340B UPDATE: FEDERAL COURT HALTS 340B ADMINISTRATIVE DISPUTE RESOLUTION RULE

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Health Care and FDA Alert

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Safety net providers participating in the 340B Drug Pricing Program (340B Program) continue to grapple with drug manufacturers imposing restrictions on 340B contract pharmacy arrangements. In response to these actions, the U.S. Department of Health and Human Services (HHS) issued an Advisory Opinion in support of these arrangements. HHS also finalized the long-awaited 340B Administrative Dispute Resolution (ADR) rule setting up a process for challenging the restrictions. Manufacturers sued HHS in multiple federal district courts challenging the Advisory Opinion as well as the 340B ADR rule.

In this regard, the U.S. District Court for the Southern District of Indiana recently granted one of these manufacturers a preliminary injunction stopping HHS from implementing the 340B ADR rule. At this point, it is unclear whether HHS will want to appeal this injunction or, instead, reissue the 340B ADR rule. Moreover, given the other pending lawsuits, the scope of the court's decision and status of the rule remain unclear. This client alert provides an overview of these developments and what to expect next.

BACKGROUND

340B ADR Rule

The Affordable Care Act (ACA) directed the Secretary of HHS to develop a formal and binding ADR process for resolving disputes under the 340B Program.[1] To this end, the Health Resources and Services Administration (HRSA) issued 340B ADR proposed regulations in 2016, noting that the regulations, when finalized, would replace the informal dispute resolution process that the agency had been relying on since 1996.[2] However, in 2017, HRSA withdrew the proposed regulations.[3] In March 2020, a HRSA official was reported to have expressed that the agency did not intend to finalize the ADR rule.[4]

Manufacturer Contract Pharmacy Actions

Notwithstanding these comments from HRSA, and as reported in our alert (here), the agency released the 340B ADR final rule in December 2020, more than 10 years after the ACA was enacted and several years after issuing and then withdrawing the 340B ADR proposed rule. Shortly thereafter, HHS released an Advisory Opinion in support of contract pharmacy arrangements.[5] As reported in our alert (here), providers had asked HHS to intervene and enforce their right to contract pharmacy arrangements in response to the manufacturer restrictions. Eli Lilly, AstraZeneca, and Sanofi filed complaints challenging the Advisory Opinion and ADR rule in Indiana, Delaware, and New Jersey district courts, respectively.[6]

FEDERAL COURT RULING

The U.S. District Court for the Southern District of Indiana heard oral arguments on Eli Lilly's challenge on 26 February 2021. Having considered those arguments, Judge Sarah Evans Barker granted Eli Lilly's motion for a preliminary injunction halting the implementation of the rule.[7] Judge Barker found that Eli Lilly established with a fair likelihood of success that HHS violated Administrative Procedure Act (APA) notice and comment requirements and that the manufacturer is likely to suffer irreparable harm.[8]

In regard to the APA's notice and comment requirements, Judge Barker held that "the agency's message regarding the ongoing rulemaking related to the ADR Rule was ambiguous, confusing, duplicitous, and misleading—the antithesis of fair notice under the APA," noting that all actions from HHS and HRSA indicated that they had withdrawn the 2016 proposed rule, which required HHS and HRSA to reopen the notice and comment period before finalizing the 340B ADR rule, which they had failed to do.[9]

Specifically, Judge Barker noted that more than three years had passed since HHS and HRSA withdrew the 2016 340B ADR proposed rule and that neither HHS nor HRSA had taken any additional action with regard to the rulemaking. Judge Barker also referenced the above-mentioned article regarding the status of the 340B ADR rule, which quoted a HRSA official as stating that "HRSA does not plan to move forward on issuing a regulation due to the challenges with enforcement of guidance."[10]

Notably, Judge Barker held that the public's interest in the implementation of the 340B ADR rule did not outweigh Eli Lilly's harm. The court noted that, while some ADR petitions have been filed, the injunction will only be putting on hold a process that is "not even currently operational," adding that the ADR process is still being implemented by the agency and the court was given no indication as to when the ADR board will be named and ADR panels will be assigned and begin reviewing ADR petitions.[11]

Finally, Judge Barker addressed the potential impact on providers, finding that "the only impact an award of preliminary injunctive relief will have on the covered entities will be to delay their ability to pursue an ADR petition against [Eli] Lilly until a procedurally valid rule is promulgated, which we assume HHS will want to undertake expeditiously in order to reduce or alleviate any harm from further delay."[12]

WHAT TO EXPECT NEXT

Despite Judge Barker's comment that HHS may want to promulgate a valid 340B ADR rule expeditiously, it is unclear whether HHS will appeal this decision or reissue the 340B ADR rule with a notice and comment period. In light of the other pending lawsuits, the scope of the court's decision and status of the rule remain unclear. In this regard, it is worth noting that some provider lawsuits against HHS were paused to have them resort to the ADR process. Accordingly, it is possible that providers may seek to have those lawsuits move forward. K&L Gates' health care and FDA practice regularly advises stakeholders on 340B Program compliance and strategy and will continue to monitor these developments.

FOOTNOTES

[1] 42 U.S.C. §256b(d)(3)(A).

[2] *See* 81 Fed. Reg. 53381 (Aug. 12, 2016).

[3] *See* Off. of Mgmt. & Budget, RIN: 0906-AA90: 340B Drug Pricing Program; Administrative Dispute Resolution Process (Aug. 2017).

[4] *See* Tom Mirga, HRSA: 340B Dispute Resolution Will Stay on Hold Until We Get Broader Regulatory Authority (Mar. 12 2020).

[5] *See* U.S. Dep't of Health & Hum. Servs., Off. of the Gen. Couns., Advisory Opinion 20-06 on Contract Pharmacies under the 340B Program (Dec. 2020).

[6] *See* Complaint, Eli Lilly and Co. v. Azar, 1:21-cv-00081 (S.D. Ind. Jan. 12 2021); Complaint, AstraZeneca Pharm. LP v. Azar, 1:21-cv-00027 (D. Del. Jan. 12 2021); Complaint, Sanofi-Aventis U.S. LLC v. HHS, 3:21-cv-00634 (D.N.J. Jan. 12 2021).

[7] *See* Order Granting Plaintiffs' Motion for Preliminary Injunction, Eli Lilly and Co. v. Azar., 1:21-cv-00081 (S.D. Ind. Mar. 16 2021).

[8] *Id*.

[9] *Id*. at 23.

[10] *Id*. at 11.

[11] *Id*. at 27.

[12] *Id*.

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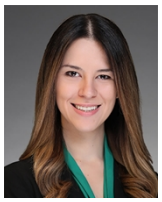

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