The Department of Health and Human Services is expected to soon release its final 340B administrative dispute resolution rule after the White House completed its final review this week.

White House Completes Review of Final Rule for 340B Dispute Process, Release Expected Soon

April 11, 2024 Rich Daly (https://340breport.com/author/richdaly/) Editor in Chief

After missing its self-imposed deadline of the end of 2023, the White House this week completed its review to implement the Administrative Dispute Resolution (ADR) process.

On April 8, the White House's Office of Management and Budget (OMB) finished its review (https://www.reginfo.gov/public/do/eoDetails?rrid=341661) of the final rule to implement the 340B ADR process, which is the last stage of regulatory review before public release. OMB began its review nearly 6 months ago on Oct. 16.

(https://rxstrategies.com/?utm_source=340breport&utm_medium=in-article&utm_campaign=brand&utm_id=brand)

Regulatory observers said they expect publication of the final regulation within days or a couple weeks.

First authorized by the Affordable Care Act (ACA) in 2010, the Health Resources and Services Administration (HRSA) ADR process aims to address disputes between providers and drug manufacturers that arise under the 340B program.

The Biden administration said in December in its agenda of forthcoming regulatory actions that it planned to publish (https://340breport.com/340b-dispute-resolution-coming-this-month-white-house-says/) the ADR final rule before the end of 2023. The timelines for rules are specified in the OMB unified agenda but administrations are not required to adhere to them.

The ADR rule has a long, winding history. The Obama administration was supposed to finalize the rule soon after the ACA was enacted but it took another 10 years for HRSA to finalize the rule late in the Trump administration.

Two trade groups, Ryan White Clinics for 340B Access (RWC-340B) and the National Association of Community Health Centers (NACHC), sued (https://340breport.com/white-house-clears-340b-dispute-resolution/) the Trump administration to require it to finalize the ADR rule.

The Biden administration scrapped the Trump administration's ADR rule and in November 2022 (https://340breport.com/breaking-hrsa-proposes-streamlined-less-trial-like-340b-dispute-resolution-process/) issued a new proposed rule to implement it.

Drug manufacturers have tried to block implementation of the ADR rule with some success (https://340breport.com/breaking-federal-judge-grants-lillys-motion-to-halt-340b-dispute-resolution-system/) in federal courts. In March (https://340breport.com/breaking-federal-judge-grants-lillys-motion-to-halt-340b-dispute-resolution-system/) 2021, a federal judge in Indianapolis granted Eli Lilly's motion for a preliminary injunction preventing the Health and Human Services Department from implementing or enforcing the ADR rule against Lilly. That ruling stays in place as Lilly and the federal government await a decision in a federal appeals court regarding whether the company's contract pharmacy restrictions are permissible.

ADR's Increased Importance

The ADR process took on increased significance with a federal judge's November 2023 ruling in a health center's lawsuit against HRSA, Genesis Health Care v. Becerra. That ruling by Chief Judge R. Bryan Harwell found that the plain wording of the 340B statute does not require a covered entity to have initiated a healthcare service resulting in a prescription filled with a 340B drug. Harwell's ruling also described the ADR process as HRSA's key way to address issues like the 340B patient definition and contract pharmacy restrictions, rather than through guidance or having courts decide them.

The importance of having a well-functioning ADR process was underscored by the Supreme Court's 2011 landmark decision in Astra v. Santa Clara County, according to Stephen Kuperberg, a partner at Feldesman Leifer, who represents 340B covered entities. When the court ruled covered entities did not have standing to sue manufacturers directly for violating 340B ceiling prices, "the court relied upon an assurance by the government that the government would finalize in a matter of months the [ADR] rules that Congress had mandated the government finalize by September 2010," he previously told 340B Report.

Final Rule Approach

HRSA said in the proposed rule (https://340breport.com/340b-dispute-resolution-proposed-rule-would-eject-cms-staff-and-hhs-lawyers-from-process-and-put-opa-in-charge/) that it wanted to make the ADR process more accessible and less trial-like.

Todd Nova, a partner at the law firm Hall Render who represents 340B providers, said he met with OMB and HRSA officials on the final rule.

"The way the rule is crafted, it will be interesting to see if the rule is rescinded or materially modified since we think there are some procedural shortcomings that should be addressed," Nova said. "If not, we hope that at a minimum the agency addresses the proposed 'same or similar' provision that would prohibit ADR adjudication of an issue currently being litigated in the courts. That could allow manufacturers to intentionally frustrate Covered Entity remedies via the ADR process. Also, whatever the result, we are hopeful that our ADR petition that has been pending for almost three years is given a chance to proceed."

Other key issues stakeholder said they are watching whether and how the final rule for the new ADR process addresses include:

- Whether the makeup of the ADR panel will reflect the recommendations that the Biden administration had previously proposed. The proposed rule would have removed representatives from the Centers for Medicare & Medicaid Services and HHS and give HRSA the only votes.
- Whether it will be authorized to address the 340B patient definition
- Whether it will accept covered entity challenges to manufacturer restrictions on contract pharmacies
- Whether it will address 340B drug diversion and duplicate discounts

In response to the proposed rule (https://340breport.com/340b-stakeholders-weigh-in-on-hrsas-proposal-to-replace-340b-dispute-resolution-process/), provider groups, citing manufacturers' contract pharmacy policies, said they want the rule to clarify that 340B covered entities may file petitions against manufacturers that will not ship 340B-purchased drugs to more than one contract pharmacy per entity. Drugmaker groups' responses criticized the proposed rule for what they said was a failure to address 340B drug diversion and duplicate discounts.

Editors' note: Feldesman Leifer is a sponsor of 340B Report.

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