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CLIENT ALERT

# Eli Lilly Prevails in Blocking Immediate Implementation of HHS's 340B Drug Discount Rule Involving Dispute Resolution Between Manufacturers and Covered Entities

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On March 16, 2021, the U.S. District Court for the Southern District of Indiana granted Eli Lilly's motion for a preliminary injunction and, citing the Administrative Procedures Act, blocked the Department of Health and Human Services ("HHS") from implementing or enforcing an Administrative Dispute Resolution Regulation ("ADR Rule"), which would have set forth a long-delayed administrative dispute resolution process for certain disputes regarding the 340B Drug Pricing Program.

The 340B Drug Pricing Program ("340B Program") is a statutorily mandated drug discount program established by Congress in 1992 and administered by the Health Resources and Services Administration ("HRSA"), a sub-agency of HHS. As a condition of having their drugs covered by the Medicaid and Medicare drug benefits, pharmaceutical manufacturers must participate in the 340B Program, which requires that they offer outpatient drugs at discounted prices, determined by a statutory formula, to healthcare providers known as Covered Entities, including certain public and not-for-profit hospitals, children's hospitals, community centers, and other federally funded clinics serving low-income patients. Specifically, pharmaceutical manufacturers participating in the 340B Program must "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price."[1]

In 2010, Congress directed HHS to promulgate regulations within 180 days establishing an alternative dispute resolution ("ADR") process for resolving price, diversion, and duplicate discount disputes between covered entities and drug manufacturers. However, HHS did not issue a Notice of Proposed Rulemaking ("NPRM") proposing ADR procedures until August 12, 2016. HHS's August 2016 NPRM proposed to resolve ADR claims through three-member panels chosen from a roster of eligible individuals from HHS's Office of Pharmacy Affairs, and alternating from claim to claim. In October 2016, several drug manufacturers, including Eli Lilly, filed timely comments to the NPRM raising concerns regarding the potential biases of the ADR panelists, given their appointment by the HHS Secretary. On August 1, 2017, the NPRM was removed entirely from the Unified Agenda of Federal Regulatory and Deregulatory Actions ("Unified Agenda") without any explanatory comment.

For approximately 10 years, Eli Lilly followed guidance set forth in an HHS 2010 Advisory Opinion, which specified that covered entities need not be limited to a single contract pharmacy and were free to contract with as many pharmacies as they chose, even if they also operated an in-house pharmacy. As a result, Eli Lilly had been shipping 340B drugs purchased by covered entities to the covered entities' designated contract pharmacies. However, in

mid-2020, Eli Lilly announced it was discontinuing this practice but stated that it would continue to honor orders by covered entities to ship 340B drugs to contract pharmacies on a limited basis. Several other drug manufacturers followed suit and imposed similar restrictions with regard to covered entities' use of contract pharmacies.

In response, many covered entities filed lawsuits against HHS seeking to compel HHS to reverse drug manufacturer restrictions and to promulgate regulations establishing an ADR process as Congress had previously directed in 2010.

On December 14, 2020, and in response to lawsuits against HHS, HHS published its final ADR Rule without providing advanced notice or an opportunity for public comment. Rather, the preamble to the final ADR Rule stated that the 2016 NPRM was not withdrawn when it was removed from the Unified Agenda in August 2017, but instead was paused as part of an immediate freeze implemented by the Trump Administration on January 20, 2017, of all regulatory actions not subject to statutory deadlines. The final ADR Rule purported to allow the Secretary of HHS to select at least six members to serve on an ADR board, comprised of individuals from HRSA, CMS, HHS's Office of General Counsel ("OCG"), and a non-voting member from HHS's Office of Pharmacy Affairs ("OPA"). Under the proposed rule, when an ADR claim is presented, the HRSA Administrator would select three members from the ADR board—one member each from HRSA, CMC, and OGC—to serve on a 340B ADR Panel to review and decide claims. The final ADR Rule dictated that once an ADR Panel renders a decision, the panel "submit[s] the final agency decision to all parties and to HRSA for appropriate action regarding refunds, penalties, removal, or referral to appropriate Federal authorities."[2]

On January 25, 2021, Eli Lilly filed a motion for a preliminary injunction to block the implementation of the ADR Rule. In granting Eli Lilly's preliminary injunction, U.S. District Judge Sarah Evans Barker held that Eli Lilly is likely to be irreparably harmed because it was not able to give feedback on the HHS final ADR Rule. Judge Barker found that

> "if the ADR Rule were permitted to go into effect and was later determined to have been promulgated without an adequate, fair opportunity for advance notice and comment, Plaintiffs would be deprived of their right, under the [Administrative Procedure Act], to provide meaningful input into the agency's decision at a time when it is most likely to be carefully considered, a harm which the Court would be unable to fully remedy after the fact."[3]

More pointedly, Judge Barker noted that HHS's removal of its 2016 NPRM in August 2017, without explanation, followed by almost three years of inaction, would have led a reasonable observer to believe the ADR rule had in fact been withdrawn and that the final ADR rule was entirely new and required a notice and comment period. "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 [Administrative Procedure Act]."[4]

We note that, in the coming months, the Biden administration will need to make a strategic decision on whether to appeal the district court ruling or restart the rulemaking process on 340B Program disputes. We will be closely monitoring policy developments at HHS for signs as to where HHS will go with this important government drug pricing issue.

*We note that government orders on the local, state, and federal levels are changing every day, and the information contained herein is accurate only as of the date set forth above.*

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For further information or questions on this opinion or the 340B Drug Discount Pricing Program and related rules, please contact T. Reed Stephens, Christopher Parker, or your Winston relationship attorney.

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[1] 42 U.S.C. § 256b(a)(1).

[2] 85 Fed. Reg. 80,646, *codified as* 42 C.F.R. § 10.24(e).

[3] *Eli Lilly and Co., et al., v. Norris Cochran, et al.*, No. 121CV00081SEBMJD, 2021 WL 981350, at *11 (S.D. Ind. Mar. 16, 2021).

[4] *Id*. at *10.

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