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The Quickening Pace of Digital Transformation in Healthcare

At the heart of digital transformation is disruption. That doesn't always mean the kind of "disruption" that is the darling of VCs and technology blogs. Sometimes, it just means chaos. The sudden influx of software and data issues to a company or organization that is accustomed to a highly regularized way of doing business can set companies scrambling. Some companies might address new software and data issues by choosing terms that they might think are one-off, solving the problem before them, and hoping that the issues will not likely arise again. Months or years later, they might find themselves tied to those terms — which have now replicated themselves across the enterprise — with little understanding of how or why they were chosen. Often software and data issues do not hold the charm that the notion of being a "disruptor" carries in other sectors. cont'd next page

Spotlight



Chad Rutkowski addresses healthcare's entanglement with data and software

The Difficulty of the Challenge

In January of this year, the Haven joint venture announced that it was dissolving. An exciting collaboration between some of the largest and most sophisticated companies in the U.S., Haven sought to leverage enormous data sets generated from over 1.2 million workers and their employer-funded health plans. Haven hoped that robust analytics could help both improve patient outcomes and control costs, providing leverage for the participating companies to negotiate better rates with insurers. Instead, Haven found itself faced with the same intractable problems that have impeded progress in data analytics for much of the healthcare industry — differing data formats, insufficient interoperability standards and segregation of data into various silos.

Disparate data formats are a function of the disparate IT infrastructure adopted over time by various healthcare provider and hospital practice groups. This "data normalization" problem is common in data analytics endeavors across practically every industry, but is particularly acute in healthcare. Finding ways to enable records from your cardiologist to be accessible to your primary care doctor and your pharmacist is difficult enough in simply rendering care, but the difficulty is compounded when those records are collected on 1.2 million people for analysis.

To address this data normalization issue and related problems, several groups have pushed for standard-setting rules to enable data to be structured and shared. Organizations and guidelines like Fast Healthcare Interoperability Resources (FHIR)

Spotlight (cont'd.)

from Health Level Seven International (HL7) have made inroads on achieving a “universal electronic medical record,” but no one standard has yet gained widespread adoption.

Finally, the silos in which healthcare data reside create further challenges to performing meaningful analytics. These silos exist as to health record type (e.g., treatment, pharmaceutical, genomic), but also as to varying degrees of proprietary interests (e.g., cost, discount, rebate and performance incentive data). Having visibility into one sector but blindness to others is a difficult problem to overcome and drives much of the advocacy for open data solutions and other resolutions.

Pushing to Solve the Problem

One partial solution to these data challenges can be seen in two recent data-sharing rules promulgated by the Department of Health & Human Services. One rule, promulgated by the Centers for Medicare & Medicaid Services (CMS), requires CMS-regulated payers to adopt



APIs that allow patients to easily access their claims information, and further requires hospitals to send electronic admissions, discharge and transfer notifications to certain providers. The second, a companion rule of the ONC, requires health IT vendors to make patient data downloadable using a common data-sharing standard and specific API criterion, and outlines what will constitute “information blocking.”

The adoption of these rules has in turn spurred tremendous activity among for-profit and nonprofit organizations, including the Healthcare Transformation Alliance, Graphite Health and the CARIN Alliance, to leverage these sharing requirements in an attempt to achieve what Haven could not.

Quickening Pace (cont'd.)

We see this phenomenon again and again with our clients in the healthcare sector, whether they're defined as providers, payors, medical device suppliers, analytics providers, pharmaceutical companies or consultants. The uneasy fit of data and technology in the healthcare industry has been highlighted this year with high-profile failures of data analytics ventures, and the equally high-profile rush by some service companies and nonprofit consortiums to succeed where those ventures failed. The healthcare industry will focus on data issues more now only because the info-blocking rules



of the Office of the National Coordinator for Health Information Technology (ONC) have come into effect. Layered on top of the data issues are emerging issues with the software that collects that data in the first place, particularly with regard to software-embedded medical devices, as the industry finds itself struggling with issues that similarly had been suddenly sprung on the automotive and video game industries.

The Emerging Fight Over Access

Although one policy-driven challenge is drawing to at least partial conclusion, another one is just beginning to develop. The owner of the copyright in software source code has considerable rights in controlling the ability to copy or modify that code. However, 17 U.S.C. § 117(c) gives to the owner of a software program a right to make a temporary copy for repair and maintenance purposes. Overlaying that right, however, are the provisions of 17 U.S.C. § 1201(a)(1)(a), which prohibits circumvention of technological protection measures that control access to copyrighted works, which can include software. To address these seemingly contradictory provisions, the DMCA authorizes the U.S. Copyright Office to adopt temporary exemptions to the anticircumvention provisions, considering a number of policy issues, including a right to repair the subject work. These exemptions are considered every three years, and are up for renewal in October 2021.

As software becomes more ubiquitous in everything from vehicles to toasters, the ability of manufacturers to use encryption and other tools to prevent access to diagnostic software to enforce copyrights and control maintenance markets has become a major policy issue, with much of the focus on things like John Deere tractors. However, these issues are equally applicable to software-enabled medical devices. Petitions for requested exemptions to the U.S. Copyright Office include circumvention of technological protection measures to access data in medical devices. Moreover, some states such as Texas, California, Arkansas and Hawaii are considering legislation to force equipment manufacturers to allow third parties to perform maintenance on and service such devices. Such legislation raises complex policy issues, including allowing unregulated entities to access equipment that is heavily regulated.

Emerging Issues

[Amazon Web Services exec talks interoperability lessons from the past year](#), *Healthcare IT News*, May 12, 2021

AWS' worldwide technical leader for healthcare discusses advanced data sharing techniques, and describes real-world examples of information exchange helping solve challenges in the COVID-19 era.

[New Medical 'Right To Repair' Legislation Endangers Patients](#), *Forbes*, May 10, 2021

Here in California, state lawmakers are currently considering legislation that would severely undermine the quality and safety standards which ensure life-saving medical devices are properly serviced and maintained.

[Data Science & Healthcare: Why Health Plans Must Do Better with Data](#), *Health Payer Intelligence*, May 3, 2021

Healthcare technology is the ultimate driver for lowering costs and improving the immediacy of clinical and non-clinical actions, and it's the payer's opportunity to effectively utilize health IT solutions and realize these technologies' full potential.

[ONC: Information Blocking Opens Doors for Interoperability](#), *EHR Intelligence*, April 29, 2021

Healthcare organizations and stakeholders must move on from a compliance mindset and begin to focus on the vast information blocking opportunities at hand, according to Micky Tripathi, national coordinator for health IT.

[Health care API adoption is slowed by security concerns and skills gap](#), *Venture Beat*, April 19, 2021

APIs may be the cornerstone of a digital transformation strategy, but the health care industry has not really benefited from widespread API adoption because of concerns over interoperability, patient data exchange, and infrastructure challenges, according to a new study.

[3 takeaways from CHIME21: EHRs, Big Tech and VCs look to the future of health](#), *Healthcare Dive*, April 19, 2021

The public health and financial devastation of COVID-19 can't be overlooked, but the pandemic has also created opportunities to leverage tech for EHR vendors, Big Tech and health IT leaders, experts said at the CHIME21 Spring Forum, hosted by the College of Healthcare Information Management Executives.



[The medical right to repair: the right to save lives](#), *The Lancet*, March 24, 2021

Throughout the COVID-19 pandemic, hospitals worldwide have reported inadequate supplies of crucial equipment such as ventilators, haemodialysis machines, personal protective equipment, and decontamination equipment. There is an opportunity now for the medical community to ensure that the medical field benefits from access rights to open data that are similar to the rights for consumer electronics and automobiles.

Hospital technicians renew urgent call for Right to Repair medical equipment, *US Public Interest Research Group*, Feb. 10, 2021

The COVID-19 pandemic still rages, but issues facing medical device repair go unresolved.

[Why Haven Healthcare Failed](#), *Harvard Business Review*, Jan. 6, 2021

Haven, the venture to disrupt U.S. health care formed by Amazon, Berkshire Hathaway, and JPMorgan Chase, is disbanding less than three years after its launch.

[How health plans can mitigate the bumps along the road to implementing CMS' interoperability rules](#), *MedCity News*, Jan. 7, 2021

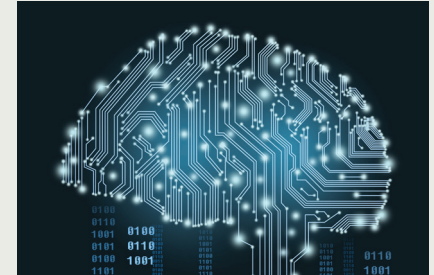
Payers have their work cut out for them, although many have hired consultants and partnered with vendors to help implement the first phase of the rule: Patient Access Application Programming Interface (APIs) and Provider Directory.

Based on conversations with customers, prospects and industry organizations, there is still ambiguity in the interpretation of the rules, and operational impacts that payers may not be ready to address. With a relatively short implementation window of January 2021 (with a 6-month grace period on enforcement), that's not a lot of time to get ready for compliance.

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