CITIZENS AGAINST GOVERNMENT WASTE

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Centers for Medicare and Medicaid Services
Department of Health and Human Services
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Attention:

CMS-5528-ANPRM
Soliciting public comments on utilizing international price controls in Medicare Part B.

Background

Citizens Against Government Waste (CAGW) is a private, nonpartisan, nonprofit, organization representing more than one million members and supporters nationwide. CAGW's mission is to eliminate waste, mismanagement, and inefficiency in the federal government. Founded in 1984 by the late industrialist J. Peter Grace and syndicated columnist Jack Anderson, CAGW was established to follow up on the work of the President's Private Sector Survey on Cost Control, also known as the Grace Commission.

For centuries, governments around the world have tried to control the prices of goods and services. These efforts have disrupted the marketplace and created shortages or excesses. The Council of Economic Advisers (CEA) wrote in their February 2018 report, "Reforming Biopharmaceutical Pricing at Home and Abroad," that "foreign governments, which are the primary buyers in their respective pharmaceutical markets, force drug manufacturers to comply with pricing rules to gain market access. Through this leverage, foreign governments are able to set drug prices below those that prevail in the United States and erode the returns to innovation manufacturers might otherwise see from selling in their markets."

Adopting international price controls is a deeply flawed proposal that has been pushed by many politicians in an erroneous effort to drive down drug costs. It would run contrary to the deregulatory achievements of the Trump administration, which have saved $23 billion from 176 actions in fiscal year 2018. Indeed, it could undermine this impressive progress by reversing the growth of government controls over industry and the economy that were rampant throughout the Obama administration.

Comment

President Trump stated in his October 25, 2018 remarks about the proposed rule that his administration was "taking aim at the global freeloading that forces American consumers to subsidize lower prices in foreign countries through higher prices in our country." The President

was correct when he said, "Americans pay more so that other countries can pay less" and that "The American middle class is effectively funding virtually all drug research and development for the entire planet. So, we are paying for it. We are subsidizing it. Everybody else is benefitting. And they are paying nothing toward research and development. The world reaps the benefits of American genius and innovation, while American citizens — and especially our great seniors, who are hit the hardest — pick up the tab. But no longer."

But, instead of addressing the problems that foreign countries cause with respect to drug pricing and market access that the CEA discussed in its February report, the proposed rule veers wildly off course and essentially adopts foreign price controls. Reimbursing providers in Medicare Part B based on international prices would be devastating to biopharmaceutical innovation in the U.S. It would also pave the way to price controls in Medicare Part D and within the private sector.

While Medicare Part B is not a true market-based payment system for drugs and could use reform, basing reimbursement on internationally-set price controls is not the answer. Medicare Part B uses a "buy and bill" under which the provider purchases the drug and then bills Medicare when the drug is dispensed. The payment is tied to the average sales price (ASP) after rebates, discounts, and any other price decrease, plus 6 percent of the ASP to cover provider handling and administration costs. Currently, the add-on payment for providers is at 4.3 percent due to the 2011 budget sequester.

An August 2017 *Health Affairs* policy brief, "Medicare Part B," by Cole Werble, stated that ASP-based reimbursement encourages providers to prescribe products with a higher ASP to capture a larger spread, and that helps to determine pricing policies in the private market.

An October 26, 2018, American Action Forum policy paper by Tara O'Neill Hayes pointed out that while there have been concerns the ASP add-on incentivizes providers "to use more expensive drugs to increase the amount of their add-on payment," this would only occur with certain drugs. For example, when generics are available, the calculated ASP includes all manufacturers' drugs, so providers would be more likely to utilize a generic since the add-on would be based on the average price.

However, Hayes noted that when it comes to therapeutic alternatives, where at least two single-source drugs may be involved, or when there are biosimilars available, providers could be more inclined to prescribe the higher-priced therapeutic alternative or the innovator's biologic drug as opposed to the biosimilar. This is why CAGW opposed grouping all biosimilars under the Centers for Medicare and Medicaid Services'(CMS) single Healthcare Common Procedure Coding System. Biosimilars may be approved for one or different indications than their reference product, leading to unintended off-label use. As a result, due to a lack of assurance that all products under one code share indications, physicians may be impelled to continue to use the higher-priced reference biologic drug than a biosimilar.

The proposed rule would test a pilot program that would supposedly lower the cost of drugs by phasing down the Medicare payment amount for selected Part B drugs (initially single source drugs, biologicals, and biosimilars) to more closely align with international prices. The model would operate over a period of five years, starting in 2020. It would allow private-sector vendors

to negotiate prices for the drugs, take title to drugs, and compete for physician and hospital business. It would change the current post-sequester 4.3 percent add-on payment to physicians for handling and administering the drug back to the historical 6 percent set payment amount.

CAGW is concerned that the Centers for Medicare and Medicaid Innovation (CMMI) is leading the charge on this proposed rule. CMMI, which is not subjected to annual appropriations and has been funded with $10 billion per decade in perpetuity, has been given board authority to test all kinds of payment models with little transparency or congressional oversight. It is not required to follow the official rulemaking process and has waived Medicare requirements. It has inserted itself between patients and doctors and wasted valuable tax dollars.

The pilot program includes "selected geographic areas" that amount to 50 percent of Medicare Part B spending, and participation of physician practices and hospital outpatient departments would be mandatory. This number of participants is far larger than any pilot program should be, and it will influence Medicaid drug rebates and payments across the country, further distorting the pharmaceutical marketplace.

The CEA February 2018 report recognized other nations free-ride and take advantage of American financed innovation and provides a warning, that must be heeded, on the impact of price controls on research and development. The report states:

> Meaningful reforms could address the free-riding that takes unfair advantage of American innovation, whether through enhanced trade policy or policies that tie public reimbursements in the United States to prices paid by foreign governments that free-ride or other methods. Meaningful reforms would address the root of the problem: foreign, developed nations, that can afford to pay for novel drugs, free-ride by setting drug prices at unfairly low levels, leaving American patients to pay for the innovation that foreign patients enjoy. Since these nations benefit from the innovations regardless of the costs to Americans, they currently have no reason to raise their own prices and exploit the fact that novel drugs are already invented. If the United States had adopted the centralized drug pricing policy in other developed nations twenty years ago, then the world may not have highly valuable treatments for diseases that required significant investment. The United States could take actions that change the incentives for these countries to price drugs at levels that appropriately reward innovation, rather than disproportionately putting that burden on American patients and taxpayers. As in other cases of under-provision of public goods, increased provision towards the public good would be desirable from free-riding parties.

The U.S. appeared to begin this process of reform in the United States-Mexico-Canada Agreement, which acknowledges the importance of biopharmaceutical patents and strengthens enforcement of intellectual property rights. But, if the United States adopts this rule, which utilizes foreign drug-pricing policy, we would soon be traveling down a 20-year path where highly valuable treatments may not be available to address complex diseases such as Alzheimer's, cancer, and autoimmune disorders.

It would be better for the administration to study other CEA-suggested reforms, such as establishing a physician reimbursement system that is not tied to drug prices or "moving Medicare Part B drug coverage into Medicare Part D, where price-competition over drug prices is better structured."

An October 28, 2018 *Wall Street Journal* editorial, "A New Trump Rule Would Impose Foreign Price Controls on U.S. Drugs" stated, "Mr. Trump is right that Europe, Australia and many others are freeloaders on U.S. innovation, and better intellectual property protections in trade deals might help. But that is no reason to repeat their price-control mistake and undermine the reasons the United States is the last, best hope for medical progress."

CMS should abandon the proposed rule and refocus on making other countries pay their fair share of U.S.-financed drug development.

Sincerely,

Thomas Schatz