Blockchain’s promise and hurdles

*Attorney outlines progress, regulatory issues around emerging platform*

AUTHORS Staff Reports
Before joining the intellectual property practice group at Waller, Kristen Johns was general counsel for a life sciences startup and part of the legal team at the former Emdeon. Those experiences and her work on cybersecurity and data privacy have transitioned nicely into her being an emerging expert in blockchain or distributed ledger technology. Here, Johns answers a few of the Post’s questions about the adoption of blockchain in health care — which, she notes, lags the finance and supply chain sectors — and where things might go in the coming years.

Is blockchain the solution for all the challenges in health data management?
Blockchain should be considered one of numerous options. Recognizing the burgeoning interest of blockchain technology in health care, the National Institutes of Standards and Technology and the Office of the National Coordinator sponsored a competition soliciting white papers about potential uses in the summer of 2016. Of the 72 papers submitted, 15 winners presented ideas including a “Health Information Exchange of One” (from Adrian Gropper) to a decentralized record management system called “MedRec” (from MIT). Uses with commercial applicability already exist in connection with clinical trial management and claims processing.

Because so much hype surrounds the blockchain discussion, some groups seek a blockchain-based solution without a thoughtful analysis of the existing problem. Similarly, some have eschewed blockchain technology without fully understanding the technology and its potential. Learning the fundamentals of the technology, including the nuances of this distributed ledger, is essential. Blockchain technology is not a panacea. Some problems can be resolved by using existing technologies, such as a centralized database or multiple databases with subscription capability.

**Which industry players are already moving in the direction of blockchain adoption?**

Many health care institutions, especially payers such as Cigna and Aetna, have blockchain initiatives. Companies such as Gem have been blazing a trail in collaborations and blockchain education. Numerous start-ups are building applications with specific focus, such as health research and clinical trials. For example, PokltDok, a Savannah startup, has built its own clearinghouse and records certain transactions on a blockchain platform. In some cases, a blockchain solution can complement existing infrastructure.

**What regulatory issues are impeding the move from conversation to action?**

From a legal perspective, there is not one gating issue or regulation that precludes the widespread adoption of blockchain technology in health care. The current, but admittedly inadequate, answer to a legal question is, “It depends.” This is because further analysis of existing federal and state laws is necessary to define potential or existing barriers to implementation and adoption.

Parts of HIPAA, for example, are based on a structure where one entity has been granted permission to have custody or control over personal health information for a specific purpose. Because blockchain is a decentralized platform, the inherent hierarchy of control and access is eliminated. Initial uses of distributed ledger technology have avoided navigating these complex regulatory issues.

The current environment is one of legislative uncertainty. The 21st Century Cures Act was enacted in December and provides a statutory definition of “information blocking.” Eliminating some of the silos that exist in today’s health care system is one of the great promises of blockchain technology. The combination of these legislative efforts and the potential of blockchain technology are some necessary steps for more widespread and rapid adoption.