



## 340B litigation update: Both Ceiling Price Rule delay and 340B rate cuts face legal challenges

October 8, 2018

On September 11, 2018, the American Hospital Association (AHA) and other major health care industry groups [sued](#) the Department of Health and Human Services (HHS), seeking to have the U.S. District Court for the District of Columbia force HHS to implement the long-delayed Ceiling Price Rule. The rule sets out the process for calculating the ceiling price of 340B drugs and allows HHS to bring monetary penalties against drug companies that overcharge for 340B drugs.

The lawsuit claims that HHS has “unlawfully delayed” putting the Ceiling Price Rule into effect, since HHS issued a final rule in January 2017.

The AHA also brought (in conjunction with other health care industry groups) another lawsuit against HHS. On September 5, 2018, the group [filed a lawsuit](#) again challenging HHS’s authority to cut the Medicare reimbursement rate for 340B purchased drugs. The first iteration of this lawsuit, which was filed November 13, 2017, was [dismissed](#) on July 17, 2018. The U.S. Court of Appeals for the District of Columbia Circuit found that the plaintiffs had not been actually harmed by the rate reduction, as at the time the lawsuit was filed, the reduction had not yet gone into effect. Hospitals, therefore, had not presented any claim for the reduced reimbursement nor received a final administrative decision regarding such a reimbursement claim. Under the September 5, 2018, suit, the parties claim that they now have standing based on evidence of actual harm from the reimbursement reduction beginning January 1, 2018.

For more information on this and other 340B issues see our earlier publication outlining [340B Program updates](#).

# Authors

---

Copyright © 2023 Bricker & Eckler LLP. All rights reserved.