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# Electronic Health Records Vendor to Pay \$145 Million to Resolve Criminal and Civil Investigations

## Practice Fusion Inc. Admits to Kickback Scheme Aimed at Increasing Opioid Prescriptions

Practice Fusion Inc. (Practice Fusion), a San Francisco-based health information technology developer, will pay \$145 million to resolve criminal and civil investigations relating to its electronic health records (EHR) software, the Department of Justice announced today.

As part of the criminal resolution, Practice Fusion admits that it solicited and received kickbacks from a major opioid company in exchange for utilizing its EHR software to influence physician prescribing of opioid pain medications. Practice Fusion has executed a deferred prosecution agreement and agreed to pay over \$26 million in criminal fines and forfeiture. In separate civil settlements, Practice Fusion has agreed to pay a total of approximately \$118.6 million to the federal government and states to resolve allegations that it accepted kickbacks from the opioid company and other pharmaceutical companies and also caused its users to submit false claims for federal incentive payments by misrepresenting the capabilities of its EHR software.

“Across the country, physicians rely on electronic health records software to provide vital patient data and unbiased medical information during critical encounters with patients,” said Principal Deputy Assistant Attorney General Ethan Davis of the Department of Justice’s Civil Division. “Kickbacks from drug companies to software vendors that are designed to improperly influence the physician-patient relationship are unacceptable. When a software vendor claims to be providing unbiased medical information – especially information relating to the prescription of opioids – we expect honesty and candor to the physicians making treatment decisions based on that information.”

The resolution announced today addresses allegations that Practice Fusion extracted unlawful kickbacks from pharmaceutical companies in exchange for implementing clinical decision support (CDS) alerts in its EHR software designed to increase prescriptions for their drug products. Specifically, in exchange for “sponsorship” payments from pharmaceutical companies, Practice Fusion allowed the companies to influence the development and implementation of the CDS alerts in ways aimed at increasing sales of the companies’ products. Practice Fusion allegedly permitted pharmaceutical companies to participate in designing the CDS alert, including selecting the guidelines used to develop the alerts, setting the criteria that would determine when a healthcare provider received an alert, and in some cases, even drafting the language used in the alert itself. The CDS alerts that Practice Fusion agreed to implement did not always reflect accepted medical standards. In discussions with pharmaceutical companies, Practice Fusion touted the anticipated financial benefit to the pharmaceutical companies from increased sales of pharmaceutical products that would result from the CDS alerts. Between 2014 and 2019, health care providers using Practice Fusion’s EHR software wrote numerous prescriptions after receiving CDS alerts that pharmaceutical companies participated in designing.

Practice Fusion executed a deferred prosecution agreement with the U.S. Attorney’s Office for the District of Vermont based on its solicitation and receipt of kickbacks from a major opioid company to arrange for an increase in

prescriptions of extended release opioids by healthcare providers who used Practice Fusion's EHR software. As detailed in the criminal Information made public today, Practice Fusion solicited a payment of nearly \$1 million from the opioid company to create a CDS alert that would cause doctors to prescribe more extended release opioids. That payment was financed by the opioid company's marketing department, and the CDS was designed with input from the marketing department. Practice Fusion and the opioid company entered the CDS sponsorship because they believed that the CDS would influence doctors' prescriptions of extended release opioids. In marketing the "pain" CDS alert, Practice Fusion touted that it would result in a favorable return on investment for the opioid company based on doctors prescribing more opioids.

"Practice Fusion's conduct is abhorrent. During the height of the opioid crisis, the company took a million-dollar kickback to allow an opioid company to inject itself in the sacred doctor-patient relationship so that it could peddle even more of its highly addictive and dangerous opioids," said Christina E. Nolan, U.S. Attorney for the District of Vermont. "The companies illegally conspired to allow the drug company to have its thumb on the scale at precisely the moment a doctor was making incredibly intimate, personal, and important decisions about a patient's medical care, including the need for pain medication and prescription amounts. This recovery is commensurate to the nature of Practice Fusion's misconduct, represents the largest criminal fine in the history of this District, and requires Practice Fusion to admit to its wrongs. It is another example of pioneering healthcare fraud enforcement by the talented Assistant U.S. Attorneys and staff of this U.S. Attorney's Office, working with their partners in law enforcement. We cannot — and will not — tolerate technology companies influencing patient treatment merely because a pharmaceutical company provided a kickback."

The criminal Information charges Practice Fusion with two felony counts for violating the Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7b(b)(1), and for conspiring with its opioid company client to violate the AKS, 18 U.S.C. § 371. This case is the first ever criminal action against an EHR vendor and the unique Deferred Prosecution Agreement imposes stringent requirements on Practice Fusion to ensure acceptance of responsibility and transparency as to its underlying conduct, and to invest heavily in compliance overhauls and an independent oversight organization. The Deferred Prosecution Agreement requires Practice Fusion to pay a criminal fine of \$25,398,300 and forfeit criminal proceeds of nearly \$1 million. In addition, the company will cooperate in any ongoing investigations of the kickback arrangement and report any evidence of kickback violations by any other EHR vendors. To ensure transparency and public awareness of the company's activities while the nation continues to battle an epidemic of opioid addiction, the Deferred Prosecution Agreement requires Practice Fusion to make documents relating to its unlawful conduct available to the public through a website. Additionally, the Deferred Prosecution Agreement mandates that Practice Fusion retain an independent oversight organization that is required to review and approve any sponsored CDS before Practice Fusion may implement the CDS, and create a comprehensive compliance program designed to ensure such abuses are not repeated.

The civil settlement with the United States resolves Practice Fusion's civil liability arising from the submission of false claims to federal healthcare programs tainted by the kickback arrangement between Practice Fusion and the opioid company. It also resolves allegations of kickbacks relating to thirteen other CDS arrangements where Practice Fusion agreed with pharmaceutical companies to implement CDS alerts intended to increase sales of their products. The \$118.6 million settlement amount includes approximately \$113.4 million to the federal government and up to \$5.2 million to states that opt to participate in separate state agreements.

"Prescription decisions should be based on accurate data regarding a patient's medical needs, untainted by corrupt schemes and illegal kickbacks," said U. S. Attorney David L. Anderson of the Northern District of California. "In deciding what is best for patients, electronic health records software is an important tool for care providers. It is critically important that technology companies do not cheat when certifying that software."

In addition to the kickback allegations, the civil settlement with the United States resolves allegations relating to two intersecting Department of Health and Human Services (HHS) programs, one at the Office of the National Coordinator for Health Information Technology (ONC) that regulates the voluntary health IT certification program, and one at the Centers for Medicare & Medicaid Services that oversees EHR incentive programs. Specifically, the United States alleged that Practice Fusion falsely obtained ONC certification for several versions of its EHR software by concealing from its certifying entity, known as an ONC-Authorized Certification Body, that the EHR software did not comply with all of the applicable requirements for certification. ONC's certification criteria were designed to promote enhanced functionality, utility, and security of health information technology, and access to patient medical information across the

care continuum. HHS implemented the certification criteria for EHR software in multiple stages, known as editions. To be certified under the 2014 Edition certification criteria, EHR software was required to allow users to electronically create a set of standardized export summaries for all patients. When Practice Fusion sought certification of this 2014 Edition criteria, Practice Fusion falsely represented to the certifying body that its software met this data portability requirement, when several versions of its software did not. The civil settlement resolves allegations that, at the time these versions of Practice Fusion's software were certified, its software was unable to permit a user to create a set of standardized export summaries. Additionally, after obtaining certification of the 2014 Edition criteria, Practice Fusion disabled access to this feature altogether. Instead, Practice Fusion required users to contact it separately to request export of this critical patient data.

In addition to failing to satisfy the data portability requirement, Practice Fusion's software allegedly did not incorporate standardized vocabularies as required for certification. The United States alleged that by fraudulently obtaining certification for its products, Practice Fusion knowingly caused eligible healthcare providers who used certain versions of its 2014 Edition EHR software to falsely attest to compliance with HHS requirements necessary to receive incentive payments from Medicare during the reporting periods for 2014 through 2016 and from Medicaid during the reporting periods for 2014 through 2017.

"As new technologies continue to develop and evolve, so too do new and innovative fraud schemes," said Shimon R. Richmond, Assistant Inspector General for Investigations of the U.S. Department of Health and Human Services. "We will continue to be vigilant in detecting and investigating these schemes in order to protect the safety of patients in federal health programs and to ensure the appropriate use of electronic health records in providing their care."

"Today's announcement shows that Practice Fusion exploited technology to profit at the expense of a vulnerable population – patients seeking medical advice," said Timothy M. Dunham, Special Agent in Charge of the FBI's Washington Field Office, Criminal Division. "The FBI is committed to working with our partners to bring to justice the perpetrators of healthcare fraud in all its forms, especially one that fans the flames of the already rampant opioid epidemic."

The U.S. Attorney's Office for the District of Vermont handled the criminal investigation and resolution. The civil investigation was jointly handled by the Civil Division's Commercial Litigation Branch and the U.S. Attorneys' Offices for the District of Vermont and the Northern District of California. The investigation was supported by the HHS Office of Inspector General and multiple HHS agencies and components. The FBI's field office in Washington, DC, also provided significant investigative support.

Except for the conduct admitted in connection with the criminal resolution, the civil claims resolved by the settlement are allegations only, and there has been no determination of liability as to such civil claims.

The year 2020 marks the 150th anniversary of the Department of Justice. Learn more about the history of our agency at [www.Justice.gov/Celebrating150Years](http://www.Justice.gov/Celebrating150Years).

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**Component(s):**

Civil Division

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