Significant 340B Drug Pricing Program Litigation May Impact 340B Scope

 Two recent federal court cases signal new significant developments with respect to the 340B Drug Pricing Program. Specifically: (1) new federal district court litigation challenging a recent HRSA Notice involving 340B Program "child site" registration and eligibility; and (2) a court decision in other litigation that implicates the scope of the 340B "eligible patient" definition. Details regarding these developments are in the client alert.

Read the client alert **here**.

Judge Dismisses Pfizer's Lawsuit Over HHS Limits on Drug Copay Assistance

 In a previous **post** published on the Washington Legal Foundation's Legal Pulse blog, Goodwin Partners Matt Wetzel and William Jackson discussed the potential implications of a high-profile recent lawsuit lodged by Pfizer against the U.S. Department of Health and Human Services ("HHS") Office of Inspector General's ("OIG") over Pfizer's drug copay assistance.

Pfizer's lawsuit sought a declaration that two copay assistance programs it designed to help patients afford its drug for the treatment of Transthyretin Amyloid Cardiomyopathy ("ATTR-CM") would not violate the Anti-Kickback Statute or Beneficiary Inducement Statute. The drug is the only FDA approved treatment for such disease. Originally, Pfizer, under the advisory opinion process, had requested OIG determine if either of the programs would violate the Anti-Kickback Statute. In an earlier **post**, we identified the need for the federal government to issue clear standards that would provide drug companies and others with clear notice as to the rules in this area.

On September 30, 2021, the U.S. District Court for the Southern District of New York **ruled** against Pfizer, (a) refusing to make a determination on one of the proposed copay programs and (b) ruling

that the government's appropriately made its prior prohibition of the company's other copay program. We examine each below.

The Independent Charity Program

Pfizer originally requested an advisory opinion approving the company's proposal to fund an existing third-party charity's copay assistance fund, which would in turn provide financial support to qualifying patients to cover the costs of their co-pays. The OIG refused to provide such an opinion. OIG indicated it was investigating a substantially similar course of action. Further, OIG stated that a Corporate Integrity Agreement with Pfizer prohibited OIG from approving a second similar program. **HHS regulations prohibit OIG** from issuing an advisory opinion where "[t]he same, or substantially the same, course of action is under investigation, or is or has been the subject of a proceeding involving the Department of Health and Human Services or another governmental agency."

Pfizer then brought suit in the U.S. District Court for the Southern District of New York, arguing that the Court had the power to issue a determination on whether the Independent Charity Program would violate the Anti-Kickback Statute or Beneficiary Inducement Statute. The Court, however, refused. The Court asserted the claim was too far remote and the facts too underdeveloped to satisfy the prudential ripeness criteria.

The Direct Program

While OIG refused to issue an advisory opinion on Pfizer's independent charity program, it did issue a advisory opinion against Pfizer's other proposal to directly fund patients' co-pays, including for government beneficiaries. OIG's **opinion** found Pfizer's controls and patient qualifications insufficient to curb the risk of fraud and abuse. It stated that, because there existed off-label treatments alternative to the FDA-approved treatment, the program would risk of patient steering and have anti-competitive effects. Further, OIG stated the program circumvented one of HHS's key pricing controls – i.e. requiring Medicare beneficiaries to cover some portion of the costs for their care in order to help ensure more considerate, comprehensive care decisions – and thereby exposing beneficiaries to the economic effects of drug pricing.

When the OIG's advisory opinion was challenged in the lawsuit, the Court stated that OIG's conclusion was *not* contrary to law. Because (i) the Anti-Kickback Statute prohibits "all remuneration that induces purchases of drugs (unless payments fall into one of the safe harbors)", and (ii) the intent of the program was to increase the number of Medicare beneficiaries who purchase the drug, the Court stated it was unable to issue a judgment in Pfizer's favor.

Key Takeaways

What is the impact of the Court's decision? Outside of its obvious impact on Pfizer's ability to fund the specific independent charity program and its own copay assistance plan at issue in the litigation, we believe the impact will be slim. The government has made clear for many years that it expects any sort of charity support or copay assistance to come with significant controls and guardrails in place. Those principles still stand. The Court's decision in the Pfizer matter reaffirms the OIG's significant discretion in deciding how to enforce and interpret the health care fraud and abuse laws. The government will continue to expect strong controls in place for these sorts of arrangements – especially if Medicare beneficiaries are involved – and will continue to scrutinize single-drug assistance funds carefully.