criticized for driving up health care costs.

Drugs that are specialty drugs under one insurance policy are sometimes classified differently in other policies. Furthermore, some specialty drugs are simple pills that do not involve complicated instructions, and thus, it is unclear why they are categorized as specialty drugs.

The second problem is the very high cost of specialty drugs. The average price tag of the more than 300 medications that are considered specialty drugs is approximately $79,000 per year. Almost half of the dollars that Americans pay for medications are spent on specialty drugs. In fact, Medicare spent $32.8 billion on specialty drugs in 2015.

Because of these exorbitant costs, some insurers have created what they call a "specialty tier" in their health plans. In this tier, patients' cost-sharing responsibilities are higher than they are for medications in other tiers. If your drug is placed in a specialty tier, your coinsurance payment, or the percentage of cost that you pay, may be 25% to 33% of the drug's price.

This leads to a situation in which you may have the least generous insurance coverage for your most expensive drugs. Under some plans you might pay $10 per month for generic drugs but hundreds of dollars per month for specialty drugs. This can translate into many thousands of dollars in annual out-of-pocket costs, even for consumers with good health insurance. There are no federal regulations in the U.S. that limit drug prices or insurers' tiering practices.

Conflict of interest and patient choice

A third problem is conflict of interest. PBMs own or co-own the top four specialty pharmacies in the U.S., which are responsible for two-thirds of nationwide specialty drug prescription revenues.

PBMs frequently require patients to purchase their medications from the

specific specialty pharmacy that they own. Thus, PBMs have much to gain from designating medications as specialty drugs. Doing so may lead to significant revenues in the form of purchases at PBM-owned specialty pharmacies.

A related problem is the limiting of patient choice. Many specialty pharmacies fill prescriptions only through mail order. Consequently, patients may be restricted to using just one pharmacy and be forced to rely on the mail for delivery.

Some patients enjoy the convenience of home delivery. Others, however, prefer the traditional approach of visiting a drugstore in person. They may worry that the mail will be late, their package will be stolen, or they will be out of town when the drugs arrive. Yet, such patients do not have the option of a brick and mortar pharmacy.

Possible corrective measures

Both political parties have stated that health care costs are a priority for them. However, they have shown a limited appetite for tackling this herculean problem.

The House recently passed a bill that would enable the federal government to negotiate prices with drug manufacturers. Such negotiations could well lower specialty drug prices. The Senate, however, is unlikely to approve the bill, and Congress is unlikely to pass sweeping legislation in a divisive election year.

There has been more success at the federal level in promoting consumer choice. Medicare rules establish that Medicare plans may not force participants to use mail-order pharmacies.

In the meantime, individual states offer useful solutions. For example,

some have provided patients with relief in the form of capping out-of-pocket costs. California limits consumers' expenditures to $250 or $500 for a 30-day supply, depending on the drug type.

At least 15 states also have pharmacy choice statutes. Several ban PBM mandates that prevent patients from freely selecting their preferred qualified pharmacy. Many ban mail-order only requirements.

Some states have recognized that PBMs should not be entirely free to designate medications as specialty drugs. Because such designations can significantly disadvantage patients and may increase patients' costs, such states have statutory definitions for the term "specialty drug."

They generally mandate that the drug require special administration, delivery, storage or oversight. Such requirements may justify purchase from a specialty pharmacy. However, drugs without complicated instructions should not be deemed specialty drugs.

One more option that some insurers have already adopted is allowing patients to obtain just a few pills or doses for an initial trial period. Sometimes individuals quickly learn that they cannot tolerate a medication or that it is ineffective. Such "partial fill" programs can spare patients the exorbitant cost of a full 30-day specialty drug supply.

Specialty drugs contribute significantly to the American health care cost crisis. Additional state, or better yet, federal laws should be enacted to constrain PBMs' authority over specialty drugs. We need further regulation concerning drug classification, pricing, conflicts of interest and patient choice.

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