

COURT CONFIRMS VALUE IN OBTAINING ADVISORY OPINION FROM OIG

Three recent cases out of New York show the value in obtaining Advisory Opinions from the Office of Inspector General (“OIG”) when considering the risk of certain arrangements under the Anti-Kickback Statute (“AKS”).

BACKGROUND

In 2022, a whistleblower who was also a physician (“Relator”) filed a False Claims Act Complaint against Platform, an online platform that helps patients find medical providers based upon specialty, location, insurance participation and other demographic criteria (“Platform”). Platform charges medical providers an annual fee, as well as a fee for each new patient who schedules an appointment.

Relator’s lawsuit alleged that the new patient fees were unlawful referral fees under the AKS. The government chose not to intervene in the case; however, Relator proceeded with the litigation on behalf of the government, and Platform moved to dismiss.

Platform’s motion to dismiss was based on whether Platform had the necessary fraudulent intent to act contrary to the AKS, not whether the fees violated the AKS.

IMPORTANCE OF ADVISORY OPINION PROCESS

Prior to Relator filing the Complaint, Platform sought and received two favorable OIG Advisory Opinions. In seeking those opinions, Platform laid out in detail its intended business model. In the relevant Advisory Opinions, OIG concluded that, while the fee structure “implicated” the AKS, it “would present a low risk of fraud and abuse,” and therefore OIG issued favorable Advisory Opinions.

Much of Relator’s Complaint was based upon an argument that the booking fee was not fair market value. OIG is precluded by statute from making fair market value determinations as a part of its Advisory Opinion process; however, the two Advisory Opinions clearly demonstrated a full disclosure by Platform, and a full understanding by OIG, of the pricing methodology.

While Platform’s Motion to Dismiss was pending, the Second Circuit Court of Appeals (the “Court”) issued its opinion in *United States ex rel. Hart v. McKesson Corp* (“*McKesson*”). In *McKesson*, the Court discussed, at length, the duty of a whistleblower to plead in a way “giv[ing] rise to strong inference of fraudulent intent.” Because the AKS uses the word “willfully,” the Court reasoned, the complaint must allege that the defendant “acted with knowledge that his conduct was unlawful.” In considering whether a defendant acted with such knowledge, a court may consider whether it sought an Advisory Opinion from OIG.

As a result, the trial court concluded that because Platform sought Advisory Opinions, and because they were truthful and proceeded as described in those opinions, Relator failed to adequately plead a strong inference of fraudulent intent. Relator’s lawsuit was therefore dismissed.

On appeal, the Court affirmed dismissal, finding that Relator alleged only that Platform performed its services just as it described to OIG and therefore there was no strong inference of fraudulent intent. Further, the Court affirmed the trial court’s refusal to allow Relator to amend his complaint, finding that any such effort would be futile.

PRACTICAL TAKEAWAYS

These three cases, when analyzed together, show the value to a provider in seeking an OIG Advisory Opinion when taking an action that could implicate the AKS and that does not fit squarely within an AKS Safe Harbor. Without receipt of the favorable Advisory Opinions, Platform would likely not have been successful in seeking dismissal at the earliest stage of litigation.

When an organization is evaluating an atypical arrangement or other scenario that does not fit within the multitude of AKS Safe Harbors, it may be prudent for the organization to consider obtaining an Advisory Opinion from OIG. This evaluation and determination of an arrangement/business model from OIG can serve as excellent comfort for organizations as they move forward in progressing their business plans.

If you have questions or would like more information about this topic, please contact:

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