

Modern Healthcare

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White House reviews rule for 340B dispute resolution

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The move comes amid heated conflict in recent months between providers and drugmakers.

The White House budget office is reviewing a final rule that could establish a long-awaited dispute resolution process for the 340B drug discount program.

The move comes amid heated conflict in recent months between providers and drugmakers over providers' use of contract pharmacies. Community health centers [sued last month](#) to force HHS to expedite creation of such a process, as providers have limited ability to directly sue drugmakers in court.

The National Association of Community Health Centers said HHS' decision to advance rulemaking validates its lawsuit, but the group still wants more direct action against drugmakers.

"We do not agree that simply reviving a highly-criticized proposed rule withdrawn several years ago will suffice to cure the significant harm caused by drug manufacturers' brazen refusal to make 340B drugs available to Federally Qualified Health Centers," NACHC spokesperson Amy Simmons Farber said.

The dispute resolution process proposed in 2016 would allow covered entities to force drugmakers into a process that would result in final, binding decisions by the agency. The establishment of the process would likely be a win for covered entities, though the timing of the rule may leave it vulnerable to the whims of an incoming Biden administration.

"Where the rule that is apparently now with OMB ends up will still likely have several more hurdles to clear before it is ever finalized and becomes effective," said K&L Gates partner and healthcare group co-leader Richard Church.

The Affordable Care Act directed HHS to establish a dispute resolution process for providers and drugmakers in the 340B program, but regulatory action has stalled so far. The [White House budget office's website](#) said the rule was received Tuesday.

The Health Resources and Services Administration has said it is [evaluating drugmakers' crackdowns](#) but has not yet made a determination on their legality. Congressional lawmakers on both sides of the aisle have urged HHS to curtail drugmakers' attempts to limit covered entities' use of contract pharmacies.

Pharmaceutical companies have [appeared to be testing](#) how far they can challenge subregulatory guidance issued by the Health Resources and Services Administration that allows 340B providers to receive discounts while working with multiple contract pharmacies. If the trend continues at its current clip, the limitations on discounts could have a big impact on some covered entities' finances.

Inline Play

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