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ALERTS

Federal Judge Grants HHS-OIG Victory For Interpretation Of Anti-Kickback Statute In Prior Advisory Opinion

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Highlights

A federal judge ruled in favor of the HHS-OIG and its interpretation of the Anti-Kickback Statute in an earlier published advisory opinion

The court also held the HHS-OIG correctly exercised its discretion in applying sanctions and appropriately followed its own prior guidance

The decision further serves as a reminder of the rules applicable to the HHS-OIG when issuing advisory opinions

Recently, a federal judge in Virginia ruled in favor of the Department of Health and Human Services (HHS), rejecting claims from a pharmaceutical coalition that an advisory opinion published by the HHS Office of Inspector General (HHS-OIG) was arbitrary and capricious.

The 2022 advisory opinion at issue, Advisory Opinion 22-19, requested the HHS-OIG's guidance on a proposed arrangement through which a group of oncology drug manufacturers would fund cost-sharing subsidies for the drugs they manufactured, additional programs, and Medicare Part

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D beneficiaries' insurance premiums, among other things. While noting the importance of Medicare Part D beneficiary access to potentially life-saving medication, the HHS-OIG ultimately concluded the proposed arrangement would violate the Anti-Kickback Statute (AKS), and the HHS-OIG would impose sanctions if the arrangement was undertaken and the requisite intent were present.

The proposed arrangement would involve prohibited remuneration, the agency said, and allow the pharmaceutical manufacturers to effectively sidestep the current Medicare Part D cost-sharing structure and increase risks of patient steering, anti-competition, and skewed clinical decision-making.

In its lawsuit, the Pharmaceutical Coalition for Patient Access (PCPA) argued the HHS-OIG "read the AKS so broadly that it improperly criminalizes innocuous or even beneficial conduct." However, Judge Roderick Young of the U.S. District Court for the Eastern District of Virginia granted a resounding victory to the HHS-OIG and the federal agency's interpretation of the AKS.

Plain Language

The PCPA argued the AKS' phrase "any remuneration… to induce" means there must have been a quid pro quo scheme and the HHS-OIG's interpretation did not align with that requirement. Without answering the question of whether or not the text of the AKS requires such interpretation, the court held the HHS-OIG satisfactorily showed the proposed arrangement would constitute quid pro quo when it explained in the advisory opinion that the arrangement would involve paying remuneration to Medicare Part D enrollees so that they would purchase the manufacturers' products.

In addition, the PCPA argued the AKS use of "induce" and "any remuneration (including kickback, bribe, or rebate)" requires corrupt, illegal, or prohibited conduct or remuneration. However, the court held that neither case law nor the text of the statute support such a narrow interpretation of the law. As such, the court held the HHS-OIG correctly interpreted and applied the AKS.

Dissimilar Treatment

Next, the PCPA argued the HHS-OIG's negative opinion was inconsistent with past opinions in which the agency concluded a proposal could violate the AKS, but the agency would not impose sanctions. PCPA believed this was dissimilar treatment compared to other advisory opinion requesters. The court disagreed, holding that an agency may rightly exercise enforcement discretion however it chooses. As such, the HHS-OIG's decision to enforce sanctions in Advisory Opinion 22-19 constitutes "agency action [] committed to agency discretion by law." The claim was dismissed.

Prior Guidance

In 2005, the HHS-OIG issued a relevant Special Advisory Bulletin that discussed patient assistance programs, Medicare Part D, the AKS, and noted ways by which risks of a potentially illegal arrangement may be

reduced. PCPA tried to align their arrangement with the Special Bulletin, but the HHS-OIG still issued an unfavorable opinion. The PCPA argued that, by not permitting PCPA's bulletin-informed arrangement, HHS-OIG changed course without a reasoned analysis indicating that prior standards were being changed. However, the court pointed to multiple instances in the bulletin where HHS-OIG made clear its future analysis of the issue would be on a case-by-case basis. As such, HHS-OIG's advisory opinion was a faithful application of its guidance, conducting a case-specific analysis and ultimately reaching an unfavorable decision.

Key Takeaways

While the decision is a victory for the HHS-OIG, it is also a reminder of the guardrails imposed on the agency and its advisory opinions:

1. Individuals are permitted to challenge advisory opinions in court if they believe an opinion is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." A large pharmaceutical company filed a lawsuit challenging an advisory opinion in 2022, which it ultimately lost.

Healthcare entities or drug manufacturers who are considering requesting an advisory opinion from the HHS-OIG but are concerned about a possible unfavorable opinion should remember that they have the option to: 1) withdraw their request before the opinion is published, or 2) challenge the opinion in court.

2. When issuing advisory opinions, the HHS-OIG must remain true to the plain language of the laws it analyzes: the AKS and the Beneficiary Inducements Civil Monetary Penalty Rules. The HHS-OIG may not extrapolate readings of the text or interpretations of either statute.

3. Any guidance issued by the HHS-OIG must note that it is broad and speculative (or in the case of advisory opinions, only applies to the requestor), so as to emphasize that the agency's ultimate determinations of violations and sanctions require a case-specific inquiry into all relevant facts and circumstances.

While many healthcare entities and drug manufacturers typically rely on the HHS-OIG's advisory opinions and guidance, they should remember that the agency has full discretion on enforcement decisions and must undertake a case-specific analysis for each proposed arrangement. Healthcare entities should not assume that a past result would automatically lead the agency to the same outcome in all circumstances and should consider consulting with counsel for further guidance.

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