THE NATIONAL LAW REVIEW

Department of Justice Announces Significant False Claims Act Settlements Tied to Electronic Health Records Arrangements

Wednesday, February 20, 2019

Robinson+Cole

Article By Robinson & Cole LLP
Conor O. DuffyHealth Law Diagnosis

Communications, Media & Internet
Health Law & Managed Care
All Federal

The Department of Justice (DOJ) recently announced two high-dollar False Claims Act (FCA) enforcement actions involving allegedly fraudulent arrangements tied to the implementation and use of electronic health record systems (EHRs). The respective settlements enable recovery by DOJ of over $100 million, and immediately precede the government's recent proposal of new rules to promote the interoperability of EHRs. The settlements thus serve as an important reminder of the importance of adhering to federal fraud and abuse laws and regulations as hospitals and other health care providers continue to implement EHR technology.

First, on January 30, 2019, DOJ announced a $63.5 million settlement with Inform Diagnostics (formerly Miraca Life Sciences, Inc.), a pathology laboratory company, for allegedly violating the Anti-Kickback Statute (AKS) and physician self-referral law (Stark Law) by paying subsidies to referring physicians for EHRs and furnishing "free or discounted technology consulting services." According to DOJ, the defendant, in this case, violated the former AKS safe harbor and Stark Law exception under which laboratory companies were permitted to donate EHR technology under certain conditions (until rescission of the availability of such safe harbor and Stark Law exception to laboratories in 2013). The settlement resolves allegations contained in three qui tam FCA suits filed against the defendant, and in settling the defendant did not admit any liability.

Second, on February 6, 2019, DOJ announced a $57.25 million settlement with Greenway Health LLC (Greenway), an EHR vendor, for allegedly causing "its users to submit false claims to the government by misrepresenting the capabilities of its EHR product "Prime Suite" and providing unlawful remuneration to users to induce them to recommend Prime Suite." DOJ alleges that Greenway falsely obtained certification for its Prime Suite EHR product in 2014 in connection with the government's "meaningful use" EHR incentive program, and incorrectly calculated certain mandatory "meaningful use" metrics that allegedly caused users to falsely attest to the government that they were eligible for EHR incentive payments under the meaningful use program. DOJ also alleged that Greenway violated the AKS by furnishing money and incentives to clients to induce recommendations of its products to prospective customers.

In connection with the settlement, Greenway agreed to enter into what DOJ characterizes as an "innovative" five-year Corporate Integrity Agreement under which Greenway must retain an independent review organization to assess its software quality control and compliance, provide prompt notice to customers of any patient safety issues, and allow Prime Suite customers to (i) obtain the latest version of that product at no charge, (ii) migrate their data from Prime Suite to another Greenway product at no charge, or (iii) have Greenway transfer their data to another EHR vendor at no additional cost.

At a time of renewed focus on the capabilities and implementation of EHRs by health care providers, the above settlements reiterate that "EHR companies should consider themselves on notice" as a DOJ official stated. Health care providers would, therefore, be well-advised to review their current EHR capabilities and compliance systems in light of federal compliance and interoperability guidance.

Source URL: https://www.natlawreview.com/article/department-justice-announces-significant-false-claims-act-settlements-tied-to