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# Insights

## Between a Rock and a Hard Place – 340B Covered Entities Sidelined as Battle Over Drug Pricing Continues

April 20, 2021

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Recent conflicting court rulings from different U.S. District Courts sitting in separate federal circuits put 340B covered entities on the sidelines as the battle over the legality of policies designed to limit the scope of that program continues. The policies ("340B Policies"), implemented by drug manufacturers, limit covered entities' from using contract pharmacies to dispense 340B drugs or impose other restrictions, which puts covered entities at risk of losing substantial amounts of money. The incompatible rulings in the lawsuits filed in response to these policies have left covered entities with few legal options. Specifically, separate U.S. District Courts ruled that: (1) covered entities cannot use courts to compel the Department Health and Human Services ("HHS") to invalidate the 340B Policies; and (2) 340B-related disputes must go through an Alternative Dispute Resolution ("ADR") process, which HHS improperly established according to one of the court's rulings. Covered entities are at risk of losing their 340B savings under the 340B Policies and may want to pressure HHS to properly establish the ADR process for claims disputes as the timeline for appealing these court decisions could be lengthy.

**Background of the Disputes and Issues**

The 340B program is critical to America's healthcare safety net, as it requires drug manufacturers to give select health care entities (or covered entities) steep discounts on their drugs for the purpose of allowing these covered entities to stretch limited financial resources, reduce the price of outpatient pharmaceuticals for patients and expand health services to patients and the communities. Over time, most covered entities have used contract pharmacies to dispense 340B drugs to their patients because they do not operate in-house pharmacies. In 2020, drug manufacturers disputed that Federal law supported the contract pharmacy model and announced restrictions on the use of contract pharmacies and other limitations designed to limit the scope of the 340B program. In the Fall of 2020, the parties, drug manufacturers, covered entities, and HHS, clarified their positions, resulting in a flurry of lawsuits in January and February 2021.

**The Lawsuits**

The various lawsuits have approached the 340B-related issues from different angles, though two recent rulings effectively limited a covered entity's legal options. In **American Hospital Association et al, v. Department of Health and Human Services, et al.**, the plaintiffs sued HHS in the United States District Court for the Northern District of California for failing to stop the drug manufacturers' 340B Policies. The American Hospital Association asked a court to require HHS to take action against the manufacturers. At the center of this lawsuit and of the court's dismissal of the lawsuit, was a prior Supreme Court holding that prohibited 340B covered entities from suing drug manufacturers without first going through the ADR process as stated under Federal

law. The District Court in California was unwilling to allow the plaintiffs to circumvent this Federal law and dismissed the lawsuit in a **ruling** dated February 17, 2021.

The second lawsuit, **Eli Lilly and Co. et al., v. Cochran, et al.**, filed in the United States District Court for the Southern District of Indiana, concerned the validity of the ADR process HHS established in December 2020. Provisions in the Affordable Care Act required HHS to establish an ADR panel to hear disputes over 340B drug pricing, diversion, and duplicate discount disputes through formal rulemaking. HHS began this rulemaking process in 2016 and appeared to remove the proposed rule from consideration around August 2017. HHS later revived the proposed rule in December 2020 ("ADR rule") in order to finalize its ADR processes and procedures. In the Eli Lilly case, the plaintiff drug manufacturers argued, among other things, that the ADR rule was invalid under Federal rulemaking laws because it had been effectively withdrawn from consideration. The District Court in Indiana agreed in a **ruling** dated March 16, 2021.

**What's Next**

These dual court rulings raise many questions as those involved consider their options. Some key questions are whether HHS will wait to initiate formal rulemaking until after the appeals and whether drug manufacturers will continue the 340B Policies during these disputes and in light of a formal **HHS Advisory Opinion** issued December 30, 2020, which informed them that such policies are not legally supported and should be discontinued. Given the uncertainty of continued litigation, the quickest relief may be for HHS to restart the rulemaking process to establish the ADR panel so that covered entities may properly challenge the 340B Policies. As such, covered entities may want to consider pressuring HHS to begin the formal rulemaking process to avoid losing substantial 340B savings as courts consider appeals.

The 340B program is complex and confusing. If you have questions regarding this alert or your company's 340B compliance, please contact **Brandon W. Shirley** or **Meghan M. Linvill McNab**.

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