

# Drug industry on edge for Obama action on prices

Peter Sullivan –The Hill  
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The pharmaceutical industry is anxiously awaiting a series of regulatory actions from the Obama administration aimed at combating high drug prices.

Drug prices have been a major issue on the campaign trail, with **Hillary Clinton**, **Bernie Sanders** and **Donald Trump** pounding pharmaceutical companies.

Martin Shkreli, the ex-pharmaceutical company CEO who made headlines for hiking the price of a life-saving drug by 5,000 percent, also has put the issue of drug prices in the spotlight.

Spending on drugs in 2014 grew by a sharp 13 percent, the most in a decade. The spike was driven partly by new high-cost drugs for Hepatitis C, but it seemed to point to a larger issue.

A Kaiser Family Foundation poll in August found that 24 percent of the public had not filled a prescription in the past year because of cost.

The administration has made it clear it intends to take action this year on the issue.

“We are continuing to try and pursue every administrative option,” Health and Human Services Secretary **Sylvia Burwell** said during a congressional hearing earlier this month.

She said her department is looking at a “wide array” of options.

Drug companies are on edge. They point out that drug spending growth is projected to come back down over the next decade and remains just 10 percent of overall healthcare spending.

“I know they’re worried about it,” said Joel White, the president of Horizon Government Affairs, who lobbies for the Pharmaceutical Research and Manufacturers of America (PhRMA). “There’s not a lot of threat on the legislative side. There’s a major threat on the regulatory side.”

Lobbyists and advocates say that the most likely actions involve new payment models that could reduce the price the government pays for drugs under Medicare.

A hint of the administration's plans came earlier this month when HHS accidentally posted a document online relating to a pilot program making changes to Medicare Part B drug payments.

Medicare Part B, which covers drugs given in doctors' offices, currently pays doctors an additional 6 percent of the price of the drug. The administration, concerned that the system gives doctors an incentive to prescribe higher-priced drugs so that they get paid more, could change how the payments are calculated.

ObamaCare empowers the Center for Medicare and Medicaid Innovation (CMMI) to use this authority.

The expected CMMI payment changes are intended to fit in with the administration's larger approach to move Medicare payments towards rewarding quality care (sometimes known as value-based purchasing) as opposed to simply rewarding the number of procedures provided.

Pharmaceutical companies are concerned that the administration might be going beyond the intended scope of CMMI pilot programs, and that it is not gathering enough feedback before acting, according to an industry source.

While HHS is in touch with pharmaceutical companies, the industry did not know about plans for the Medicare Part B payment changes before the document was posted online, the source said.

Rep. John Shimkus (R-Ill.) pressed Burwell on possible changes at a hearing this week, saying the accidental posting of the document had set off "red flags."

Burwell said HHS would be coming out with more details "soon."

Beyond the pilot programs, there are also more drastic changes being considered, although they are seen as less likely.

A group of more than 50 House Democrats wrote to the administration in January asking HHS to put forward guidelines for exercising rights under a 1980 law. Those "march-in rights" refer to the significant step of breaking a drug patent when the price is too high and not "available to the public on reasonable terms."

Rep. Lloyd Doggett (D-Texas), the lead author of the letter, **pressed** Burwell to take action at a hearing this month.

“Clearly legislation is required, but you and I know that lightning could strike the Capitol dome in the same place not twice but 10 times, and this Congress would not be willing to stand up to the pharmaceutical lobby,” Doggett said. “It is essential that the administration use every tool at its disposal.”

Even more drastically, Senate Finance Committee Chairman **Orrin Hatch** (R-Utah) raised the possibility of an executive order granting Medicare the ability to negotiate drug prices. President Obama has proposed allowing such authority in his budget, but that proposal would require action from Congress.

Lobbyists do not see an executive order as likely, though the administration is not completely ruling out the possibility.

“It’s a near metaphysical certainty that something’s going to happen on the regulatory side on pricing,” said White, the lobbyist. “The question is what?”