President Finalizes Penalty for Drug Companies That Overcharge 340B Hospitals

Soaring prescription drug costs that only seem to go in one direction have beer many people's minds in recent years. President-elect Trump and several fellow Republicans have mentioned the goal of developing policies that would address spiraling medication prices.

And in his final month as commander-in-chief, President Obama is issuing a warning to potentially exploitative drug companie ink.

"Knowingly and intentionally" leads to $5K per instance

The Obama administration recently finalized a rule that will penalize pharmaceutical companies that overcharge healthcare fa for drugs procured through the government's discount program. If the drug companies "knowingly and intentionally" collect mo than allowed through the 340B program, they open themselves up to fines of $5,000 per occurrence, in addition to the obligat reimbursing providers for the overpayment.

Although the rule, in proposal form, was initially released in 2015 (with comments due within the year), Health and Human Se (HHS) was criticized by multiple commenters for failing to clarify what exactly would bring about a penalty and how medicatio costs would be determined. Therefore, HHS ultimately provided a new comment period causing an overall delay in finalizatio

The final rule was released by HHS's Health Resources and Services Administration (HRSA) earlier this month and includes a blueprint for determining "ceiling prices" for outpatient medications, even though some critics claim the department does not possess the necessary authoritative reach to set those costs.

For drug companies that are in the 340B program, the rule will go into effect on April 1st of this year.

Is the 340B program more likely to be misused?

The 340B discount pricing program has been operating since 1992; Congress set it up with the intention of assisting hospitals clinics that care for relatively high percentages of low-income patients. Pharmaceutical companies participating in Medicaid a required to sell those medical facilities outpatient drugs at 20% to 50% less than retail.

There are industry insiders that point to the 340B program as vulnerable to exploitation. The Government Accountability Offic (GAO) conducted an investigation in 2015 and discovered that some 340B-participating facilities were submitting medication to Medicare that were actually steeper than what non-340B facilities were billing for the same drugs. (Because these are outp drugs, they are often dispensed in a doctor's office.)

According to the GAO: "This indicates that, on average, beneficiaries at 340B disproportionate-share hospitals were either

prescribed more drugs or more expensive drugs than beneficiaries at the other hospitals in GAO's analysis."

In own their defense, hospitals criticized the GAO for "faulty methodology" in their investigation and analysis, and further, said they agency failed to consider that 340B facilities are likely to see patients with more serious or chronic conditions than non-3 hospitals.

Although the savings to providers afforded by the 340B program is approximated at around $6 billion for 2015 alone (accordin the HRSA; the savings two years prior to that were roughly $3.8 billion), the program itself is not immune to criticism. An analy by Avalere Health (2014) revealed that around 66% of 340B facilities actually provide less charity care to patients than the av non-340B hospital.

However, a 2015 study by the healthcare consulting firm Dobson DaVanzo & Associates showed that 340B facilities provided services to Medicaid and low-income Medicare patients at a rate of almost two times higher than hospitals not in the program

To cap or not to cap: Does the HHS have the authority to impose price ceiling?

In 2014, a U.S. District Court struck down a 340B rule that would allow healthcare providers to receive discounts on costly "or drugs" intended to treat rare medical conditions in the event the meds were actually being used to treat common conditions. Therefore, the fact that the final rule includes regulations on drug ceiling costs is noteworthy.

In the final rule, HHS acknowledged some commenters' arguments that the government does not possess the requisite autho create regulations that cap prices. The agency ultimately rejected that stance, instead noting that Congress had charged it wit developing a method to come up with a cost ceiling.

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