Hospital claims it was ‘drastically’ overcharged by pharma in a federal drug discount program

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ADOBE

For several years, some of the world's largest pharmaceutical companies that participate in a U.S. drug discount program overcharged the federal government and numerous hospitals by hundreds of millions of dollars, according to claims made in a recently unsealed lawsuit.

The allegations, which were made by Adventist Health System, turn on the complicated, behind-the-scenes calculations used to provide medicines to what is known as the 340B program. The federal government program requires drugmakers to offer discounts on all outpatient drugs used by hospitals and clinics that primarily serve lower-income patients.

There are roughly 12,400 hospitals and clinics that participate across the U.S. and their number has grown over the years. As a result, the program has become a big market for pharmaceutical companies, which must agree to sell their medicines at discounts — typically at 25% to 50% — if they want their medicines covered and reimbursed by Medicaid and Medicare Part B outpatient insurance.

The lawsuit, however, charges that a handful of big drugmakers — AbbVie, AstraZeneca, Novartis, and Sanofi and some subsidiaries — disregarded rules for what they could charge 340B hospitals. But only after a new regulation went into effect in January 2019 — which allowed the federal government to levy penalties — did the drug companies appropriately adjust their pricing practices.

Specifically, the lawsuit contends the drug companies sold various medicines at prices that greatly exceeded inflation rates from 2011 through 2018. This occurred even though a regulation went into effect in 2011 that required all drug companies, whose prices surpassed the inflation rate, to subsequently charge just one penny for each unit of a medicine sold to 340B hospitals.

As an example, Sanofi charged Adventist, which is based in California and operates 26 hospitals in four states, anywhere from $71.19 to $88.92 for a package of Lantus insulin. But once the regulation went into effect in early 2019, the company slashed its price to 10 cents per package, or 1 cent per unit. By then, Adventist argued countless other hospitals were grossly overcharged for the medicine.

Another example allegedly involved Byetta, an injectable drug pen for type 2 diabetes sold by AstraZeneca. From 2015 through 2018, the company charged hospitals, as well as Medicare and Medicaid programs, $17.86 for the 5-microgram formulation package.

"Not until the first quarter of 2019 did AstraZeneca begin charging the statutorily mandated penny ceiling price," the lawsuit claims.

In all, Adventist alleged that the drug companies overcharged 340B hospitals and clinics hundreds of millions of dollars and, as a result, countless false claims were submitted to the Medicaid and Medicare programs. An exact dollar amount was not stipulated, however, because 340B purchase data is not public, so Adventist was unable to more specifically quantify the alleged overcharging.

"Some of the largest drug manufacturers in the world … drastically increased the prices for many of their drugs far in excess of the rate of inflation for many years," the lawsuit argued. "Instead of following the very simple statutory formula, [the companies] knowingly disregarded the formula." Adventist originally filed its lawsuit as a whistleblower, but the Department of Justice declined to join the case.

The failure to follow the penny pricing policy was noted in a report issued in 2006 by the Office of Inspector General of the U.S. Department of Health and Human Services and again in 2011 in a report released by the U.S. Government Accountability Office. Both agencies maintained the Health Resources and Services Administration, which is part of HHS, should have bolstered oversight.

We asked the drug companies for comment and will update you accordingly. But in court filings, the companies denied the allegations. Among several points, they argued that penny pricing was not mandatory until the Health Resources and Service Administration, which oversees the 340B program, issued a guidance in 2019. Since then, the companies insisted they complied with the law.

The lawsuit illustrates various problems with the opaque pharmaceutical pricing system in the U.S., but whether Adventist can successfully argue that the federal government overpaid remains to be seen, according to Ameet Sarpatwari, the assistant director of the Program on Regulation, Therapeutics, and Law at Brigham and Women's Hospital and an assistant professor at Harvard Medical School.

"The case offers a window into the long-standing dysfunction of the pharmaceutical market, including skyrocketing drug price increases, widespread non-compliance with laws and regulations, and the fleecing of government payors, while foreshadowing the continued erosion of the 340B Program that will occur without [heightened] enforcement powers," he wrote us.

"The allegations point to a plausible, troubling, willful disregard of Congress's clear intent. However, whether that is sufficient to meet the high bar required for a violation of the False Claims Act is a different matter."

This is only the latest controversy surrounding the 340B program.

Established in 1992, the 340B program was created with the intention that hospitals would reinvest savings from discounted drug purchases in order to improve care for low-income and uninsured patients. But the program has ballooned over the years as more hospitals and clinics participated. Drugs purchased through the program reached $53.7 billion in 2022, an 18% increase from the previous year.

Consequently, the program has generated increased scrutiny. Some hospitals have been accused of abusing the program and diverting cash flows to other uses. A 2014 analysis found hospitals used profits generated by purchasing discounted medicines to open clinics in more affluent areas. Such concerns have prompted lawmakers to call for more guardrails requiring hospitals to account for their savings.

Meanwhile, more than two dozen drug companies over the past two years have limited discounts when hospitals or clinics bought medicines and then shipped them to contracted retail or specialty pharmacies for patients to pickup or for delivery, instead of using their own in-house pharmacies. The drug companies, which have filed various lawsuits, alleged that using contract pharmacies led to abuses, such as duplicate billings.

In this context, the lawsuit may be seen as an attempt by a major hospital system to not only address improper practices by drug companies, but also argue that the pharmaceutical industry is the real culprit when it comes to taking advantage of the program, according to Antonio Ciaccia, who heads 3 Axis Advisors, a consulting firm that tracks prescription drug pricing.

"The well-known opacity, complexity, and vague governance of the 340B program naturally lends itself to uncertainty and waste. You can add lawsuits like this to the mountain of reasons to create greater clarity, guardrails, and accountability within the 340B program," he wrote us.

"Without taking sides on the legitimacy of the suit itself," Ciaccia continued, "considering the massive expansion of the 340B program and the subsequent growth of the spreads harvested by covered entities from that expansion, the claims of financial harm and ruin from hospitals would appear to be more theatrical in nature than grounded in reality."

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