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Government Puts Electronic Health Records Companies "on Notice" of Vigorous Enforcement

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Federal prosecutors announced yesterday the Government's settlement with electronic health records ("EHR") vendor Greenway Health, LLC ("Greenway") of False Claims Act ("FCA") allegations for a payment of \$57.25 million and Greenway's acceptance of a <u>Corporate Integrity Agreement</u> ("CIA"). The Government's FCA <u>complaint</u> was filed by the U.S. Attorney's Office for the District of Vermont, the same office that handled the May 2017 civil settlement with EHR company eClinicalWorks for \$155 million. The Greenway settlement is the second largest civil settlement in the District of Vermont's history, topped only by the eClinicalWorks settlement.

The U.S. Attorney for Vermont, Christina Nolan, was clear that her office would continue to use its developing expertise to pursue nationwide cases dealing with EHR companies, stating that "[t]his is the new frontier of health care fraud." According to Nolan, "[t]his resolution demonstrates [her] office's initiative and resolve to vigorously uncover and to doggedly pursue these complex cases...**EHR companies should consider themselves on notice**" (emphasis added).

Much like the eClinicalWorks settlement, the Greenway settlement resolves allegations that Greenway caused purchasers of its products to falsely certify that they were using EHRs that complied with Government standards for the use of EHR technology, knowing that its products and their use did not in fact meet these standards. Under the American Recovery and Reinvestment Act of 2009, the Government offers incentives to health care providers that meet these standards and, in so doing, demonstrate "meaningful use" of certified EHR technology. According to the Government, Greenway knowingly marketed technology that resulted in the payment of incentives to providers who did not actually meet meaningful use standards.

In particular, the Government alleged that Greenway modified the test software it presented to its certifying entity for its 2014 edition to pass the entity's test, concealing the fact that its software – Power Suite – did not truly meet Government standards. This alleged deception allowed Power Suite users to receive Government incentive payments even though they were not using a compliant product. The Government also alleged that Greenway was aware of a bug in an earlier version of its software that caused incorrect calculations of the percentage of office visits for which users distributed clinical summaries, causing users to falsely attest to eligibility for incentive payments.

Finally, and also similar to the allegations made against eClinicalWorks, the Government alleged that Greenway paid money and incentives to its clients to recommend its software to new customers, in violation of the federal health care program Anti-Kickback Statute.

In the face of the Government's aggressive enforcement efforts against – and direct warning to – EHR companies, the industry may reasonably feel threatened. The costs and consequences of a Government investigation can be severe; in addition to Greenway's cash settlement, it will be saddled with the substantial cost of implementing and adhering to a five-year CIA, including retention of an Independent Review Organization to provide regular assessments of and reports on its quality control, compliance systems, and arrangements with health care providers. The CIA also requires Greenway to offer the latest versions of Prime Suite to its customers for free, to offer data migration from Prime Suite to other Greenway software products for free, and to offer data transfer to other software vendors without penalties, service charges, or other fees.

Industry participants and EHR companies in particular, therefore, should consider proactive measures to avoid even the appearance of misconduct and to emphasize their commitment to full compliance. In concert with and at the direction of their counsel, companies should consider:

- Developing or strengthening policies and procedures for technical staff to report software bugs and other deficiencies, and to ensure that any identified issues are promptly and fully addressed:
- Implementing or increasing regular quality control testing of any software products and versions in use by customers, including for compliance with Government standards;
- Implementing or strengthening reporting and correction protocols to address audit results;
- Comparing test software against final versions to ensure that test software is an accurate representation of the product provided to customers;
- Developing or strengthening mechanisms for transparent communication with customers about identified software issues, given the implications of the certifications that customers make to the Government;
- Developing, strengthening, and auditing compliance with policies and procedures related to customer relationships in order to minimize risk of liability under the Federal health care program Anti-Kickback Statute

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