

# Feds Exhibit Continued Interest in Prosecuting Illegal Relationships Between Laboratories and Marketers

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On July 8, 2019, Anthony Camillo, owner of Allegiance Medical Laboratory and AMS Medical Laboratory, was sentenced to 30 months in prison by a federal judge in the Eastern District of Missouri. He was ordered to pay \$3.4 million in restitution for violations of the anti-kickback statute, associated conspiracy charges, and illegal kickbacks related to various health care fraud schemes to defraud federal health care benefit programs. Those operating in the clinical laboratory testing space or referring specimens to such laboratories should know that what happened in this case is likely a bellwether of continued enforcement action by the federal government with respect to marketing arrangements involving laboratory testing of human tissue.

In July of 2017, Camillo, as well as eight of his co-conspirators, were charged in a 31- count indictment with conspiracy, false statements to a federal agency, engaging in a healthcare fraud scheme, and illegal kickbacks for referrals. According

to the indictment, the defendants conducted an elaborate scheme wherein they paid illegal kickbacks to marketers for sending biological samples to their laboratories. Camillo's labs would then bill Medicare and Medicaid for lab testing services, and Camillo would split the profits between himself and his marketers. Some specimens were reimbursed at over \$600 per sample, amounting to millions of dollars in illegal profits. Because both Medicaid and Medicare only reimburse for tests ordered by an appropriate medical provider, the defendants utilized doctors who were willing to put their names on the test orders without ever actually seeing the patient. In fact, some doctors claimed that they did not know their names were being put on the testing orders at all. Many of these samples were obtained at churches and public fairs.

The anti-kickback statute prohibits exchanging anything of value for referrals of services which are payable by federal programs, including Medicaid and Medicare. There are safe-harbors that permit limited defined business relationships; however, in 2018, Congress passed the Eliminating Kickbacks in Recovery Act of 2018 ("EKRA"). This statute prohibits the exchange of anything of value for many types of referrals to laboratories, as well as other enumerated healthcare entities. EKRA does not limit its scope to government payors—instead, EKRA applies to all healthcare benefit programs, which includes private as well as public Medicaid and Medicare plans.

In March of 2018, Camillo pled guilty to 30 charges pursuant to a plea agreement with the government. In that plea agreement, Camillo admitted that his presumptive sentencing guidelines range under the U.S. sentencing guidelines was at least 70 months. However, court filings revealed that Camillo agreed to testify at the trials of his co-conspirators, which is, ostensibly, why he received a sentence less than half of his pre-cooperation sentencing guidelines range. All of Camillo's co-conspirators were convicted of felonies and received sentences ranging from imprisonment to house arrest, along with hefty monetary penalties.

Camillo's status as the lead-named defendant in this case is evidence that the government considered him to be the ringleader of this conspiracy. However, that he was used by the government to testify against presumably less culpable co-conspirators is telling of the government's significant interest in prosecuting participants in illegal laboratory marketing agreements to the fullest extent of the law—regardless of the optics of using those most culpable to make cases against those who are less culpable. Expect DOJ's increased commitment to clinical laboratory fraud prosecution to result in more robust federal investigations to come, especially with the expanded jurisdiction it has over clinical laboratories, emanating from EKRA.

*Devon Minnick, a 2019 Summer Associate (not admitted to the practice of law) in the firm's Washington, DC office, contributed significantly to the preparation of this post.*

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