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EHR Vendors Beware: eClinicalWorks Settles with DOJ for $155 Million

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The Department of Justice ("DOJ") announced on May 31, 2017, a $155 million settlement of its lawsuit alleging False Claims Act ("FCA") and Anti-Kickback Statute ("AKS") violations committed by eClinicalWorks ("eCW"), one of the nation's largest electronic health records ("EHR") software vendors. Brendan Delaney, the original qui tam plaintiff in the case, will receive approximately $30 million as a result of the settlement.

The DOJ's complaint alleges that eCW knowingly made or used false records or statements material to false claims paid or approved by the Government and knowingly caused healthcare providers to present false or fraudulent claims for federal incentive payments that were paid or approved by the Government. More specifically, the complaint alleges eCW falsely attested to its certifying body that it met certification requirements under the Meaningful Use program, and in turn eCW caused its healthcare provider customers to make false claims for incentive payments under the Meaningful Use program by representing to those customers that eCW met applicable certification requirements. The Meaningful Use program, which was established by the Department of Health and Human Services ("HHS") pursuant to the HITECH Act, provides for incentive payments to healthcare providers who demonstrate meaningful use of certified EHR technology.

The complaint contends that eCW implemented certain "hardcoding" practices to pass certification tests without developing software that actually met certification requirements. EHR software is required to generate and transmit prescriptions using "Rx.Norm," a standardized drug vocabulary, in order to meet certification requirements for the Meaningful Use program. However, the complaint alleges that eCW used publicly available test scripts, which identified sixteen drugs that would be tested for compliance during certification testing, to "hardcode" only the sixteen drugs necessary to pass testing into its software rather than programming the capability to retrieve any code from the database using Rx.Norm codes, which would be required for all of the other drugs. Thus, according to the complaint, eCW was able to pass certification testing without actually

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meeting certification requirements and falsely attested to meeting certification requirements. Relying on eCW's representations regarding meeting certification requirements, its healthcare provider customers then made claims for incentive payments believing they satisfied Meaningful Use program requirements through their use of eCW's software.

The complaint also alleges that eCW's system and software failed to satisfy a number of additional certification requirements, including data portability requirements, audit log requirements, and requirements to reliably record diagnostic imaging orders and reliably perform drug-drug and drug-allergy checks. According to the complaint, eCW had a number of internal communications and/or communications with customers acknowledging issues that demonstrated its failure to satisfy these certification requirements. Again, despite these alleged failures, eCW attested to meeting certification requirements.

In addition to causing customers to make false claims for incentive payments under the Meaningful Use program, the complaint also alleges a number of AKS violations by eCW. First, pursuant to a "referral program," eCW allegedly paid current users for each provider they referred who executed a contract with eCW, resulting in payments totaling in excess of $140,000 to users between 2011 and 2015. Second, through a "site visit program," eCW allegedly paid current users to host prospective customers at their facilities, with final payouts to current users based on the number of users at the prospective customer's practice and an additional payment if the visiting practice purchased eCW's software, resulting in payments totaling in excess of $240,000 to users between 2011 and 2015. Third, through its "reference program," eCW allegedly paid current users to serve as references for prospective customers and would pay an additional amount if the prospective customer purchased eCW's software. Finally, eCW allegedly paid "consulting" and "speaker" fees to influential users who promoted its software. Unfortunately, the complaint spends much less time on AKS issues and does not provide a detailed analysis as to the aspects of these arrangements it found objectionable (e.g., the complaint fails to analyze any of the arrangements under the multi-factored test often used for AKS implications of "marketing activities," as exemplified in OIG Advisory Opinion 12-02).

As part of the settlement, eCW entered into a five-year Corporate Integrity Agreement ("CIA") with the HHS Office of Inspector General ("OIG"). Among other things, the CIA requires eCW to: establish a corporate compliance program addressing identified issues; engage a "Software Quality Oversight Organization" to assess the effectiveness, reliability, and thoroughness of various aspects of eCW's EHR software, policies, and practices, and to submit reports to eCW and OIG; engage an "Independent Review Organization" to review eCW's arrangements with actual or potential sources of health care business or referrals and internal practices related to such arrangements; and provide at no cost certain options to its customers, such as free upgrades to software updated to address eCW's noncompliance issues and the option for existing customers to transfer data to another vendor without penalties or service charges.

It remains to be seen whether this settlement signals (or catalyzes) an increasing scrutiny of EHR software vendors under the False Claims Act. Regardless, the settlement serves as a warning and reminder for EHR software vendors to review current practices and products to ensure compliance with certification requirements and to analyze marketing and other activities for compliance with AKS rules.