A Misguided Solution to Drug Prices

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The Trump administration has made important progress in loosening the federal government's grip on private health insurance, freeing up more options for affordable health insurance. But the administration has veered off this free-market track with its recent proposal to, among other things, slap a form of imported price controls on a specific class of prescription drugs in Medicare.

To its credit, on larger health reform issues the administration recently offered new guidance that will allow states more flexibility in overseeing coverage supported by Obamacare funds, and it has proposed a new rule that could give up to 10 million small business employees the ability to receive a defined contribution to purchase coverage of their choice through Health Reimbursement Arrangements.

This builds on action by Congress, which removed the penalties for not purchasing often prohibitively expensive Obamacare-mandated health coverage and lifted some taxes that were adding to the cost of policies and inhibiting innovation in medical technology.

While there was too little discussion of these free-market solutions during the 2018 general campaigns, they have been a breath of fresh air after the Obama administration's suffocating regulatory cloud over the health insurance market.

So it was all the more surprising when the Trump administration announced last month that it plans to make major changes to Medicare payment for drugs reimbursed through Part B of the program. (Part B pays for drugs generally administered in physicians' offices and hospitals as opposed to Part D, which covers drugs purchased at the pharmacy.)

HHS issued an Advance Notice of Proposed Rulemaking announcing a demonstration project to experiment with lower payment rates for Medicare Part B. The new rates will be calculated using a basket of prices from 14 countries that are "economically similar" to the U.S. to effectively import their price controls on these medicines. The Center for Medicare and Medicaid Innovation (CMMI) will administer the program through demonstration projects that will account for half of Part B spending.

This new International Pricing Index model for Medicare Part B drugs will be based on the average price paid for these drugs in the U.K., France, Greece, and 11 other countries to develop a target price.
The government sets the prices for pharmaceutical products in all of these countries, and access, especially for new drugs, is often severely limited as a result.

A recent report by the Assistant Secretary for Planning and Evaluation at HHS found that the average price paid in these countries for 27 of the most commonly administered drugs covered by Medicare Part B was 80 percent lower than the average price for the same drugs in the U.S., and in one instance seven times lower.

CMS will pay vendors the new target price established for a drug, equal to 126 percent of the average price paid for the drug in these other countries. The administration says that this would still be a fair price, above the prices paid by these other countries, with only a marginal revenue reduction to pharmaceutical companies.

But this is a foot-in-the-door for price controls that have decimated the pharmaceutical industries in other countries. Democrats in Congress can be counted on to drive a price-controlling truck through this small opening. Sen. Bernie Sanders (I-VT) recently announced plans to introduce a bill that would strip companies of patent rights if they charged prices that exceeded median prices in Canada, the UK, France, Germany and Japan.

Investment in drug research will diminish when companies face the prospect of even further price cuts down the road, likely cutting returns to below break-even levels. It will deter investment in long and risky drug trials, with fewer cures discovered for new treatments in the future.

The rest of the world relies on drug companies in the U.S. for the majority of the advances in pharmaceutical development. For more than 30 years, the U.S. biopharmaceutical industry has been the world leader in the development of new medicines. The biopharmaceutical industry invested an estimated $90 billion in research and development in 2016. Other countries have crippled their research-based pharmaceutical industries by refusing to pay for the investment required in bringing new drugs to market — an estimated $2.6 billion and up to 15 years for each new drug introduced in the U.S.

Drug companies must bow to the prices demanded by foreign governments or walk away, thereby denying the

new treatment to patients who need them. Of the 74 cancer drugs launched from 2011 to 2018, 95% are available in the U.S., but only 74% in the U.K. and 8% in Greece.

Patients are denied access to these newer, often much more effective drugs because their governments won't pay. If the drug company refuses to take the rock-bottom price the country's health minister is offering, these countries can threaten to make copies of the drug and violate the company's patent under "compulsory licensing" policies. The company's investment in this intellectual capital goes up in smoke.

Because the companies cannot charge a market-based price in these other countries for their products, prices are higher in the U.S., reflecting more of the drug development costs.

President Trump, who announced the Part B proposal in a speech at HHS, said he wants to put a stop to the "global freeloading" by foreign nations on prescription drugs. "Americans pay more so other countries can pay less," he said. "It's wrong. It's unfair."

But experts dispute the President's charge of "global freeloading."

"He is fundamentally wrong on that," Craig Garthwaite, director of healthcare at Kellogg School of Management at Northwestern university, told Newsweek. Garthwaite attributes higher drug prices in the U.S. to laws that protect intellectual property and to the higher purchasing power of Americans, relative to citizens of other countries, making our domestic market willing to spend more money on quality and biomedical innovation. Garthwaite expressed concern that the CMS proposal could lead to a significant decrease in innovation in U.S. pharmaceutical innovation.

The administration says that drug companies will need to demand that other countries pay higher prices for their drugs since the U.S. is paying less. But what incentive do other countries have to negotiate higher prices with drug companies? It's hard to see any.

Larger international trade negotiations are the right place to have conversations about how to better equalize prices. There, the U.S. government has leverage that individual companies do not have in demanding that other countries pay a larger share of drug development costs.

In addition, we don't believe the Center for Medicare and Medicaid Services has the authority to implement such a sweeping Medicare payment change without legislative approval from Congress. As Doug Badger has written,

> Congress established CMMI in the Obamacare statute with the goal of finding ways to reduce federal spending on medical care without diminishing its quality. That, of course, is the responsibility of Congress, which created the Medicare program and which alone bears responsibility for making legislative changes to it.

Medicare currently pays for Part B drugs based on the average sales price of the drug in the private market, with an added payment to physicians for administering the drugs. The formula is based on law, enacted by Congress.

Constitutional law authority Michael A. Carvin wrote about similar flaws in an earlier Obama administration Part B demonstration project:

> CMMI's revision of congressionally-mandated reimbursement standards is a naked attempt to grab core legislative authority by vesting the power of the purse and the law-making power in the Executive Branch... the Executive Branch of government cannot unilaterally revise or ignore express requirements for the amount of reimbursement that providers are entitled to under a law duly enacted by Congress and signed by the president.

Another part of the administration's new plan would have private vendors acquire, store, and distribute Part B drugs for physicians and hospitals. This is another puzzling feature that is contrary to other administration plans to reduce the costs added by middlemen. Congress created a similar program, the Competitive Acquisition Program, under the Medicare Modernization Act of 2003, using vendors to acquire drugs for distribution to providers, but it failed to gain traction.

Here's a better idea: Amgen just cut its list price by 60% for Part B biologic Repatha, significantly lowering out-of-pocket costs for this drug that can control cholesterol for patients at a high risk of heart attack and stroke and for whom traditional statins don't work. This was a market-based solution in response to demand from consumers and health plans.

The administration's latest move will significantly deter companies from looking for creative ways to lower their prices and increase market share. The Part B price-control announcement is a sledge hammer borrowed from European price controllers and is not the bottom-up competitive solution that is the foundation of so many other promising administration proposals.

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