BLOG

DOJ Scrutiny of EHR Vendors Continues with $45 Million Settlement For Alleged Kickbacks and False Claims

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On November 1, 2022, the Department of Justice ("DOJ") announced that Florida-based electronic health record ("EHR") vendor, Modernizing Medicine ("ModMed"), agreed to a $45 million settlement with the United States to resolve civil claims that it violated the False Claims Act ("FCA") and Anti-Kickback Statute ("AKS") by accepting and providing unlawful remuneration in exchange for referrals, causing users to submit tainted claims for federal incentive payments.[1] The settlement reflects DOJ's heightened focus on EHR companies and the growing role that health technology plays in managing and directing patient care. EHR companies and those who do business with them, including life sciences companies, should structure their arrangements thoughtfully to ensure sufficient safeguards to protect against potential abuses.

Allegations

The Anti-Kickback Statute prohibits the exchange, or offer to exchange, of anything of value to induce the referral of, or recommend or arrange for, business covered by Medicare, Medicaid, and other federal health care programs. The claims against ModMed were initiated on September 22, 2017 through a whistleblower suit filed pursuant to the FCA's whistleblower provisions. The Relator, a former vice president of product management at ModMed, filed the action on behalf of the United States in the United States District Court for the District of Vermont.[2] DOJ intervened on March 15, 2022.[3]

In its Complaint in Intervention, which was filed on the same date that the settlement was announced, the United States alleged that ModMed violated the FCA and AKS through three marketing programs. First, ModMed allegedly conspired with Miraca Life Sciences, Inc. ("Miraca") to donate ModMed's EHR software to healthcare providers in exchange for referrals of lab tests to Miraca, in violation of the AKS. In particular, DOJ alleged that Miraca made EHR donations based on the value of the potential recipient's anticipated referrals to Miraca, and that "ModMed was instrumental in propelling Miraca's efforts."[4]

Second, the United States claimed that ModMed solicited and received payment from Miraca in exchange for recommending and arranging for their customers to use Miraca's pathology lab services. According to the Complaint in Intervention, Miraca paid ModMed per specimen fees that were in excess of fair market value and increased with the volume of specimens and agreed to a guaranteed minimum monthly payment of $20,000 should the aggregate per specimen fees fall below that amount. DOJ alleges that, in exchange, ModMed agreed to provide exclusive access to Miraca for certain enhanced interface features in their EHR software. The Complaint in Intervention alleges that these arrangements resulted from a letter of intent signed by both ModMed and Miraca describing a desire to establish a "mutually beneficial" partnership with "strategic and financial alignment."[5] The Complaint in Intervention goes on to allege that ModMed and Miraca engaged in joint marketing activities, such as joint roadshows and dinners with potential customers.[6] The United States contended that the arrangement violated the AKS and caused the submission of false claims to federal health care programs for pathology services performed by Miraca.[7]

Third, the United States alleged that ModMed made payments to customers, consultants, and other third parties in exchange for recommending its EHR software. The United States contended that these payments were illegal kickbacks because they did not represent fair market value for personal services rendered. According to the United States, this conduct resulted in ModMed users submitting tainted claims for incentive payments under the Medicare/Medicaid Electronic Health Record Incentive Programs (the "Meaningful Use Programs"), which provide incentive payments to healthcare providers for demonstrating "meaningful use" of certified EHR technology.[8] Relatedly, the government also contended that ModMed knew that its EHR product did not meet all of the standards under the Meaningful Use Programs, which caused certain health care provider customers to submit false claims for incentive payments.

The settlement requires ModMed to pay $45 million to this United States, of which $19.5 million is restitution. The United States will pay the Relator $9 million upon receipt of the settlement amount. For its part, Miraca (now Inform Diagnostics) agreed to pay $63.5 million for their role in the ModMed agreements in a settlement agreement announced by DOJ on January 30, 2019.[9]

KEY TAKEAWAYS

Continued Scrutiny of Participants in the EHR Sector

This is the sixth False Claims Act/Anti-Kickback Statute settlement between the United States and an EHR vendor in the last five years.[10] These settlements signal an ongoing effort by the DOJ to pursue both vendors and the companies that do business with them.

DOJ's scrutiny of these types of arrangements reflects the growing role that EHR technology plays in helping providers manage and direct care. As these technologies, and other health IT innovations, continue to become integral parts of care management, increasing government enforcement is likely. EHR companies, and life sciences companies and other suppliers who do business with them, should exercise care in structuring their arrangements to ensure adequate safeguards against potential abuse. We can expect that the government will be focused on arrangements they view as improperly driving business to certain providers, suppliers, or manufacturers.

More broadly, the allegations in this case also serve as a cautionary reminder that the Anti-Kickback Statute's prohibition extends to remuneration offered to induce a party to *"recommend"* or *"arrange for"* covered items and services. Companies doing business in the health care sector need to structure their marketing arrangements carefully, but they should also closely review other arrangements with parties in a position to refer, recommend, or arrange for services where the nature and structure of the arrangement might create implicit marketing expectations.

If you have additional questions or need further assistance, please reach out to T. Reed Stephens (Partner, White Collar, Regulatory Defense & Investigations), Christopher Parker (Associate, White Collar, Regulatory Defense & Investigations), Elayna Napoli (Law Clerk, General Litigation), or your Winston & Strawn relationship attorney.

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[1] The DOJ press release is available here: https://www.justice.gov/opa/pr/modernizing-medicine-agrees-pay-45-million-resolve-allegations-accepting-and-paying-illegal. The settlement agreement entered into by the DOJ, ModMed, and the Relator is available here: https://www.justice.gov/opa/press-release/file/1548661/download. (ModMed Settlement Agreement). The complaint in intervention is available here: https://www.justice.gov/usao-vt/press-release/file/1548626/download.

[2] *See United States ex rel. Long v. Modernizing Medicine, Inc.*, Case No. 2:17-cv-179 (D. Vt.)

[3] ModMed Settlement Agreement, at 1.

[4] *Id.* at 4.

[5] *Id.* at 16.

[6] *Id.* at 20.

[7] ModMed Settlement Agreement, at 2-3.

[8] *Id.* at 3.

[9] *See* https://www.justice.gov/opa/pr/pathology-laboratory-agrees-pay-635-million-providing-illegal-inducements-referring.

[10] On May 31, 2017, the DOJ announced that it reached a $155 million settlement with eClinicalWorks. https://www.justice.gov/opa/pr/electronic-health-records-vendor-pay-155-million-settle-false-claims-act-allegations. On February 6, 2019, DOJ announced that Greenway Health LLC agreed to a $57.25 million settlement. https://www.justice.gov/opa/pr/electronic-health-records-vendor-pay-5725-million-settle-false-claims-act-allegations. On January 27, 2020, the DOJ announced a $145 million settlement with Practice Fusion, Inc., https://www.justice.gov/opa/pr/electronic-health-records-vendor-pay-145-million-resolve-criminal-and-civil-investigations-0, and roughly one year later, January 28, 2021, they announced that athenahealth, Inc. agreed to an $18.25 million settlement. https://www.justice.gov/usao-ma/pr/athenahealth-agrees-pay-1825-million-resolve-allegations-it-paid-illegal-kickbacks. Finally, on April 30, 2021 the DOJ announced the $3.8 million settlement agreement with CareCloud Health, Inc. https://www.justice.gov/usao-sdfl/pr/miami-based-carecloud-health-inc-agrees-pay-38-million-resolve-allegations-it-paid.

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