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Recent Trump Administration Proposals to Lower the Cost of Pharmaceuticals

In mid-October, the U.S. Department of Health and Human Services (HHS) issued what it describes as a "historic plan" to require pharmaceutical companies to disclose drug prices in television advertisements. The proposal, issued through the Centers for Medicare & Medicaid Services (CMS), is part of the Trump administration's crusade to lower the cost of drugs and has garnered great bipartisan support. Building on its efforts, in late October, the administration threw another proposal into the mix that would tie the costs of pharmaceuticals to the prices paid by consumers overseas.

The first proposal would require any pharmaceutical company marketing a drug covered by Medicare or Medicaid with a list price greater than $35 (based on a 30-day supply or typical course of treatment) to disclose the price in commercials. As a softener, HHS allows drug companies to include a disclaimer that states, "If you have health insurance that covers drugs, your cost may be different." Companies are also permitted to reference "an up-to-date competitor product's list price, so long as they do so in a truthful, non-misleading way." These disclosures must be made in an easily readable font that is "placed appropriately" on the screen. HHS plans to post a list of companies that violate the rule. The proposal induces a new layer of transparency expected to pressure pharmaceutical companies to lower prices and to create more informed purchases by consumers, most of whom have no "anchor price" against which to gauge whether what they are paying for medicine is reasonable.

The second proposal would establish an "international index" of the average prices paid for prescription drugs in other industrial countries in order to determine how much to pay for drugs covered by Medicare Part B. The Trump administration believes the proposal will lower domestic drug costs so they are on par with the prices pharmaceutical companies charge to countries with public health care. Currently, the United States pays 80 percent more than other countries per drug. HHS projects that the pricing index will save American taxpayers a total of $17.2 billion over a five-year period. In conjunction with the proposal, the administration plans to develop a new competitive acquisition program and to alter the average sales price model already in effect.

Interestingly, both proposals were issued through CMS – not through the Food and Drug Administration. Although CMS does not directly regulate the pharmaceutical industry, its purchasing power gives it some leverage to control drug prices. The FDA, by contrast, does not have the legal authority to investigate or control pharmaceutical prices. The preamble to the first proposal further explains the connection to the Medicare and Medicaid programs, describing the intent to "reduce the price to consumers of prescription drugs and biological products" and "improve the efficient administration of the Medicare and Medicaid programs by ensuring that beneficiaries

are provided with relevant information about the costs of prescription drugs and biological products so they can make informed decisions that minimize not only their out-of-pocket costs, but also unreasonable expenditures borne by Medicare and Medicaid."

The Pharmaceutical Research and Manufacturers of America (PhRMA) has voiced its opposition to both proposals. PhRMA argues that disclosing sticker prices in television advertisements is misleading and may dissuade prospective patients from seeking medical care out of fear of inability to pay. PhRMA has already advised that it may commence First Amendment litigation if the rule creates an erroneous belief among the public that almost all drugs are unaffordable, because list prices are typically much higher than the out-of-pocket cost for most consumers.

If passed, the rule may increase the number of private litigation suits filed under the Lanham Act for unfair competition based on false advertising. The Lanham Act, a competitor protection law, allows competitors or parties with a commercial relationship to the violator to sue for false advertising. Because drug prices change frequently, pharmaceutical companies may be particularly vulnerable to such suits. HHS's anticipated "wall of shame" will, as intended, give plaintiff attorneys a direct line to targets. If codified into law, the rule will also preempt state law claims based on deceptive practices and false advertisements.

PhRMA also disagrees with the Trump administration's plan to use the international pricing index, noting that "the Administration is imposing foreign price controls from countries with socialized healthcare systems that deny their citizens access and discourage innovation." PhRMA further suggests that the plan could reduce access to life-saving drugs by lowering physician reimbursement. Further, if pharmaceutical companies do not expect a significant profit for developing and producing medications for rare diseases, they may be forced to cut back on research and development in these areas.

CMS is soliciting public comment on both proposals. Comments on sticker price disclosure will be accepted until December 17, while comments on the international pricing index proposal are due by December 24.

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