Pathology Lab Agrees to Pay $63.5M to Settle Illicit Kickback Allegations

The Department of Health and Human Services' Office of Inspector General (OIG) recently announced a settlement reached in a False Claims Act case involving a pathology laboratory. And, as always, healthcare professionals are wise to take notice of the government's seriousness in approaching allegations of fraud.

Before company ownership changed hands in 2017, the Irvine, Texas-based Inform Diagnostics operated as Miraca Life Sciences Inc., a subsidiary of the Japanese company Miraca Holdings Inc. The company was the subject of three *qui tam* actions that alleged Inform/Miraca participated in financial entanglements that violated the Anti-Kickback Statute and the Stark Law. In order to resolve those allegations, the company has agreed to pay $63.5 million.

DOJ warns that kickbacks "can alter a physician's judgment"

"The Department of Justice has longstanding concerns about improper financial relationships between health care providers and their referral sources because those relationships can alter a physician's judgment about the patient's true health care needs and drive up health care costs for everybody," said Assistant Attorney General Jody Hunt of the Department of Justice's Civil Division in an OIG press release. "In addition to yielding a substantial recovery for taxpayers, this settlement should deter similar conduct in the future and help make health care more affordable."

Allegedly, Inform Diagnostics/Miraca Life Sciences subsidized electronic health records (EHR) systems for referring physicians, as well as lower cost (or no-cost) tech consulting services, thereby violating the federal Anti-Kickback Statute and the Stark Law, which limit the types of financial arrangements healthcare providers may transact with physicians who send patients their way. Labs are not exempt from these restrictions.

Fraud enforcement as an ongoing effort: "We will continue to enforce the laws . . ."

The OIG's press release on the matter includes this statement by U.S. Attorney Don Cochran of the Middle District of Tennessee: "The wellbeing and needs of the patient should always be a medical provider's primary considerations. The restrictions imposed by federal statutes exist to prevent improper influence on the parties prescribing and providing medical services, including laboratory tests. We will continue to enforce the laws that protect the integrity of federal health care programs."

The case against Inform Diagnostics/Miraca Holdings was investigated by the Civil Division's Commercial Litigation Branch, the U.S. Attorney's Office for the Middle District of Tennessee, the U.S. Attorney's Office for the Middle District of Florida, the Department of Health and Human Services Office of Inspector General, and the FBI. Although the settlement resolves the matter, it is not an admission of guilt on the company's part; the allegations remain just that.

And although on the surface it looks like the government and the whistleblowers are the parties benefitting from the resolution of the case, it's true that the public benefits when physicians aren't making referral decisions based on illegal inducements.

"When health care providers are distracted by suspect financial arrangements, the interests of patients can be cast aside," said Special Agent in Charge Derrick L. Jackson of HHS OIG. "Our agency, working closely with our law enforcement partners, will continue to protect patients and the federal health care programs that serve them."

U.S. Attorney sees this action as "commitment" to fight healthcare fraud

"Patients deserve the unfettered, independent judgment of their health care professionals. Offering financial incentives to physicians and medical practices in exchange for referrals undermines citizens' trust in our health care system," said United States Attorney Maria Chapa Lopez of the Middle District of Florida. "With this settlement, our Civil Division confirms its commitment to our nation's critical struggle against practices that put public health programs at risk."

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