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# Enforcement and Health Care Technology: Navigating Fraud and Abuse Issues in Emerging Digital Health Care Areas

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Like many industries, the health care industry has become increasingly digitized and reliant on technology. Technology advancements also have had a major effect on enforcement. In his comments to the Federal Bar Association on February 17, 2021, Acting Assistant Attorney General Brian M. Boynton described the benefits of data analytics to the government when choosing how to use its enforcement powers.<sup>[1]</sup> Although the role of the traditional whistleblower has not been usurped, the increased focus of the Department of Health and Human Services (HHS) Office of Inspector General (OIG), Civil Division attorneys, and local Assistant U.S. Attorneys on Medicare data outlier costs and diagnostic code usage trends cannot be ignored.<sup>[2]</sup> And while the government relies on data analytics to *uncover* potential fraud, it has also applied particular scrutiny to health care companies' own use of technology that could

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be used to *commit* potential fraud. Suffice to say, companies entering the tech space should be forewarned and proceed cautiously.

## “Traditional” Health Care Technology Enforcement Actions

The digitalization of health care skyrocketed after the implementation of the Health Information Technology for Economic and Clinical Health (HITECH) Act signed by President Obama on February 17, 2009. To encourage providers to make use of electronic health records (EHR) in lieu of continued reliance on paper files, and, in turn, to improve compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the government offered incentive payments to providers who met “meaningful use” metrics and criteria for EHR. The EHR Incentive Programs were retitled the Promoting Interoperability Programs in 2018. According to the Centers for Medicare & Medicaid Services (CMS), more than 1.5 million health care providers received nearly \$40 billion in incentive payments through the Programs between 2011 and September 2018.<sup>[3]</sup>

The HITECH Act has resulted in numerous enforcement actions, which continue even ten years after its inception, although the theories of liability have changed. Initial enforcement actions by the government in the EHR realm focused on provider certification of compliance, alleging that providers fabricated documents to obtain the incentive payments when their practices were not actually up to EHR standards.<sup>[4]</sup> Recently, the government turned its attention to EHR developers instead, accusing them of being untruthful about the capabilities of their products,<sup>[5]</sup> or paying bribes to generate sales of their products resulting in the recoupment of millions of dollars.<sup>[6]</sup>

## 2019 Right of Access Initiative and Resulting Actions

HHS developed the Right of Access Initiative to prioritize enforcement of an individual’s right to timely access their health records at reasonable costs. The initiative comes under the HIPAA Privacy Rule.<sup>[7]</sup> In 2019, the Office for Civil Rights at HHS announced five settlements stemming from complaints it investigated under the initiative. Each complaint alleged that a provider failed to timely give a patient access to their records. The settlements ranged in amounts from \$3,500 to \$70,000.<sup>[8]</sup> Though the individual settlements seem small compared to other HHS enforcement actions, the settlements are all the result of a single complaint. Organizations that have systematic issues with granting patients access to their records could expose themselves to substantially higher monetary risk.

Conversely, health care providers have sued HHS under the HITECH Act and HIPAA over the Department’s rules surrounding how patient records must be delivered to the patient by a provider. In *Ciox Health, LLC v. Azar*,<sup>[9]</sup> the district court held that HHS’

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amended rule requiring that an individual's medical records be delivered to third parties making requests for such information regardless of whether it was contained in an EHR was arbitrary and capricious.<sup>[10]</sup> The court vacated the rule as it related to the expansion of the HITECH Act's third-party directive beyond requests for a copy of "an [EHR] with respect to [PHI] of an individual . . . in an electronic format" and also vacated the corresponding guidance for failure to go through notice and comment.<sup>[11]</sup>

## The New Wave of Enforcement Actions—Clinical Documentation Integrity Programs and “Biased” EHR

Although some companies and providers continue to struggle with implementation, meaningful use, and providing EHR access to patients, others have made advantageous use of the wealth of information at their fingertips as a result of ever-evolving technologies associated with health care data. By improving the documentation and information described in health records using analytic tools, hospitals can better understand their patients and improve the level of care provided, while improving their case mix and appropriately increasing revenue.

So long as they are accompanied by guardrails in the form of human oversight—namely, a robust compliance program and employee training—data analytics can be an invaluable tool to improve the accuracy of medical records in an EHR system. After all, prior to the implementation of HITECH, CMS stated: “We do not believe there is anything inappropriate, unethical or otherwise wrong with hospitals taking full advantage of coding opportunities to maximize Medicare payment that is supported by documentation in the medical record.”<sup>[12]</sup>

And, importantly, providers are clamoring for access. According to a 2018 survey of 2,920 hospital and physician financial executives, 93% of providers stated that “they are actively seeking ways to link care with analytics and outcomes.”<sup>[13]</sup> Between 2016 and 2018, the number of survey respondents confident that their EHRs effectively captured patient data to meet developing clinical documentation needs increased from 50% to 70%.<sup>[14]</sup> Although the government uses its own data analytics tools, it has not readily encouraged health care providers to do the same with clinical documentation integrity (CDI) programs based on EHR analytics. As technology has developed, the government's skepticism of analytics as a way to improperly persuade and manipulate physician judgment or falsely inflate Medicare billing has dampened excitement in the industry.

Despite resembling a traditional kickback case in some respects, the government's recent settlement with Practice Fusion for \$145 million signaled a course by the government to scrutinize and pursue what it perceives to be “biased” EHR systems or processes.<sup>[15]</sup> As part of a criminal resolution, Practice Fusion admitted that, in

exchange for kickbacks from pharmaceutical companies, it developed clinical decision support alerts in its system to prompt providers to prescribe more opioids.

In the Medicare Advantage arena, UnitedHealth, one of the largest insurers involved in the Medicare Advantage program, has been involved in ongoing litigation with the government on several fronts about its use of data analytics to identify potential suspect conditions missed by providers in patient medical records.

Under the Medicare Advantage program, private insurers enter into contracts with CMS, whereby the insurers (Medicare Advantage Organizations, or MAOs) provide Medicare benefits to their enrollees through health care providers.<sup>[16]</sup> In return, the MAOs receive prospective payments from CMS on a per-member-per-month basis that reflects the expected costs of providing care to enrollees under each contract. The Medicare Advantage program is designed to compensate MAOs for the risks they assume according to the expected costs of treating enrollees. CMS therefore applies a system known as risk adjustment, which adjusts the payments to MAOs based on enrollees' demographic information and health status. CMS bases the health status component on diagnosis data received from the MAOs, which, in turn, is based on diagnosis codes generated by physicians and other providers. CMS expects MAOs to "mak[e] good faith efforts to certify" the data is "accura[te], complete[], and truthful[]" based on "best knowledge, information, and belief," and insurers must submit data conforming to relevant national standards, including the ICD coding guidelines.<sup>[17]</sup> Under ICD coding guidelines (and CMS guidance), diagnoses should be supported by complete documentation in the medical record.<sup>[18]</sup>

In 2014, CMS released its Final Rule (2014 Overpayment Rule) purporting to define the process for identifying overpayments.<sup>[19]</sup> Per the 2014 Overpayment Rule, "[i]dentification" of an overpayment occurs, not only when an insurer has actual knowledge of an overpayment, but also when it "should have determined through the exercise of reasonable diligence," defined as "at a minimum . . . proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of overpayments," that an overpayment has occurred.<sup>[20]</sup> Under the Affordable Care Act, failing to return an overpayment is a violation of the False Claims Act.<sup>[21]</sup>

The government takes the legal position that MAOs must strictly police the data they submit for inaccuracies that could have resulted in overpayments, and to delete unsupported diagnosis codes or face False Claims Act liability, particularly where the MAOs are already voluntarily conducting reviews of patient medical records to identify potential missed diagnosis to increase reimbursement.<sup>[22]</sup> From a factual standpoint, the government sees these chart reviews as a scheme to "mine for diagnoses that the providers themselves did not report."<sup>[23]</sup> The counter-position is that an analysis that is able to sweep a patient's complete EHR and claims data to generate a list of suspect conditions for a physician to consider based on the documentation, when physicians often do not have the time to review every detail of what have become extensive patient

histories since the onset of EHR, is a way to make diagnosis more accurate, and accordingly improve patient care—not a scheme to influence providers.

From a legal standard perspective, one unique open question, and one of the issues at the heart of the government’s False Claims Act suit against UnitedHealth (*Poehling*), and UnitedHealth’s countersuit against the government under the Administrative Procedure Act (*Azar*), is whether the law requires MAOs to affirmatively seek out and delete unsubstantiated diagnosis codes. Agreeing with UnitedHealth on summary judgment that such a “reasonable diligence” requirement impermissibly imposes a negligence standard for False Claim Act liability, the U.S. District Court for the District of Columbia in *Azar* concluded that CMS had exceeded its legislative authority and refused to impose such a burden.<sup>[24]</sup> On appeal, the D.C. Circuit reversed the district court on grounds relating to UnitedHealth’s actuarial-equivalence, methodology, and arbitrary and capricious challenges, but took no position on the district court’s holdings related to the impact of the “reasonable diligence” standard on False Claims Act liability, which CMS had not appealed.<sup>[25]</sup> The U.S. District Court for the Central District of California, facing a motion for summary judgment by the government six months later, concluded in *Poehling* that it could not determine “that it is clear as a matter of law that United was required to delete unsubstantiated diagnosis codes.”<sup>[26]</sup>

The government’s enforcement focus on CDI programs in the Medicare Advantage arena has not been limited to MAOs. In *Sutter Health*, the government alleged that providers also should be liable under the False Claims Act where they “embark[] on a campaign to maximize the number of risk-adjusting codes . . . reported . . . regardless of whether those codes accurately reflected the patients documented medical conditions.”<sup>[27]</sup> The government settled some of its allegations for \$30 million.<sup>[28]</sup>

Other allegations and the relator’s complaint have continued. And, unlike the *Poehling* and *Azar* district courts, the U.S. District Court for the Northern District of California, where *Sutter Health* is pending, has sided with the government thus far. The *Sutter Health* court denied the defendants’ motion to dismiss, finding that “Problem Lists,” lists of potential health problems with corresponding diagnosis codes generated from the defendants’ EHR systems and sent to physicians; queries and messages to physicians in the EHR based on “data mining”; and “pre-populate[d] medical records of physician-patient encounters with risk-adjusting diagnosis codes before physicians saw their patients” plausibly resulted in false diagnosis codes entered by physicians, which in turn were reported to MAOs, who reported the data to the government.<sup>[29]</sup> The court rejected *Azar*’s interpretation of the 2014 Overpayment Rule, but, regardless of whether a “reasonable diligence” requirement exists, was swayed by the factual allegations of the specific case as the facts pleaded demonstrated that the defendants had knowledge that physicians were being pressured into false diagnoses, and were reckless to the possibility that their pressure was causing the submission of false codes and resulting false claims. The remaining allegations were recently settled in principle, with negotiations about settlement terms continuing.<sup>[30]</sup>

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*Poehling* is proceeding through discovery, additional dispositive motions, and ultimately trial in 2023 if the case is not otherwise resolved. In light of the D.C. Circuit’s reversal and remand instructions to enter judgement in favor of CMS, the impact of *Azar*’s holding relating to “reasonable diligence” is unknown. Importantly, ambiguity on the “reasonable diligence” question has not stopped the government from continuing to pursue False Claims Act suits based on the theory.<sup>[31]</sup>

The use of data analytics to identify outliers in the use of diagnosis codes is not limited to the government. Outside of the Medicare Advantage context, a professional relator, Integra Med Analytics, LLC (Integra), filed a handful of lawsuits against health care providers alleging that, because an Integra proprietary method of inpatient claims data indicated high usage of certain “Complication or Comorbidity” or “Major Complication or Comorbidity” codes and therapy utilization compared to peer providers, the respective defendants must have committed fraud.<sup>[32]</sup> Integra’s case against Baylor Scott & White Health was dismissed by the district court, which held that Integra’s analysis “overlook[ed] one major alternative hypothesis: Defendants were simply better than their peers in their efforts to ensure their medical documentation and coding maximized the opportunities for legitimate reimbursement from CMS.”<sup>[33]</sup> The Fifth Circuit affirmed.<sup>[34]</sup> In a sister case before the U.S. District Court for the Western District of Texas, some claims by Integra against the owner of a network of skilled nursing facilities survived dismissal, with the court holding that the appropriate weight of the statistics was better suited for a fact finder, and that by pairing its proprietary analysis with “witness interviews,” Integra created the strong inference that the defendants submitted false claims.<sup>[35]</sup> In the U.S. District Court for the District of California, Integra also initially had luck at the pleading stage, with the court pointing to government guidance on the use of statistics.<sup>[36]</sup> The Ninth Circuit reversed and entered a dismissal, supported by strong language in favor of the defendants: “We hold that Integra failed to state a plausible claim for relief because its allegations do not eliminate an obvious alternative explanation—that Providence, with JATA’s assistance, was more effective at properly coding for better Medicare reimbursement than others in the healthcare industry.”<sup>[37]</sup>

Despite the fact that the government did not intervene in these cases, CDI industry professionals fear the “chilling effect” such lawsuits may have on innovations in CDI.<sup>[38]</sup> After all, as mentioned above, *Creative Solutions* survived dismissal and is still pending, while *Providence* initially survived dismissal. Although EHR usage may seem like standard operating procedure at this point, pitfalls and unknowns remain, and the government has only just begun digging into the depths of data analytics fraud.

## Conclusion

While just touching on a few of the technology-related issues in health care enforcement, the above examples illustrate the increased focus of the Department of Justice and related agencies on technology—both as a tool to uncover fraud and means

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for fraud to be committed. With advancements in data analytics and an even faster-growing post-COVID emphasis on technology for health care delivery, providers and companies will continue see such technology shape not just the health care industry, but also the way regulators police it.

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