

Welcome

Across the economy, businesses are using digital technology to pivot into innovative service lines, accelerate growth and transform their businesses altogether. These businesses' digital strategies and data assets play important roles in their success. In the healthcare industry, the COVID-19 pandemic provides a significant use case for interoperability of health information. Regulations are catching up to resolve this need, and healthcare industry actors are using their data assets accordingly. In this issue, we are highlighting Kyle Gregory and how his practice intersects with these aspects of digital transformation and data economy.

Spotlight



Kyle Gregory addresses new regulations to promote interoperability of health information.

The healthcare industry generates staggering amounts of data. However, health information has long been trapped in electronic silos, which prevents the seamless exchange of such information between stakeholders. Recent regulations issued by the U.S. Department of Health and Human Services (HHS) represent the latest effort to break down these barriers to interoperability.

The problem of siloed health information is not new. Before electronic medical records (EMR), health information was stored primarily in paper records. In an effort to promote interoperability, HHS invested billions of dollars through its Meaningful Use program that provided financial incentives to healthcare providers to use HHS-certified EMR systems. These efforts have been incredibly successful, with almost 98 percent of health systems using certified EMRs as of 2018. Despite the successful transition to a digital medium, seamless sharing of health information remains limited. According to a 2020 report from HHS, only half of hospitals in 2018 were considered "interoperable," meaning they could send, receive, find and integrate information outside of their health system.

Health information faces unique barriers to interoperability not present in other data-rich industries. First, there is the nature of the information itself. Health information and clinical data is often incredibly dirty, characterized by incompleteness, inconsistency, redundancy and disorganization. Second, the

Spotlight (cont'd.)

main sources for healthcare information – EMR systems – operate with each having its own set of technical specifications, clinical terminologies and unique customizations that produce nonstandardized, disparate data. Adding to this challenge is that healthcare entities may use multiple EMR systems within their organization, resulting in health information being spread across a multitude of disconnected data silos. Finally, health information is sensitive, often including some of the most intimate details about a person's life, including their physical and mental health and financial status. As a result, identifiable health information is protected by numerous federal and state privacy laws, most notably the Health Information Portability and Accountability Act (HIPAA), which greatly restrict how this information can be used or disclosed.

Last year, HHS issued a number of sweeping regulations to improve interoperability among players in the healthcare space. Chief among these is the so-called information blocking rule, which prohibits healthcare providers, health IT developers, and health information networks or exchanges from engaging in practices that block the access, exchange or use of electronic health information (EHI). The penalties for engaging in such practices, which HHS calls "information blocking," are serious, with violators potentially facing civil monetary penalties of up to \$1 million per violation. This prohibition on information blocking represents a paradigm shift because the regulations require the applicable entity to provide access to, exchange or use EHI in response to a request unless that entity is prohibited from doing so under an existing law or is covered by one of the limited exceptions outlined in the regulations. While under HIPAA and other medical privacy laws entities may share health information with providers, payers and others for certain limited purposes (e.g., treatment, payment, healthcare operations), the information blocking rule now requires healthcare entities to share this information with patients, providers and other parties unless an exception is met or the entity is prohibited from sharing this information under an existing law.

In addition to the prohibition on information blocking, the recent HHS regulations take steps to consolidate the number of methods

used to exchange health information. In particular, HHS declared the Fast Healthcare Interoperability Resources (FHIR) to be the official standard that defines data formats and elements and is an application programming interface (API) for exchanging electronic health records. Simply put, by designating the FHIR API framework as the standard, HHS hopes to establish a common language that the disparate players in the healthcare industry can use to facilitate more meaningful exchanges of health information between their systems.

These regulations will have significant impact on a broad cross-section of the healthcare industry, requiring healthcare entities to rethink nearly every step of how they manage the flow of health information throughout its life cycle. This task, while daunting, cannot be delayed. Many of the most important compliance requirements, including the information-blocking restrictions, become effective in April of this year.

I recommend that entities convene relevant stakeholders, including compliance, legal, health information management and cybersecurity, to identify the organizational systems impacted by these new regulations. For many clients, we have found that developing a clear understanding of the flow of information within their organization is imperative as a first step, even before identifying which systems involve requests or disclosures of health information. Healthcare organizations have a number of disparate organizational and IT systems in place. Without taking such a holistic approach at the outset, an organization hampers its ability to respond accurately and quickly to information requests and potentially risks inadvertently violating the information-blocking requirements. Once these systems have been recognized, consider what practices currently exist that may interfere with the access, exchange and use of your health information. My goal when advising clients during this process is to help them navigate the interoperability regulations without sacrificing their other, often equally important, obligations or objectives, such as ensuring the privacy and security of their information.

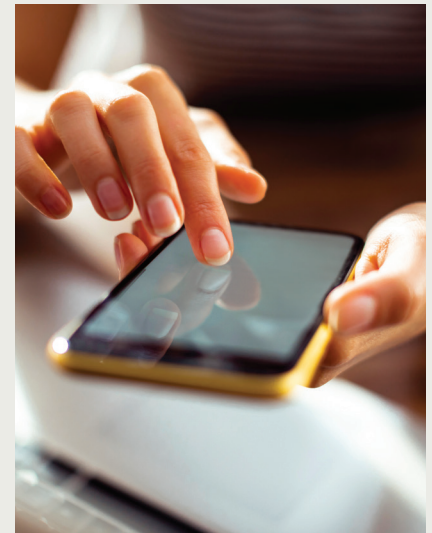
OF RECENT NOTE

Client Alerts

[CISA Updates Advisory on Large-Scale Impending and Credible Ransomware Threat to Healthcare to Include Additional Indicators of Compromise](#)

Blog Posts

[Apple to Require New Privacy Disclosures for Apps as of December 8, 2020](#)



[Ted Kobus and Katherine Lowry Discuss Trajectory of IncuBaker in Q&A with The American Lawyer](#)

[The New IoT Cybersecurity Act Is Here](#)

[Privacy and Product Counseling: 2020 in Review](#)

[A Risk-Based Approach to the SolarWinds Vulnerability Disclosures](#)

[New York Legislature Introduces CCPA Clone with Private Right of Action](#)

Podcasts

[BakerHostetler Blockchain University: What You Need to Know About the Most Common Blockchain Networks](#)

[Podcast: AD-torneys@law: Consumer Reviews: Paid? Fake? Negative?](#)

Emerging Issues

CLOUD

[Amazon Web Services to launch HIPAA-eligible data management service](#); *Healthcare IT News*, Dec. 8, 2020

Amazon Web Services announced the launch of HealthLake, a cloud storage and analysis service available to healthcare and life sciences organizations. The service allows organizations to store, tag, index, standardize, query and apply machine learning to analyze data in the cloud, as well as automatically structuring information into HL7's FHIR standard.

[Google moves into health research with mobile app, starting with respiratory illnesses like COVID-19](#); *Fierce Healthcare*, Dec. 9, 2020

Google is upping its focus on health research with a new mobile app that lets smartphone users participate in virtual health studies. Google also launched a study of respiratory illnesses in partnership with Harvard Medical School and Boston Children's Hospital to identify how these types of illnesses evolve in communities and differ across risk factors. The study is open to adults with an Android phone in the U.S., and study participants will use the Google Health Studies app to regularly self-report how they feel, what symptoms they may be experiencing, any preventative measures they've taken, and additional information such as COVID-19 or influenza test results, according to Google Health.

INDUSTRY SPOTLIGHTS: HEALTHCARE

[HealthCare Analytics Needs To Go Beyond "Admiring The Problem"](#); *Forbes*, Nov. 18, 2020

The world of healthcare analytics – and, in fact, all analytics – is not monolithic, but ranges from solutions that “admire problems” to those that “prescribe actions that create value.” The further healthcare institutions move to the right of this spectrum (i.e., using analytics that create valuable prescriptions rather than just describing them), the more they will experience the real benefits of analytics.

[As Coronavirus Strikes, Crucial Data In Electronic Health Records Hard To Harvest](#); *Kaiser Family Foundation*, Apr. 30, 2020

Pooling data from the digital records systems in thousands of hospitals has proved a technical nightmare thus far. That's largely because software built by rival technology firms often cannot retrieve and share information to help doctors judge which coronavirus treatments are helping patients recover.

[Here are the major issues facing healthcare in 2021, according to PwC](#); *Healthcare IT News*, Dec. 16, 2020

The healthcare industry has six big challenges ahead in 2021: rightsizing after the telehealth explosion; adjusting to changing clinical trials, encouraging digital relationships that ease physician burdens, forecasting for an uncertain 2021, reshaping health portfolios for growth, and building a resilient and responsive supply chain for long-term health.

PRIVACY

[Improving Patient Privacy Regulations for Interoperability Rule](#); *EHR Intelligence*, Dec. 14, 2020

With the release of the Office of the National Coordinator of Health Information Technology (ONC) final rule standardizing how patients can connect apps of their choice to their provider's electronic health record (EHR), there is concern among privacy professionals that additional controls are needed to address privacy protections for third-party consumer apps. One potential solution advocated in the *Journal of the American Medical Informatics Association (JAMIA)* is to use the Healthcare Interoperability Resources (FHIR) framework to present consumers with standardized information about app behavior.

[Sharing medical imaging data with AI apps raises concerns](#); *Search Enterprise AI*, Dec. 9, 2020

Applying artificial intelligence (AI) to medical imaging data is one of the fastest-growing applications of AI in healthcare, but the practice is also fraught with patient privacy challenges, especially as third-party applications enter the fray. Data privacy concerns stem from the fact that technology advancements, such as the ability to connect and share medical images with third-party AI apps, are outpacing federal healthcare privacy regulations.

REGULATORY NEWS

[OCR Issues Proposed Modifications to HIPAA Privacy Rule to Remove Barriers to Coordination of Care and Reduce Regulatory Burden](#); *The National Law Review*, Dec. 18, 2020

The HHS Office of Civil Rights has proposed modifications to the HIPAA Privacy Rule in an effort to support individuals' engagement in their care, remove barriers to coordinated care and reduce regulatory burdens in the healthcare industry. This proposal is part of HHS's Regulatory Sprint to Coordinated Care, initiated under HHS Secretary Alex Azar's value-based transformation agenda, which seeks to promote value-based healthcare by examining federal regulations that impede efforts among healthcare providers and health plans to better coordinate care for patients.

[OIG Issues Final Rule Regarding the Exception for the Provision of Telehealth Technologies for In-Home Dialysis](#); *The National Law Review*, Dec. 7, 2020

In its final rule, the HHS Office of Inspector General (OIG) defined what constitutes “telehealth technologies” more broadly than in its proposed rule, but otherwise chose to track the conditions for the exception contained in the underlying statute and not to implement any of the additional conditions that were included in the proposed rule.

[CMS Proposes Rule to Streamline Prior Authorization, Data Exchange](#); *EHR Intelligence*, Dec. 14, 2020

The Centers for Medicare & Medicaid Services (CMS) proposed a new rule aiming to boost patient data exchange and streamline prior authorization to alleviate clinician burden. CMS said the proposed rule would force Medicaid, the Children's Health Insurance Program (CHIP) and Qualified Health Plan programs to develop application programming interfaces to back patient data exchange and prior authorization.