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Safety-Net Hospital Lobbying Surges as Medicare Slashes Payments

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- Lobbying around drug-discount program hits all-time high
- Medicare payment cuts spark safety-net hospitals' ire

Lobbying related to discounted prescription drugs for hospitals serving the needy spiked in 2017 as safety-net hospitals and their allies voiced concerns about Medicare reimbursement cuts and bills in Congress that would impose new transparency requirements.

Meanwhile, pharmaceutical industry groups supported the transparency measures to ensure oversight of a drug discount program, known as 340B, they say is distorting prices in the health-care marketplace. Under 340B, eligible hospitals can get discounts of from 20 to 50 percent on outpatient medications, and critics of the program say the hospitals are not using the discounts properly to help the indigent as the law creating the program intended.

The fourth quarter of last year saw the most lobbying activity the 340B drug-discount program has ever seen, according to Senate lobbying filings analyzed by Bloomberg Law.

Lobbying filings that mention the 340B program are up almost 14 percent from last year, which was already a high-water mark because of lobbying related to 340B and the 21st Century Cures Act, a 2016 law that aims to spur drug development.

Challenges for Hospitals

The 340B program is growing, which makes it ripe for scrutiny and criticism. A recent House committee report said covered hospitals and clinics saved approximately \$3.8 billion on their outpatient drugs in fiscal 2013, then \$4.5 billion in FY 2014, and \$6 billion during calendar 2015.

Congress is debating a slew of bills, reports, and policy changes that would put the brakes on the drug-discount program. Also, the Centers for Medicare & Medicaid Services has instituted a significant reimbursement cut for physician administered drugs paid to 340B-participating hospitals. The Medicare pay rule was finalized in November 2017 and took effect Jan. 1 this year.

Effective Jan. 1, the CMS reduced the Medicare Part B reimbursement for 340B-obtained drugs, from Average Sales Price (ASP) plus 6 percent to ASP minus 22.5 percent. A hospital representative said that amounts to about a 27 percent pay cut for the 340B hospitals.

Representatives for 340B hospitals told Bloomberg Law that reversing the CMS pay cut remains their highest priority, and they support a bill, H.R. 4392, that would unwind it.

Transparency Bills

Meanwhile, pharmaceutical groups are pushing for other bills, including H.R. 4710 (the 340B PAUSE Act) and S. 2312 (the HELP Act), both of which would increase transparency into the 340B pricing structure.

The Pharmaceutical Research and Manufacturers of America (PhRMA) recently stated that it supports both the PAUSE and HELP Acts to ensure profits from 340B discounted drugs are spent only on vulnerable and uninsured patients.

Richard Sorian, spokesman for the pro-hospital group 340B Health, told Bloomberg Law that, while the group is against the HELP and PAUSE Acts, it wants also to move towards greater transparency for hospitals and drug manufacturers, but Medicare pay cuts aren't the right way forward.

Hospital groups are still hoping that the Health Resources and Services Administration, the part of the Department of Health and Human Services that oversees 340B, will finally implement ceiling price calculations for 340B drugs, which set limits to what drug companies can charge safety net hospitals. They're also waiting for a rule authorizing and detailing civil monetary penalties on drug companies when they charge above those limits.

Meanwhile PhRMA supported HRSA's plan to delay the rules back in September. The civil penalty rule was originally planned to be implemented six years ago.

Criticism of Medicare Payment Change

The Medicare outpatient prospective pay system (OPPS) change that took effect Jan. 1 will cut reimbursements to the 340Bparticipating hospitals by an estimated \$1.6 billion. But the Medicare rule will redistribute that money across hospitals for Medicare Part B outpatient services.

The payment reductions would not affect critical access hospitals, childrens' hospitals, and cancer hospitals.

Shahid Zaman, senior policy analyst for America's Essential Hospitals, told Bloomberg Law that the payment changes are an effective 27 percent cut to Medicare Part B drug reimbursements and that they take issue with the methodology used to justify the cuts.

"Our hospitals are level one trauma centers that treat a disproportionate number of uninsured and operate on thin margins— 3 percent compared to 7 percent for other hospitals—and there's a concern that the cuts will impact life-saving services," he said.

Because they are not part of the 340B program, private for-profit hospitals are not affected. But large non-profit and government-run facilities which tend to serve a higher proportion of low-income patients would see a \$90 million loss according to numbers compiled by Bloomberg Law, and one-quarter of teaching hospitals would see a loss.

As a result, hospitals with a higher share of low-income patients would see less reimbursement. The median disproportionate share patient percentage for hospitals that received more money was less than one-fourth than those that took a loss. Disproportionate share hospitals are a category of hospitals serving a largely low-income population.

A representative for the CMS would not comment on the how payment changes were determined, but in response to comments on the rule the Medicare agency denied that the policy punitively targets safety-net hospitals.

Justin Linder, health-care and life sciences attorney at Dughi, Hewit & Domalewski told Bloomberg Law that 340B is a contentious topic because of the large number of stakeholders, including the pharmaceutical industry and major hospitals, and the ambiguities in the program.

"There are aspects of the program that have not been subject to definitive regulatory guidance from [HRSA], which makes it complicated and confusing for both sides. No one is sure where the boundaries lie and everybody is jockeying for the best position," Linder added.

An Avalere Health study published in January touted a benefit from the payment changes, particularly to rural hospitals. But the report did not look at the effect on teaching, government-run, non-profit, or large urban hospitals.

But according to an analysis by Bloomberg Law, non-critical rural hospitals—those not exempt from the 340B cuts—saw only a small increase, 0.9 percent, which is in line with inflation.

Linder criticized the Avalere study's conclusion about benefits to out-of-pocket costs by the changes.

"Since the savings from the 340B payment reduction are being redistributed dollar-for-dollar in a budget neutral manner, the result is a higher beneficiary copayment liability for services, as opposed to drugs," he told Bloomberg Law.

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