UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF VERMONT

UNITED STATES OF AMERICA *ex rel.* **Amanda B. Long,** **Plaintiff,** **v.** **MODERNIZING MEDICINE, INC.** **Defendant.**	**Case No. 2:17-cv-179** **UNITED STATES' COMPLAINT IN INTERVENTION**

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The United States of America, for its complaint in partial intervention, states:

NATURE OF ACTION

1. The United States of America files this complaint in partial intervention for the limited purpose of settlement to recover damages arising from false statements made and caused by Defendant Modernizing Medicine, Inc. ("ModMed") and false claims that ModMed caused to be submitted to the Department of Health and Human Services (HHS) for reimbursement for services tainted by kickbacks, and for federal incentive payments through the Medicare and Medicaid Electronic Health Record Incentive Programs (the "Meaningful Use Programs") of the Centers for Medicare & Medicaid Services (CMS).

2. Pursuant to the Health Information Technology for Economic and Clinical Health Act (HITECH Act), HHS established the Meaningful Use Programs, which provided incentive payments to healthcare providers who demonstrated "meaningful use" of certified Electronic Health Record (EHR) technology. ModMed developed an EHR software product known as the Electronic Medical Assistant, or more commonly "EMA," which ModMed marketed and sold to healthcare providers throughout the United States.

3. From January 2010 through July 2017, ModMed engaged in multiple kickback schemes, including:

(a) conspiring with the diagnostic and pathology laboratory services company, Miraca Life Sciences, Inc. (Miraca), to "donate" EMA to healthcare providers to induce the submission of lab orders to Miraca by ModMed's customers;

(b) soliciting and receiving kickbacks from Miraca to arrange for and recommend Miraca's services to ModMed's customers; and

(c) paying kickbacks to healthcare providers and other influential industry sources to recommend EMA to potential customers.

These kickback schemes violated the Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7b(b), and caused the submission of false claims to Medicare and Medicaid, in violation of the federal False Claims Act (FCA), 31 U.S.C. §§ 3729 *et seq*.

4. In addition, during the time period from April 2014 through July 2017, EMA did not always enable users to conduct transactions using required standard vocabularies. As a result, ModMed users reported inaccurate information in connection with claims for incentive payments pursuant to the Meaningful Use Programs. ModMed's false and fraudulent statements and conduct therefore violated the FCA.

PARTIES

5. Plaintiff, the United States of America, acting through HHS, administers the Medicare Program, Title XVIII of the Social Security Act (SSA), 42 U.S.C. §§ 1395 *et seq.*, and administers grants for State Medicaid Programs, Title XIX of the SSA, 42 U.S.C. §§ 1396 *et seq*. On March 15, 2022, the United States partially intervened in this action pursuant to Section 3730(b)(2) and (4) of the FCA.

6. Relator is a resident of Boca Raton, Florida who worked at ModMed from May 5, 2014, to July 13, 2017. She was initially hired by ModMed as Product Director – EMA Enterprise, and after multiple promotions assumed the role of Vice President of Product Management. On September 22, 2017, Relator filed this case under the FCA's *qui tam* provisions. On May 25, 2021, Relator filed an amended complaint.

7. Defendant ModMed is a privately held Delaware corporation with headquarters in Boca Raton, Florida. ModMed and its affiliated companies manufacture and sell medical specialty-specific EHR technology products. ModMed's principal EHR product, called the Electronic Medical Assistant (EMA), is a cloud-based EHR system. EMA is used in dermatology, gastroenterology, ophthalmology, orthopedics, otolaryngology, pain management, plastic surgery, rheumatology and urology practices. Several healthcare providers located in this District have purchased EMA.

8. In May 2017, Warburg Pincus, LLC (Warburg), made a substantial investment in ModMed. Following Warburg's investment, the size, structure, and composition of ModMed's Board changed significantly, including the addition of independent directors and the formation of a compliance committee. Certain changes to voting and approval rights under ModMed's governing documents and other controls also resulted from Warburg's investment.

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730. This Court also has subject matter jurisdiction over this action under 28 U.S.C. § 1345. The Court may exercise personal

jurisdiction over ModMed under 31 U.S.C. § 3732(a) because ModMed transacts business in this District and can be found in this District.

10. Venue is proper in this District under 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b) because ModMed transacts business in this District and events giving rise to these claims occurred in this District.

LEGAL AND REGULATORY BACKGROUND

I. The False Claims Act

11. The FCA imposes civil liability on any person who, *inter alia*: (1) knowingly presents, or causes to be presented, to an officer, employee, or agent of the United States a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim; or (3) conspires to commit such a violation of the FCA. 31 U.S.C. §§ 3729(a)(1)(A)-(C).

12. The FCA defines a "claim" to include "any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property that- (i) is presented to an officer, employee, or agent of the United States; or (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest . . . ." *Id.* § 3729(b)(2).

13. The FCA defines the terms "knowing" and "knowingly" to mean "that a person, with respect to information (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." *Id.* § 3729(b)(1)(A). The FCA does not require proof of specific intent to defraud. *Id.* § 3729(b)(1)(B).

14. The FCA defines "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *Id.* § 3729(b)(4).

15. Any person who violates the FCA is liable for a mandatory civil penalty for each such claim, plus three times the damages sustained by the Government. *Id.* § 3729(a)(1).

II. The Anti-Kickback Statute

16. The Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7b(b), arose out of Congressional concerns involving physicians' conflicts of interest, overutilization of medical services and items, patient steering, and unfair competition. First enacted in 1972, Congress strengthened the statute in 1977 and 1987 to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, Medicare-Medicaid Anti-Fraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93. The AKS prohibits the payment of kickbacks in order to protect the integrity of federal health care programs such as Medicare, Medicaid, and TRICARE.

17. In pertinent part, the AKS provides:

> b. Illegal remunerations
>
> (2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person
>
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) to purchase, lease, order or arrange for or recommend purchasing, leasing or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined

> not more than $100,000 or imprisoned for not more than ten years, or both.

42 U.S.C. § 1320a-7b(b).

18. "[A] person need not have actual knowledge of [the AKS] or specific intent to commit a violation of [the AKS]." *Id.* § 1320a-7b(h). Rather, all that is required to establish a willful AKS violation is "a voluntary, intentional violation of a known legal duty." *Pfizer, Inc v. HHS*, 42 F.4th 67, 77 (2d Cir. 2022) (citations omitted). "In other words, the AKS does not apply to those who are unaware that such payments are prohibited by law and accidentally violate the statute . . . the *mens rea* element goes no further." *Id.*

19. Likewise, the inducement of a referral need not be the primary purpose for which a kickback is offered, solicited, or paid. Rather, all that is required is that one purpose of the remuneration was to induce the referral. *See, e.g., United States v. Mallory*, 988 F.3d 730, 741 (4th Cir. 2021), *cert. denied sub nom. Dent v. United States*, 211 L. Ed. 2d 294, 142 S. Ct. 485 (2021).

20. Pursuant to the AKS, "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g); *see also, Guilfoile v. Shields*, 913 F.3d 178, 190–91 (1st Cir. 2019) ("§ 1320a-7b(g)'s obviation of the 'materiality' inquiry essentially codifies the long-standing view that AKS violations are 'material' in the FCA context."); *Pfizer*, 42 F.4th at 79.

21. The Office of Inspector General for HHS (OIG) has promulgated "safe harbor" regulations that define practices that are not subject to the AKS because such practices are unlikely to result in fraud or abuse. 42 C.F.R. § 1001.952. However, safe harbor protection is afforded to only those arrangements that meet all requirements of the safe harbor.

22. In August 2006, HHS established a limited Safe Harbor exception to the AKS that allowed certain parties to pay some of the cost incurred by physicians when acquiring, implementing, or upgrading EHR systems. 71 Fed. Reg. 45110 (Aug. 8, 2006); 42 C.F.R. § 1001.952(y). By following the provisions of the Safe Harbor, pathology laboratories like Miraca could make donations to physicians for up to 85 percent of the cost of EHR systems without violating the AKS. 71 Fed. Reg. at 45112.

23. In promulgating this limited exception, however, HHS recognized that there was a "substantial risk that free or reduced price goods or services may be used as a vehicle to disguise or confer an unlawful payment for referrals of Federal health care program business." 71 Fed. Reg. at 45111. For that reason, HHS mandated that to fall within the scope of these limited exceptions, "neither the eligibility of a recipient for the items or services, nor the amount or nature of the items or services, is determined in a manner that directly takes into account the volume or value of referrals or other business generated between the parties." *Id.* at 45136; 42 C.F.R. § 1001.952(y)(5).

III. The Medicare Program

24. In 1965, Congress enacted the Health Insurance for the Aged and Disabled Act, known as the Medicare program, to pay for the costs of certain healthcare services. 42 U.S.C. § 1395 *et seq*. Entitlement to Medicare benefits is based on age, disability, or affliction with end-stage renal disease. *See* 42 U.S.C. §§ 426 to 426-1. Medicare is a "Federal health care program" for purposes of the AKS. *See* 42 U.S.C. § 1320a-7b(f).

25. HHS is responsible for administration and supervision of the Medicare program. The Centers for Medicare & Medicaid Services (CMS), an agency within HHS, is directly responsible for administering the Medicare program.

26. To participate in the Medicare program, a healthcare provider must file a provider agreement with the Secretary of HHS. 42 U.S.C. § 1395cc. The provider agreement requires compliance with the requirements that the Secretary deems necessary for participation in the Medicare program and in order to receive reimbursement from Medicare, including compliance with the AKS.

27. Healthcare providers must also submit a Medicare Enrollment Application (Form CMS-855I) to enroll in Medicare, to change information, or to reactivate or revalidate Medicare enrollment. Form CMS-855I requires, among other things, signatories to certify:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to me or to the organization listed in section 4A of this application. The Medicare laws, regulations, and program instructions are available through the Medicare Administrative Contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations and program instructions (including, but not limited to, the Federal Anti-Kickback Statute, 42 U.S.C. section 1320a-7b(b) . . . .
>
> * * *
>
> I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare and will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

IV. State Medicaid Programs

28. State Medicaid programs are authorized by Title XIX of the Social Security Act. 42 U.S.C. §§ 1396 *et seq*. Medicaid is a joint federal-state program that provides healthcare benefits for certain groups including the poor and individuals with disabilities.

29. Medicaid is a "Federal health care program" for purposes of the AKS. *See* 42 U.S.C. § 1320a-7b(f). The federal portion of each state's Medicaid payments is based on a state's per capita income compared to the national average. 42 U.S.C. § 1396d(b).

30. To participate in state Medicaid programs, providers must agree to comply with applicable healthcare laws and regulations, including the AKS.

V. The Meaningful Use Programs

31. On February 17, 2009, Congress enacted the Health Information Technology for Economic and Clinical Health Act ("HITECH Act"), to promote the adoption and meaningful use of certified EHR technology. Under the HITECH Act, CMS makes incentive payments to healthcare providers for demonstrating "meaningful use" of certified EHR technology. Individual practitioners ("Eligible Professionals") could qualify for up to a total of $43,720 over five years from Medicare (ending after 2016) and up to a total of $63,750 over six years from Medicaid (ending after 2021).

32. To qualify to receive an EHR incentive payment from the Government, providers must attest to demonstrating meaningful use of an EHR product each year that the provider applies for the reimbursement. As part of the attestation process, CMS requires each eligible professional and eligible hospital to confirm that it is using an EHR product that is certified and meets the regulatory requirements for participation in the Meaningful Use Programs.

33. These incentive payments were intended to cover both the cost of purchase and implementation of an EHR product. *See* 75 Fed. Reg. 44314, 44446 (July 28, 2010) (stating that the incentive payments cover the costs associated with "the adoption, implementation, upgrade, or meaningful use of [EHR] technology").

34. In creating these incentive programs, CMS elected to provide these incentives in the form of enhancements to payments to providers made under Medicare Part B. 42 C.F.R. § 495.2(a) ("This part implements the following: (a) Section 1848(o) of the Act by establishing

payment incentives under Medicare Part B for eligible professionals who adopt and meaningfully use certified electronic health record (EHR) technology.")

35. For most of the years at issue, incentive payments were paid to providers as a seventy-five percent increase in their Medicare reimbursement rates for services rendered and reimbursed under Part B. *See* 42 C.F.R. § 495.102(a). Funding for these incentive payments was provided via the Federal Supplemental Medical Insurance Trust Fund – a source which may only be used to fund Medicare.

36. In later years, incentives were replaced with downward payment adjustments if providers failed to meet meaningful use requirements.

37. To qualify for incentive payments in each Stage of the Meaningful Use Programs, healthcare providers were required to attest each year that they used certified EHR technology and satisfied the applicable Meaningful Use objectives and measures accompanied by, among other things, data reflecting the real-world use of the EHR technology by the attesting physician and a certification providing:

> [T]he foregoing information is true, accurate, and complete. I understand that the Medicare EHR Incentive Program payment I requested will be paid from Federal funds, that by filing this attestation I am submitting a claim for Federal funds, and that the use of any false claims, statements, or documents, or the concealment of a material fact used to obtain a Medicare EHR Incentive Program payment, may be prosecuted under applicable Federal or State criminal laws and may also be subject to civil penalties.

ALLEGATIONS

I. ModMed Conspired with Miraca to Make Improper "Donations" of ModMed's EHR Technology.

38. As discussed above, the EHR Donation Safe Harbor created a limited exception to the AKS that permitted pathology laboratories like Miraca to make donations to physicians for up to 85 percent of the cost of an EHR system.

39. However, HHS recognized the "substantial risk that free or reduced price goods or services may be used as a vehicle to disguise or confer an unlawful payment for referrals of Federal health care program business." 71 Fed. Reg. at 45111. For that reason, HHS mandated that to fall within the scope of the EHR Donation Safe Harbor, "neither the eligibility of a recipient for the items or services, nor the amount or nature of the items or services, is determined in a manner that directly takes into account the volume or value of referrals or other business generated between the parties." 71 Fed. Reg. at 45136; 42 C.F.R. § 1001.952(y)(5).

40. ModMed recognized the limitations on the EHR Donation Safe Harbors. In 2010 and 2011, company executives discussed these limitations in internal emails, including the requirement that "donation[s] cannot be dependent upon referrals" and that laboratories "cannot demand a quid pro quo for their donation."

41. Despite this understanding of the limitations on EHR donations, ModMed conspired with Miraca to make EHR donations to healthcare providers in exchange for referrals of pathology lab orders to Miraca, in violation of the AKS.

42. Miraca provides clinical pathology laboratory services to healthcare providers. When providers order laboratory tests for their patients, they send tissue or fluid samples to

pathology labs, such as Miraca, where pathologists analyze the samples for disease and advise the ordering providers of their findings.

43. From January 2010 until December 2013, Miraca decided whether to make an EHR donation based on the expected value of the business that the donation recipient would generate for Miraca.

44. Before a donation would be approved, Miraca required its sales force to compute the "return on investment" (ROI) associated with the proposed donation by projecting the number of referrals that a healthcare provider would send to Miraca in return for the EHR donation, and the aggregate value of these referrals. Miraca management used the ROI analysis to evaluate which providers would receive a donation and the amount of the donation. Miraca's ability to at least "break even" on a particular donation was a significant factor in the donation approval process.

45. For its part, ModMed was instrumental in propelling Miraca's efforts to gain business via improper EHR donations. Although the EHR donations were intended to induce healthcare providers to make referrals to Miraca, ModMed benefitted from the scheme because each healthcare provider that received a donation was a new EHR software customer. As one ModMed sales manager explained, Miraca's EHR donations helped her and ModMed "succeed."

46. Miraca and ModMed exchanged sales leads and data that detailed provider behavior in an effort to target new customers for one or both companies and maximize both companies' ROI from Miraca's EHR donations.

47. For example, in November 2012, a ModMed sales manager provided Miraca with a spreadsheet entitled "EMA + Miraca Target List" that included nearly 150 prospective clients. The ModMed manager explained that these "targets" represented "50% of the practices in [her]

pipeline" and that she had selected these practices "exclusively" for Miraca because she knew these practices were not currently working with other pathology labs.

48. The ModMed manager encouraged Miraca to let these practices know that donation dollars were available and "sell" the practices on value of "EMA + Miraca." The ModMed manager's express goal in sharing this information with Miraca was to "close some year-end business" and to "work together" to take sales "to the next level" in advance of the expiration of the EHR Donation Safe Harbor.

49. As part of these same exchanges, the ModMed manager expressly encouraged Miraca to provide a safe harbor donation to one such practice, explaining the practice "ha[s] not discussed any other lab. A [safe harbor] donation might push [Practice] to get this done sooner." The ModMed manager followed up again with Miraca about this practice in April 2013, explaining that the practice in question remained interested in receiving an EHR donation and was willing to switch pathology labs to Miraca. The ModMed manager noted that she had given Miraca "a strong recommendation."

50. In response, Miraca explained that it "require[d] an office to send cases [to Miraca] before doing a donation to make sure we are a good fit before we invest in their practice." When deciding to make a donation to this specific practice, Miraca considered whether the practice was a current Miraca customer and whether they faced competition from another pathology lab for this practice's business.

51. ModMed understood that Miraca's EHR donations were made with the intent to induce providers to send business to Miraca. For example, following the expiration of the EHR Donation Safe Harbor, ModMed executives internally discussed Miraca's need to find new ways

to gain a competitive advantage and offer new services in part to make up for the fact that Miraca could no longer make EHR donation to generate additional revenue.

52. ModMed also understood that Miraca considered the volume of potential new business that a provider could generate when determining whether to make an EHR donation. For example, a ModMed salesperson emailed his Regional Sales Director about a new client who committed to purchasing ModMed's EHR but "was waiting on [her EHR] donation amount prior to moving forward because cost is a serious concern." The salesperson noted that although Miraca was "fighting for the business" of this practice, he expected that Miraca's donation amount would be "small" because the practice was "a small practice with not a lot of volume."

53. By the time the Safe Harbors expired in December 2013, ModMed and Miraca had conspired to make EHR donations to over 40 dermatology practices that later purchased ModMed's EHR technology and referred pathology lab orders to Miraca, resulting in false claims to federal health care programs.

II. ModMed Violated the AKS by Driving Laboratory Orders to Miraca in Exchange for Improper Remuneration.

54. In early 2013, after the EHR Donation Safe Harbor had terminated, Miraca and ModMed began negotiating a new "strategic partnership" through which Miraca would directly compensate ModMed when its users sent laboratory orders to Miraca.

55. One goal of the arrangement was to "incentivize [ModMed's] sales team and corporate leadership to direct potential customers to Miraca."

56. In other communications, ModMed employees stated that the objective of the "partnership" was to increase Miraca's "account penetration (share of wallet)," meaning the

share of an EHR user's laboratory orders that were directed to Miraca compared to other laboratories.

57. To accomplish the goal of inducing ModMed to increase the flow of lab orders that its users sent to Miraca, the parties created an arrangement that (1) provided Miraca with exclusive access to EMA laboratory interfaces that would drive ModMed users to Miraca, and (2) financially remunerated ModMed for referring and recommending Miraca to EMA users.

58. ModMed sought and received financial premiums from Miraca over and above what other laboratories paid ModMed. ModMed provided Miraca with data regarding ModMed clients' use of Miraca so that Miraca could estimate how much it would profit from the remuneration it provided to ModMed.

59. In August 2013, Miraca transmitted a draft letter of intent ("LOI") to ModMed explaining that Miraca "tried to make the partnership mutually beneficial and allow both Miraca and MMI [ModMed] to share in success and … tried to ensure strategic and financial alignment for both organizations." The LOI contemplated that ModMed would provide "co-marketing/promotion" that included recognizing Miraca as a partner, issuing a joint press release, and co-development of marketing materials, among other things. ModMed signed the LOI with Miraca on August 22, 2013.

60. On September 20, 2013, ModMed and Miraca executed a contract (the "Electronic Data Interchange Services Agreement" or "EDI Agreement") to formalize their arrangement. The EDI Agreement had several key features.

61. First, in the EDI Agreement, Miraca agreed to pay $250,000 to ModMed to develop "enhanced features" in its EHR software for laboratory referrals, including an "enhanced orders interface" and an "enhanced results interface."

62. The "enhanced orders interface" allowed physicians to electronically transfer attachments with each pathology sample directed to Miraca. Specifically, the enhanced orders interface allowed physicians to include in order requisition forms "(i) history of present illness, (ii) family history of melanoma if present, (iii) previous history of melanoma with melanoma staging if applicable, (iv) a Continuity of Care Document (CCD), and (v) digital photographic images."

63. The "enhanced result interface" allowed physicians who sent orders to Miraca to electronically receive the laboratory results directly back into EMA, which made them immediately available and improved accuracy. In addition, the enhanced results interface automatically prepopulated laboratory results, action, and plan for physicians.

64. The enhanced features were highly attractive to physicians, improved medical care and patient safety, saved physicians time and money, and ensured more accurate medical notes. However, if a physician sent a laboratory order to a lab other than Miraca, the physician could not use the enhanced features.

65. Specifically, the EDI Agreement expressly stated that ModMed could "not make any Enhanced Features available for use by [ModMed]'s medical practice customers in connection with the transmission of pathology test orders by such customers to, or the receipt of pathology test result by such customers from, any pathology labs other than [Miraca]" for a minimum period of 180 days after ModMed provided notice to Miraca that it was terminating exclusivity.

66. The parties recognized that exclusive access to the enhanced features was a "game changer" for Miraca and produced a "major selling point for Miraca."

67. In exchange, and to induce ModMed to give Miraca exclusive access to the enhanced features and thereby improve Miraca's "penetration" at physician practices that used ModMed, Miraca agreed to pay ModMed transaction fees that were far above fair market value.

68. In the EDI agreement, Miraca agreed to pay a "per specimen" fee to ModMed for each specimen that a ModMed user sent to Miraca. Miraca adjusted the amount of these per specimen fees based on the percentage of laboratory orders that ModMed users sent to Miraca compared to other laboratories. For example, if a ModMed user sent 20 percent or less of its specimens to Miraca, then Miraca would pay $1.50 per specimen. But if a ModMed user sent 95 percent or more of its lab specimens to Miraca, then Miraca would pay $3.10 per specimen.

69. These per specimen fees were significantly higher than the fees that ModMed received from any of Miraca's competitors. Even the fees at the lowest end of the sliding scale were above market rate. The lowest per specimen fee of $1.50 reflected an 18 percent premium over typical fees paid by other small laboratories, and a 325 percent premium over what ModMed received from large laboratories.

70. ModMed recognized that the inflated transaction fees were intended to induce referrals to Miraca. In the words of one ModMed employee: "the transaction fees paid by [Miraca] are higher than fees paid by other labs . . . so that there is some financial incentive for ModMed to refer business to Miraca (though there is no contractual obligation to do so)." Another ModMed employee observed: "As we all know, we make more money when Miraca has full saturation . . . ."

71. In addition to the per specimen transaction fees, ModMed secured a guaranteed minimum payment from Miraca every month. Specifically, the EDI Agreement provided that if the aggregate "per specimen" fees due from Miraca dropped below $20,000 in any given month,

Miraca would pay ModMed the difference between the aggregate "per specimen" fees and the $20,000 guaranteed minimum payment.

72. Miraca recognized that paying ModMed more than any other laboratory provided a strong incentive for ModMed to refer laboratory orders to Miraca. Thus, in the EDI Agreement, Miraca negotiated for the right to pay ModMed at least as much as any of Miraca's competitors. The EDI Agreement provided that if another laboratory offered ModMed a higher transaction fee, the parties would "negotiate in good faith to amend the Per Specimen Fee schedule . . . such that the lowest amount payable by [Miraca] to [ModMed] under the Per Specimen Fee schedule then in effect is increased to at least match the lowest amount payable to [ModMed] by such Higher Paying Lab."

73. In exchange for the significant financial perks from Miraca that increased based on both the volume and percentage of specimens sent by ModMed users to Miraca, ModMed steered EMA users to Miraca by recommending Miraca and by prohibiting Miraca's competitors from developing enhanced features.

74. Soon after ModMed and Miraca executed the EDI Agreement, ModMed worked to "drive" EMA users' laboratory orders to Miraca. On August 7, 2014, one ModMed executive noted that the "ModMed sales and BizDev teams [were] aligned and assigned to actively drive improved Miraca penetration and net new accounts."

75. ModMed shared physician-client information—including the volume of specimens ordered—with Miraca so that the parties could work together to "target" physician practices to induce them to switch from their current pathology lab to Miraca as part of the parties' growth strategy.

76. ModMed's regional sales managers were paired with their counterparts at Miraca to work together to close deals on Miraca's behalf. The ModMed and Miraca teams conducted bi-weekly calls during which they worked to analyze "prospects, pipeline, wins, etc."

77. The parties additionally conducted joint road shows and hosted dinners with key Miraca targets. After one such event in February 2016, Miraca described one of ModMed's managers as "a walking billboard of representation for our EMA/Miraca partnership." ModMed employees stated that "Miraca is a true extension of the MMI organization" and that ModMed is an "[ex]tension of sales force" for Miraca.

78. ModMed was warned that its arrangement with Miraca violated the AKS. For example, ModMed received and reviewed an April 2014 OIG Advisory Opinion (No. 14-03) alerting that EHR vendors could violate the kickback statue through arrangements that favored one laboratory over another. In addition, Miraca competitors contacted ModMed after the OIG advisory opinion to complain that the exclusivity arrangement with Miraca was contrary to OIG's position.

79. On February 2, 2016, a Miraca competitor emailed ModMed stating it had "raised concerns with Modernizing Medicine on several occasions regarding your exclusive lab arrangement with Miraca since its inception." The competitor noted that its "desire, and expectation, is to have nothing more than a level playing field."

80. ModMed developed messaging for its employees when laboratories complained about the Miraca arrangement. Specifically, ModMed instructed its employees to tell Miraca competitors that ModMed was "lab agnostic," and that ModMed did not favor Miraca over other labs.

81. ModMed's arrangement with Miraca was contrary to ModMed's own policies and guidelines, which prohibited ModMed from promoting or favoring one laboratory over another and entering marketing arrangements that intended to improperly induce referrals of healthcare products or services.

82. ModMed's illegal referrals to Miraca and use of Miraca's exclusive access to the enhanced interfaces to arrange for orders to be sent to Miraca created the significant competitive advantage the parties anticipated and that Miraca paid ModMed to provide.

83. Miraca's key performance metrics improved dramatically as a result of ModMed's referral activities, including Miraca's (a) "penetration rates," meaning the percentage of a ModMed user's laboratory orders that were directed to Miraca versus its competitors, (b) "cases per day," meaning the average daily number of laboratory cases ordered in a given month that Miraca received from ModMed users, and (c) "specimens" received from ModMed users.

84. Federal health care programs also experienced the impacts of ModMed's efforts on behalf of Miraca. In September 2013, ModMed users submitted 5,315 claims to Medicare for Miraca's laboratory services, resulting in Medicare payments of $365,242. By September 2016, ModMed users submitted 17,705 claims to Medicare for Miraca's laboratory services—a 233% increase. Medicare payments to ModMed users for Miraca's laboratory services exceeded $1.2 million in September 2016.

85. ModMed and Miraca terminated the EDI Agreement in November 2016.

III. ModMed Violated the AKS by Providing Illegal Remuneration to ModMed Users and Other Influential Parties in Exchange for Referrals of EHR Clients.

86. In addition to the kickback arrangements with Miraca described above, ModMed also unlawfully paid current EMA users and industry influencers to recommend ModMed's EHR technology to prospective new users.

87. ModMed knew that it was illegal to provide remuneration in exchange for referrals. As of 2014, ModMed had a corporate policy that explicitly barred the paying, offering or receiving of kickbacks. In March 2016, ModMed amended its corporate policy prohibiting kickbacks, and the updated policy expressly cited the AKS in connection with referral sources and financial relationships with healthcare professionals.

88. And communications between ModMed executives reflected an understanding that payments for referrals implicated the AKS. In one instance, a ModMed executive warned "We have to be *very* careful here not [to] convey that Modernizing Medicine is providing a 'gift' of any means. Gifts over $50 to doctors can get both parties into trouble." Similarly, in May 2016, a ModMed executive offered stock equity to a large orthopedic practice if it selected ModMed and provided "continued feedback and support as an orthopedic champion." In response, another ModMed executive noted that "[y]ou can't give consideration back to a practice for getting a sale."

89. Despite this recognition on the part of ModMed that paying kickbacks in exchange for referrals was illegal, ModMed knowingly and willfully paid remuneration through several different programs to its customers and industry influencers in exchange for endorsements and recommendations of EMA. Each of the claims that resulted from, and were tainted by, ModMed's unlawful provision of remuneration are false claims, including claims made by providers under the Meaningful Use Programs.

A. ModMed's Referral Program

90. Between 2011 and 2017, ModMed rewarded users who referred prospective clients to ModMed without regard to what a reasonable rate would be for time spent on the activity. Instead, ModMed's payments to its users were conditioned on the success of the referral—a prospective client's completing an EMA demonstration or signing with ModMed.

91. For referrals that occurred before 2014, ModMed provided referring practices with a three-month credit toward licensing fees if prospective clients adopted EMA. In 2014, ModMed switched to offering $200 gift cards to referring practices if prospective clients completed an EMA software demonstration. In 2016, ModMed began offering a $200 service credit fee to referring providers if a prospective client participated in a demonstration and a $1,500 service credit fee if the prospective client executed a contract with ModMed.

92. The referral payments were not based on any fair market value analysis or requirement that the referring practice have expended a certain amount of time or resources to justify payment from ModMed. Rather, payment of the referral credit was solely based on the success of the referral in inducing a new user to adopt and continue to use EMA.

93. In internal emails, ModMod employees openly acknowledged that the referral program was intended to drive sales. For example, in 2014, one ModMed executive noted the "need to goose the pipeline a bit" for a particular product and that "having the referral fee accomplishes that."

94. These payments distorted the market by incentivizing ModMed users to recommend EMA to prospective customers, with referring providers making clear that they expected compensation in exchange for their referral activities.

95. For example, in December 2014, Dr. H requested referral credits from past referrals of three physicians who became customers of ModMed. ModMed informed Dr. H that he would receive a three-month credit for two of the referrals and a $200 gift card for the third referral (Dr. J). Dr. H responded that Dr. J was a very close friend who had one of the largest dermatology practices in the country and had been hesitant to use an EHR until Dr. H told him how happy he was with EMA. Dr. H stated: "Given his [Dr. J's] trust in me and the discussions we had regarding your product, and that his 30 plus physicians/providers are now users, I think it would be appropriate to provide a more generous referral incentive than the $200 gift card." Dr. J and other physicians referred by Dr. H later obtained Meaningful Use incentive payments based on their use of ModMed's product.

96. One of Dr. H's referrals – Dr. G – later sought remuneration from ModMed in exchange for referring other providers. In 2015, ModMed applied a three-month credit, valued at $1,950, to Dr. G's account for his referral of another physician. Dr. G later requested payment for other referrals he made. In a spreadsheet entitled "2014 Incentive Tracking," ModMed noted that "[Dr. G] requested so we provided incentive because we need him as a reference."

97. The referral program was terminated in June 2017.

B. ModMed's Reference Program

98. ModMed also relied heavily on EMA users to host site visits and field calls from prospective users. One sales executive noted: "We live by these references."

99. ModMed generally paid $500 per site visit and $25 to $50 per phone call regardless of time spent on the visit. But the company was willing to pay even more to key references. For example, in 2015, an important reference (Dr. S) demanded increased payment amounts to participate in reference calls. In its response, ModMed expressly referenced the

applicability of kickback laws, but nonetheless agreed to pay $100 per 15-minute phone call. Likewise, in 2016, ModMed paid $1,000 to Dr. S for a single site visit, ostensibly because two providers attended.

100. The financial incentives paid by ModMed to induce reference activities played an important role in EMA clients' willingness to participate, with one practice in 2016 demanding compensation "to continue to be a reference" and stating, "[our practice] can be a great referral source for MM in helping them to close deals with prospective customers. We would like to discuss how to create a mutual benefit to both companies."

101. ModMed assessed whether clients would provide positive references, steered prospective customers away from practices that experienced problems with EMA and coded dissatisfied customers with a "red status" in ModMed's internal database. For example, in seeking to sign a "whale of an opportunity" in 2014, a sales representative asked that the "largest, happiest, most satisfied practice" using EMA be identified as a reference for the prospective client. ModMed was not paying for providers' time but rather for their positive—and only positive—reviews of EMA.

102. In another example, in 2014, after a prospective client was hosted by an EMA user and chose to sign with another company, ModMed employees stated they "should insist that [the EMA client] not promote physicians coming to see her use EMA" and immediately removed the practice from the reference list.

103. Providers who were referred to ModMed and acquired EMA via these reference and referral programs subsequently submitted tainted and therefore false claims to CMS for Meaningful Use incentive payments.

C. Improper Remuneration to Industry Influencers

104. In 2010, ModMed approached a well-known expert in dermatology billing, seeking an endorsement of EMA and assistance in developing the product.

105. In October 2010, while negotiating with ModMed, this billing expert promoted her potential value to ModMed: "Worst case we feel we can have 300 dermatologists sold on the system in the next 12 months and at least twice as many in the second year."

106. In November 2010, ModMed and this billing expert entered into a Letter of Understanding, which provided that the billing expert would endorse EMA as the best electronic medical record for dermatologists in promotional materials, advertise EMA in her newsletter, and host webinars focused on EMA, among other promotional activities. In exchange, ModMed agreed to offer the billing expert's customers a 50% discount on EMA.

107. In July 2011, ModMed and the billing expert extended and expanded their agreement. The billing expert agreed to engage in additional marketing activities, and ModMed agreed to use 10 percent of the monthly service fees collected from all new EMA-Dermatology customer accounts to sponsor other joint marketing activities to further promote the ModMed brand and its relationship with the billing expert.

108. In August 2012, ModMed and the billing expert extended the agreement for nine years. The extended agreement required that the billing expert give her "exclusive endorsement" of EMA as "the best electronic medical record offering for dermatologists," to advertise EMA in her newsletter, emails, and on her website, and appear at six national shows or conferences scheduled by ModMed per year. In exchange, ModMed agreed to pay the billing expert a fee equal to 5 percent of the monthly subscription fees earned by ModMed from the billing expert's customers' monthly subscription fees during the first year of use of EMA.

109. ModMed announced to investors that it had signed "on[]e hell of a deal" with the billing expert. ModMed would be "taking care" of the 120 billing practices that worked with the billing expert by offering them a discount on ModMed's EMA. In exchange, the billing expert would "massively promote EMA" and be "gushing with good things to say." ModMed predicted a "massive waive" of new customers and prospects as a result of the billing expert's endorsement.

110. ModMed's compensation of the billing expert under the agreement was tied to the amount of business generated, not any fair market value for the marketing activities contemplated. The more money ModMed made from the relationship, the more money it paid to the billing expert.

111. ModMed discussed the success of marketing activities in terms of business generation. For example, on January 3, 2011, the billing expert sent out an endorsement email as contemplated by the agreement. The following day, a ModMed executive noted that in response to this email, ModMed "received over 20 demo requests and 325 new visits to our website" in a six-hour time period. He also wrote that "[w]e have closed 27 practices" and "raised 2.1 million."

112. On February 2, 2011, a ModMed executive wrote in an email to the billing expert that its promotion of ModMed had been "incredibly successful, and we have already closed 55 practices to date, and climbing."

113. Over the course of the relationship, ModMed paid the billing expert approximately $930,000.

114. ModMed benefitted enormously from the relationship with the billing expert, with one ModMed sales manager opining that the billing expert "helped put [ModMed] on the map

through their endorsement," and was "THE reason we took off as quickly as we did with EMA sales – endorsing us & doing many webinars for us early on."

IV. ModMed's EHR Software Did Not Always Record Medical Records Using Required Vocabularies.

115. As discussed above, the Meaningful Use Programs provided incentive payments to healthcare providers who attested to using, and demonstrated "meaningful use" of, certified EHR technology.

116. As part of the certification program, EHR developers that seek to have their software certified must provide documentation and evidence to authorized accredited testing laboratories (ATLs) and authorized certification bodies (ACBs) that the relevant software meets the full scope of the certification requirements established by the HHS Office of National Coordinator for Health Information Technology (ONC). The ATLs and ATBs test and certify that developers' EHRs are compliant with the certification requirements.

117. After obtaining certification, an EHR developer must maintain that certification by complying with all applicable conditions and requirements of the certification program. Among other things, the EHR product must be able to accurately, reliably, and safely perform its certified capabilities in the field.

118. Through the Meaningful Use Programs, CMS made incentive payments to healthcare providers for demonstrating meaningful use of certified EHR technology. Individual practitioners ("Eligible Professionals") could qualify for up to a total of $43,720 over five years from Medicare (ending after 2016) and up to a total of $63,750 over six years from Medicaid (ending after 2021).

119. CMS payment rules concerning the Meaningful Use Programs recognize that healthcare providers rely on certification for assurance that an EHR product meets the applicable certification criteria, including that it possesses the certified capabilities that healthcare providers will need to use to achieve relevant objectives and measures, and that the software will perform in accordance with applicable certified capabilities.

120. In order to qualify for incentive payments under the Meaningful Use Programs, Eligible Professionals were required, among other things, to: (1) use an EHR system that qualified as certified EHR technology; and (2) satisfy certain objectives and measures relating to their meaningful use of the certified EHR technology.

121. HHS implemented the certification criteria and incentive payment requirements in multiple stages. On January 13, 2010, HHS published in the Federal Register an interim final rule setting forth the "2011 Edition" certification criteria for certified EHR technology, and a proposed rule setting forth the "Stage 1" meaningful use requirements for incentive payments. HHS finalized these rulemakings by publication in the Federal Register on July 28, 2010.

122. On September 4, 2012, HHS published in the Federal Register the final rules setting forth the "2014 Edition" certification criteria for certified EHR technology, and "Stage 2" meaningful use requirements for incentive payments. As established in that final rule, in Stage 2, an Eligible Professional's use of certified EHR technology generally needed to satisfy seventeen "core objectives" and three out of six "menu set objectives."

123. On October 16, 2015, CMS published in the Federal Register a final rule with comment period setting forth the "Modified Stage 2" meaningful use requirements for incentive payments. For years 2015 through 2017, Modified Stage 2 eliminated the concept of "menu set

objectives" and required all Eligible Professionals to attest to a single set of objectives and measures.

124. To qualify for incentive payments in each Stage of the Meaningful Use Programs, healthcare providers were required to attest each year that they used certified EHR technology and satisfied the applicable Meaningful Use objectives and measures. Use of certified EHR technology and satisfaction of applicable Meaningful Use objectives and measures are material to payment under the Meaningful Use Programs.

125. Eligibility for Meaningful Use Stage 2 incentive payments required healthcare providers to use 2014 Edition certified EHR technology that, *inter alia*, utilized certain standard required vocabularies including RxNorm codes - a vocabulary used to provide normalized names for clinical drugs; and standardized clinical terminology known as Systematized Nomenclature of Medicine – Clinical Terms ("SNOMED CT") in order to conduct certain transactions.

126. During the time period from April 2014 through July 2017, ModMed's EMA software did not always enable users to conduct transactions using required standard vocabularies.

127. As a result, ModMed users who attested to being meaningful users of ModMed's EHR during this time period reported inaccurate information in connection with claims for incentive payments pursuant to the Meaningful Use Programs.

COUNT I

Violations of the Federal False Claims Act, 31 U.S.C. § 3729(a)(1)(A)

128. Paragraphs 1 through 127 of this Complaint are realleged and made a part of Count I.

129. Defendant ModMed knowingly caused to be presented false or fraudulent claims in violation of 31 U.S.C. § 3729(a)(1)(A) by causing provider users to submit claims for pathology lab services and meaningful use incentive payments that falsely certified compliance with all applicable Medicare rules, regulations, including the AKS. These claims were false within the meaning of the FCA because ModMed knowingly and willfully received improper remuneration from Miraca in exchange for recommending, referring, or otherwise arranging for its provider users to utilize Miraca's services in violation of the AKS.

130. Defendant ModMed also knowingly caused to be presented false or fraudulent claims in violation of 31 U.S.C. § 3729(a)(1)(A) by causing provider users to submit claims for meaningful use incentive payments that falsely certified compliance with all appliable Medicare rules and regulations, including the AKS. These claims were false within the meaning of the FCA because ModMed knowingly and willfully paid current ModMed's users and industry influencers to recommend, refer or otherwise arrange for healthcare providers to purchase ModMed's EHR software.

131. The United States would not have paid the false claims if it had known that the requests were associated with referrals obtained as a result of violations of the AKS.

132. Defendants also knowingly caused to be presented false or fraudulent claims paid or approved by the Government in violation of 31 U.S.C. § 3729(a)(1)(A) by causing provider users to submit claims for meaningful use incentive payments that included inaccurate data regarding certain use metrics as a result of EMA's failure to always enable a user to electronically record medical records using all required standard vocabularies.

133. As a result of the false or fraudulent claims ModMed knowingly caused to be presented, the United States has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

COUNT II

Violations of the Federal False Claims Act,
31 U.S.C. § 3729(a)(1)(C)

134. Paragraphs 1 through 127 of this Complaint are realleged and made a part of Count II.

135. ModMed conspired with Miraca to structure EHR donations in a manner that was a knowing, intentional, and/or willful violation of the AKS. ModMed further conspired with Miraca to cause physician users to submit claims to Medicare and Medicaid for meaningful use incentive payments that were the fruit of this illegal EHR donation. This conspiracy resulted in the presentation of false claims for meaningful use incentive payments, in violation of 31 U.S.C. § 3729(a)(1)(A).

136. These claims were false, within the meaning of the FCA, because the EHR donations were in violation of the AKS, and the resulting claims for meaningful use incentive payments that were submitted by providers who received improper EHR donations were a direct and intentional result of these violations.

137. By these actions, ModMed conspired to commit violations of 31 U.S.C. § 3729(a)(1)(A), in violation of 31 U.S.C. § 3729(a)(1)(C), making Defendant liable under the FCA. ModMed took one or more overt acts in furtherance of the conspiracy, including providing target lists and other physician information to Miraca in an effort to inform Miraca's

improper donation decisions, and by actively encouraging providers to solicit EHR donations from Miraca in order to induce improper donations.

138. By virtue of this conspiracy, the United States has suffered actual damages in an amount to be determined at trial and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

PRAYER

WHEREFORE, the United States prays that the Court enter judgment against ModMed in an amount equal to three times the amount of damages the United States has sustained because of ModMed's actions, plus a civil penalty for each violation of 31 U.S.C. § 3729, and provide such other relief as the Court deems just and proper.

Dated at Burlington, in the District of Vermont, November 1, 2022.

Respectfully submitted,

UNITED STATES OF AMERICA

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