

## Compliance Today – July 2020 EHRs are a DOJ priority: Recent cases may explain why

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In late February, Joseph (Jody) Hunt, assistant attorney general (AAG) for the Department of Justice (DOJ) Civil Division, told the Federal Bar Association about the DOJ's civil enforcement priorities for 2020. Alongside elder justice initiatives and skilled nursing facilities—the presentation preceded the coronavirus pandemic taking hold in the United States—AAG Hunt listed electronic health records (EHR) systems as targets for future action.<sup>[1]</sup> Scrutiny of EHR-related issues is not new, and it is not surprising given that the federal government has invested more than \$35 billion in meaningful use incentive payments over the last decade.<sup>[2]</sup> A brief review of the history of EHR-related False Claims Act (FCA) settlements and two newer cases may shed some light on where DOJ is heading in the EHR arena.

### **EHR-related cases historically**

Over the last few years, EHR-centered fraud and abuse cases have fallen primarily into two categories.<sup>[3]</sup> “The first is cases where healthcare companies, like laboratories, allegedly paid kickbacks in the form of subsidies for EHR systems to referring physicians and physician groups.” These financial arrangements fell outside of the Anti-Kickback Statute safe harbor and the Stark Law exception that the Centers for Medicare & Medicaid Services had put in place to permit certain EHR donations. The two lead cases in this category are Inform Diagnostics<sup>[4]</sup> and OURLab.<sup>[5]</sup> While these were significant dollar-value cases—Inform Diagnostics was one of the ten largest FCA settlement in 2019<sup>[6]</sup>—they do not directly involve the features or functions of the EHR systems themselves.

In the second category of cases, DOJ has alleged that EHR developers fraudulently obtained certifications for their EHR software through misrepresentations about the systems' capabilities. According to the government, healthcare providers using those systems submitted false claims for meaningful use incentive payments in violation of the FCA because the systems' deficiencies rendered the providers' submissions inaccurate. EHR developers like Greenway Health LLC<sup>[7]</sup> and eClinicalWorks<sup>[8]</sup> have paid large settlements to resolve these types of allegations. The fraudulent conduct in this category of cases directly implicates the functionality of the EHRs, but not necessarily the manner in which their features are employed daily by the systems' end users.

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