Blockchain Basics: Overview of Distributed Ledger Technology, Application in Health Care, and Legal Considerations

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In August 2016, the Office of the National Coordinator for Health Information Technology (ONC) and the National Institute of Standards and Technology (NIST) co-sponsored the Use of Blockchain in Health IT and Health-related Research Ideation Challenge, soliciting whitepapers on how blockchain technology can be used in health care. They received over 70 submissions from academia, consultants, enterprises, and individuals, which makes apparent the enormous potential of this technology in health care. While adoption in health care is still early, attorneys must soon begin advising on blockchain. This article is designed to introduce health care attorneys to blockchain and decentralized ledger technology, explaining key concepts, identifying applications in health care, and providing legal considerations in the areas of business law and governance.

Distributed Ledger Technology

Overview and Process. Blockchain is a colloquial term for distributed ledger technology, where all transactions are stored on a “ledger” in a decentralized manner. This means that no one entity has exclusive ownership or control of the record of information or a transaction. Blockchain technology is so-named because as a record or collection of records of transactions are captured in a block, each block references a preceding block, and as the batches of transactions are recorded, it forms a chain. Hence, the name, blockchain technology. Once added to the ledger as part of the chain, the block, and the associated transactions, become a permanent feature on the ledger.
permission is likely to depend on the purpose of the blockchain. In the health care context, most applications of blockchain technology are using a permissioned blockchain.

**Smart Contracts.** A fundamental component of blockchain technology is the use of smart contracts. A smart contract is a self-enforcing digital agreement where parties to the contract agree to certain conditions, and if those conditions are fulfilled, an agreed upon action is performed. A transactional input into the ledger will indicate a triggering condition has occurred, resulting in instantaneous action on the smart contract and the record of the transaction on a blockchain.

**Application in Health Care**

As applied to health care, a transaction may be a single health care delivery event. For example, when a patient sees a provider, the information stored as part of the transaction can include the service performed, the date of delivery, the location, the associated cost, and/or provider notes. When added to a blockchain network, this information can be used to serve numerous purposes.

Structured as a smart contract, the information can be used for more efficient prior authorization required in numerous health care interactions. For example, a blockchain network could be pre-programmed with treatments and prescriptions that may be authorized if specific conditions are met. When a triggering event occurs, such as a diagnosis or test result, the event would result in the output of an efficient, almost instantaneous authorization. This application has extended beyond mere concept. In August 2017, the Medical Society of Delaware partnered with Medscient, a Delaware startup, to test a pre-authorization process using blockchain technology as part of the Delaware Blockchain Initiative.

Moreover, a number of entries in ONC’s “Use of Blockchain in Health IT and Health-related Research” Ideation Challenge discussed the use of blockchain for electronic health records (EHRs). Blockchain technology lends itself well to interoperable and secure EHRs because it allows for decentralized distribution of information blocks, decreasing fragmentation in EHR information among providers. In addition, using blockchain for EHRs would mean that a permissioned blockchain network could be established with specific privileges for certain users—a patient can only access his or her EHR, and providers could access the EHRs of some or all patients. While blockchain technology for EHRs is promising, many federal and state laws, including the Health Information Portability and Accountability Act of 1996 (HIPAA), 42 C.F.R. Part 2, and mental health record laws have led many of these efforts to become dormant.

Use of blockchains in health care can span much further than the aforementioned examples, and companies are continuously innovating. On September 25, 2017, Change Healthcare, a Nashville-based health technology company, announced that it will commercially release revenue cycle and claims processing management blockchain technology to providers by the end of the year. Many payers, including Cigna and Aetna, as well as start-ups, such as Gem and PokltDok, are developing several other health care blockchain initiatives, gradually expanding the application of blockchain in health care.

**Legal Considerations**

As blockchain use increases, health care attorneys may need to counsel on this technology in their everyday practice. Whether advising providers, technology developers, or other stakeholders, consider the following issues in the area of business law and governance:

**Governance Structure.** Identifying an equitable and effective governance structure with a decentralized model can be difficult. Participants in a blockchain network can elect to create a new entity with management and oversight over the network and participants. Alternately, all participants can enter into a common agreement, agreeing to abide by certain terms and conditions established in a smart contract. In addition, although beyond the scope of this article, attorneys should consider how intellectual property rights to blockchain technology affect governance.
Enforceability of Smart Contracts. In the case of smart contracts, attorneys should assess the enforceability, and if necessary, take prudent steps to ensure that written agreements are in place. The enforceability of a smart contract depends on numerous factors, including whether: (1) a contract was legally formed; (2) certain contractual term requirements are fulfilled; (3) the blockchain network has problems affecting contract validity; and (4) the contract satisfies relevant laws of the jurisdiction. If a smart contract can be valid and enforceable, attorneys should ensure that important legal constructs, such as dispute resolution, choice of law, and indemnification are addressed.

Securities Laws. Many companies in blockchain, including several in the health care blockchain space, have used initial coin offerings (ICOs), or token sales, to raise capital. ICOs get their name from initial public offerings (IPOs), but differ in that companies offer ‘coins’ or digital tokens in exchange for regular currency or cryptocurrency from investors. These tokens are typically distributed among stakeholders. Token sales have been popular in the blockchain space, but there is ambiguity and evolution in securities laws and regulations worldwide. On July 25, 2017, the Securities Exchange Commission issued commentary stating that virtual coins or tokens may fall under the purview of the U.S. federal securities laws depending on facts and circumstances. Health care attorneys should rely on their colleagues with securities law expertise when advising health care blockchain technology companies on raising capital funds.

Conclusion

With the speed of innovation in distributed ledger technology, particularly in health care, understanding this technology and its applications in its early stages is imperative. This article was designed to give health care attorneys a high level overview of the technology, and address some business law and governance legal considerations. These legal considerations are not all-inclusive, however, and practitioners should further consider various other areas in which legal issues may arise, including privacy and security, health technology laws, and other federal and state laws and regulations.

2 Id.
3 Id.
4 Id.
7 Id.
8 Id. at 5.
9 Id. at 5.
13 Kristen Johns, Blockchain’s Promise and Hurdles, NASHVILLE POST MAGAZINE (May 19, 2017).
15 Id.
17 Id. “Inserting a dispute resolution mechanism into a smart contract may help to address the issues around enforceability and jurisdictional variations,” see id.