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Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
P.O. Box 8013  
Baltimore, MD 21244-1850

Attention:  
Docket CMS-4187-P

Proposed Rule that would revise the Medicare and Medicaid programs to require direct-to-consumer (DTC) television advertisements for prescription drugs and biological products to include the Wholesale Acquisition Cost (WAC), or the "list price," of that drug or biological product.

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.

The Food and Drug Administration (FDA) oversees prescription drug advertising. The agency makes sure that the information is "truthful, balanced, and accurately communicated." This is "accomplished through a comprehensive surveillance, enforcement, and education program, and by fostering better communication of labeling and promotional information to both health professionals and consumers." The FDA notes that in the 1990s, pharmaceutical manufacturers began informing consumers, especially maturing baby boomers, about their products to enable them to become more informed and more involved with their own healthcare decisions.

Comments:

The proposed rule will require DTC television advertisements for prescription drug and biological products paid for by Medicare and Medicaid to include the list price, or Wholesale Acquisition Cost (WAC), if it is greater than \$35 for a month's supply or a course of therapy. The WAC will be "conveyed in a legible textual statement at the end of the advertisement, meaning that it is placed appropriately and is presented against a contrasting background for sufficient duration and in a size and style of font that allows the information to be read easily."

According to the Department Health and Human Services (HHS), the 10 most commonly advertised drugs have list prices ranging from \$535 to \$11,000 per month or usual course of therapy.

The supposed purpose of the rule is to reduce prices for prescription drug and biological products. While it is true that markets operate more efficiently when consumers have relevant information, and patients should know the price they will pay for a medical product or procedure that they will utilize, using the WAC in an advertisement will provide misleading, inaccurate, and irrelevant information for them.

Unlike most products, prices for prescription medicines are a result of negotiations among pharmaceutical manufacturers, insurers, pharmacy benefit managers (PBM), employers, wholesalers, and pharmacists. The WAC represents a starting point from which negotiations begin. The PBMs negotiate on behalf of their sponsors, which are payors such as insurance companies or employers, that manage the drug benefit for their customers or employees. Ultimately, the patient pays the price that has been negotiated for them, such as a co-pay or co-insurance, not the list price. With respect to consumers that have a Health Savings Account and have a high deductible, they will pay the full price for many healthcare items and services, including prescription drugs, that have been discounted on their behalf.

Requiring pharmaceutical manufacturers to post the list price of their drugs has been erroneously compared to what happened 60 years when federal action was taken to force car manufacturers to post their sticker prices.

There is a large difference between buying a car and prescription drugs. People who are purchasing a car do not have an intermediary that negotiates on their behalf and pays for a portion of their automobile, like they do with their healthcare and an insurer. Most car buyers have a loan, but they are still paying for the entire cost of the car. Privately-run services such as CarFax, Consumer Reports, Edmunds, and TrueCar provide more realistic pricing than the manufacturer's sticker price.

The Pharmaceutical Research Manufacturers Association (PhRMA), the trade association that represents biopharmaceutical research companies, announced a proposal on October 15, 2018. PhRMA members would voluntarily help patients access more useful information about the cost of their medicines by directing them to a company-created website that would include the list price of a drug and average, estimated, or typical patient out-of-pocket costs, or other background information on the possible cost of their medicine. PhRMA planned for this proposal to become effective on April 15, 2019.

This information would seem to be more in line with what private companies offer, such as Consumer Reports and TrueCar provide for automobiles. CAGW urges CMS to allow this service to be given an opportunity to go into effect before the government intervenes with more control over advertising and pricing.

The proposed rule is “forced speech” and will not get at the root of the pharmaceutical cost problem, which is a distorted pharmaceutical marketplace due to a proliferation of price controls.

Price controlled structures were implemented in 1990 when Medicaid rebates were passed into law and again in 1992 when the VA pricing structure and the 340B discount program were created.

In 2010, under the Affordable Care Act (ACA), or Obamacare, Medicaid rebates were increased from 15.1 percent to as much as 23.1 percent for brand-name drugs and Medicaid was expanded to include abled-bodies adults, beyond its original purpose of helping poor pregnant woman and children, low-income seniors, and people living with disabilities.

Under ACA, Congress instituted price controls in Medicare Part D's coverage gap, more commonly called the donut hole, and required pharmaceutical companies to provide a 50 percent discount. This year, Congress doubled down on this price control by requiring a 70 percent discount, making Part D act less like a private drug benefit insurance plan and more like Medicaid.

Pharmaceuticals are priced controlled across the world with countries threatening to use compulsory licensing or deny marketing access if a pharmaceutical manufacturer does not provide the price that coincides with their single-payor system of price fixing and rationing to control health costs. It is no wonder that Americans are paying the bulk of pharmaceutical research and development.

HHS recognized in the proposed rule that DTC advertising brings benefits. According to FDA [surveys](#), most physicians agreed that because a patient saw an ad, more informative and thoughtful questions were asked about their condition and possible treatments. Only 8 percent of physicians felt compelled to prescribe a specific brand-name drug when asked. This is important because the doctor has the final say on whether the drug should be prescribed and will know whether the drug advertised will be effective for the patient's ailment.

CAGW is concerned that the WAC could deter patients from contacting their physician about a drug, and the medical condition it treats, if they believe the WAC is what they will pay as opposed to a negotiated price.

The proposed rule will not bring down drug costs; that requires greater competition and reduced regulations. HHS has proved it can do this by approving more generic drugs and releasing improved guidance and regulations such as those promulgated for association health plans; short-term, limited-duration health insurance plans; and, Section 1332 waivers. These achievements have given states and citizens more options and encouraged more competition to lower healthcare costs then forcing drug companies to notify consumers of the WAC of certain drugs ever will.

CAGW opposes this regulation and urges HHS not to adopt them as it will not help to lower drug costs. Instead, it will confuse patients about the amount they will pay for a drug.

Sincerely,

*Thomas Schatz*