Blockchain Application Feasibility in Telehealth for DSCSA Compliance

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Fungal meningitis outbreak rocks U.S.

19 out of 64 deaths were in MI

Figure 1. Cases of meningitis reported in the U.S. as of October 19, 2012.

Licensure violation: Pharmacy mass-produced Rx rather than filling individual patient Rx

2012 New England Compounding Center Meningitis Outbreak

Cause of death: basal stoke (fungus traveled from injection site, through spine, to brain)

Last fall, 17,000 vials of a steroid were shipped to clinics and hospitals in 23 states. The drug had to be sterile because patients would have it injected into their joints or their spines to relieve chronic pain. What happened next is the worst pharmaceutical disaster in decades.

The steroid was contaminated with fungus. Forty-eight people have been killed, 720 are being treated for persistent fungal infections. The tragedy has exposed a failure in drug safety. And, in a moment, you will hear the commissioner of the FDA acknowledge that she can no longer guarantee the safety of many high risk drugs.

The steroid was produced by New England Compounding Center and in the six months since the first deaths, no one at New England Compounding has revealed what happened. But tonight they will. As for the victims, this has been an unrelenting horror after just one injection of lethal medicine.
DSCSA Introduced and Signed into Law (2013)

The DSCSA (Title II of the Drug Quality and Security Act)

• Set the federal requirements for the tracking of prescription medications across the pharmaceutical supply chain, from manufacturing, ordering, storage, and distribution to disposal

• Established a multi-year timeline for building “an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States”

• Supports the DEA’s initiatives to prevent the distribution of imported counterfeit medications in the U.S.

• Places new requirements on pharmacies, including independent pharmacies, grocery store pharmacies, in-hospital pharmacies, nursing homes, etc.


DSCSA Requirements (2013-2023)

**TITLE II—DRUG SUPPLY CHAIN SECURITY**

Sec. 201. Short title.
Sec. 203. Enhanced drug distribution security.
Sec. 204. National standards for prescription drug wholesale distributors.
Sec. 205. National standards for third-party logistics providers; uniform national policy.
Sec. 206. Penalties.
Sec. 207. Conforming amendment.
Sec. 208. Savings clause.

**Summary of Requirements and Affected Parties**

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Manufacturer</th>
<th>Repackager</th>
<th>Wholesaler</th>
<th>Dispenser</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provide prior transaction information at each transfer of ownership</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Provide transaction documentation the event of a recall or for the purpose of investigating a suspect product or an illegitimate product</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Ensure that all of one’s trading partners are authorized</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Affix or imprint a product identifier on each package and homogenous case</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Implement systems to investigate suspect products and handle illegitimate products</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Verify returned products before further distribution</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

Source: https://en.wikipedia.org/wiki/Drug_Quality_and_Security_Act
Multiple timeline delays (2019 and 2020)

- November 27, 2013: DSCSA Enacted
- November 27, 2017: Manufacturers serialize product
- November 27, 2023: Unit level traceability with aggregation & inference
  - Interoperable electronic system

2013
- November 27, 2013: DSCSA Enacted

2014

- January 1, 2015: Authorized Trading Partners
- Manufacturers send and repackagers, wholesalers receive transaction history, information & statement (T3)
- Repackagers send T3
- Wholesalers send direct purchase statement
- Transmitted electronically or by paper
- Suspect product / verification requirements effective

2015
- July 1, 2015: Dispensers receive T3
- Suspect product/verification requirements effective
- March 1, 2016: T3 enforcement discretion ends
- November 27, 2018: Repackagers serialize product
  - Repackagers associate & verify SNI

2016

2017
- November 27, 2017: Manufacturers verify SNI
- T3 transmitted electronically

2018

2019
- November 27, 2019: Wholesalers receive and ship serialized product
- Wholesalers verify SNI including returns

2020
- November 27, 2020: Dispensers receive and ship serialized product
- Dispensers verify SNI

Source: https://bellwyck.com/the-race-to-the-dscsa-deadline/
DSCSA Serialization Requirement

Mandates a product identifier for each package/drug case

Product identifier must store the following information:

<table>
<thead>
<tr>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global trade identification number</td>
</tr>
<tr>
<td>Standardized numerical identifier</td>
</tr>
<tr>
<td>Batch/Lot number</td>
</tr>
<tr>
<td>Expiration date</td>
</tr>
</tbody>
</table>

Blockchain for DSCSA Compliance?

Blockchain, a peer-to-peer (P2P) public ledger software maintained across a distributed computer network, can utilize real-time data to track, detect, and respond to harmful prescription drugs.

Reliable tracking for:

- Package-level distribution monitoring via a product identifier
- All Rx distribution partners
- Regulators to review
- Suspect product investigations
- Notifying regulators and distribution partners when a product has been removed
- Products that meet compliance for distribution
- Products that are repackaged, resold or returned
- Products via an interoperable, electronic system

Source: https://101blockchains.com/ultimate-blockchain-technology-guide/
Key Takeaways

• As incremental tracking requirements are phased in through 2023, when the DSCSA goes into full effect, research on blockchain as a solution has demonstrated its effectiveness, with the most recent wide-scale success documented in the FDA’s 2020 DSCSA Blockchain Interoperability Pilot Project Report.

• One pilot program, UCLA-LedgerDomain (BRUINChain), found blockchain to be effective at tracking and verifying drugs in real-time for a dispenser using only commercial-off-the-shelf technology.


• Engelhardt [8] outlined examples of companies attempting to record each transfer of ownership for a prescription using a blockchain network that provides each relevant stakeholder with an unbroken, identical chain of information.


• Our systematic review yielded no research into blockchain-enabled drug supply chain tracking specific to remote prescribing via telehealth.
Emerging Study: PharmaLedger (Europe)

- A blockchain infrastructure, using multiple chains that rest on a root blockchain and use the blockchain protocol
- Built on self-sovereign applications (non-identity based)
- Formed in January 2020
- Partially funded by EU’s Innovative Medicines Initiative (IMI) and 29-member organization, including Merck and Novartis
- Next Steps in Europe: Partner with health authorities to deploy blockchain-enabled app in pilot markets

<table>
<thead>
<tr>
<th>Domain</th>
<th>Use Case</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supply Chain</td>
<td>Clinical Supply (Traceability)</td>
</tr>
<tr>
<td>Supply Chain</td>
<td>Finished Goods Traceability</td>
</tr>
<tr>
<td>Supply Chain</td>
<td>Anti-Counterfeiting</td>
</tr>
<tr>
<td>Health Data</td>
<td>Clinical Trials Recruitment</td>
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<tr>
<td>Health Data</td>
<td>Personalized Medicines</td>
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<tr>
<td>Health Data</td>
<td>Dynamic Permissioning</td>
</tr>
<tr>
<td>Clinical Trials</td>
<td>eConsent</td>
</tr>
<tr>
<td>Clinical Trials</td>
<td>IoT Medical Device Trials</td>
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</tbody>
</table>

With PharmaLedger, a patient will be able to download an app and scan a 2D matrix on the outside of the drug package. Similar to a QR code, the data matrix is a collection of black and white dots that encodes information, including the serial number. The scan recognizes the manufacturer and then sends a request for the most up-to-date digital leaflet for that particular drug.
State of DSCSA Preparation

- DSCSA data system testing is delayed
- DSCSA does not mandate that a specific data system is used

- Stakeholders are opting for the GS1 EPCIS (electronic product code information service) standard that contains what/when/where/why event data
- Major delay is with manufacturers not using EPCIS
- Smaller manufacturers are less prepared to test data systems
- Many stakeholders are manually entering transaction data in spreadsheets

The COVID-19 pandemic expanded telehealth access and introduced new supply chain models for pharmaceuticals, which can be more easily prescribed across state lines, and DSCSA compliance.

With this increased utilization across platforms and state lines, health information collected by telehealth remains more fragmented than in-person care, complicating continuity of care for patients as well as prescription tracking for providers, manufacturers, and the FDA. To integrate telehealth into the health care delivery system, blockchain is a potential solution to the fragmentation of prescription data from telehealth activity which also verifies the accuracy of this data from a range of platforms and applications.
Recent regulatory relief enabling telehealth expansion across the United States, coupled with drug tracking requirements mandated by the Drug Supply Chain Security Act (DSCSA), necessitates an evidence-based understanding of feasible blockchain applications for the DSCSA-compliant tracking of drugs prescribed to remote patients who use personal devices to access telehealth.

The purpose of this project is twofold:
• first, to identify use cases for DSCSA-compliant blockchain applications for telehealth; and
• second, to formulate stakeholder recommendations with regard to implementation issues surrounding the current regulatory framework for blockchain applications in health care in the U.S.

Nonadoption, abandonment, scale-up, spread, and sustainability framework and complexity assessment tool (NASSS-CAT) (Greenhalgh et al., 2017)
Blockchain Use Cases for Telehealth DSCSA Compliance

Fig. 1 depicts a simplified model, with use cases (i-v), in which blockchain is applied to telehealth care delivery. In use case (i), the manufacturer creates the first “block” which stores an individual code and timestamp for a manufactured drug unit and generates a hash. Then, the wholesaler verifies the integrity of the scanned drug using the hash and records the transaction with the manufacturer in a new block which is added to the ledger (ii). Like the wholesaler, the pharmacist then uses the hash to verify the integrity of the scanned drug and records the transaction with the wholesaler in a new block (iii). After receiving the prescribed drug, the patient opens the telehealth mobile app and uses his phone camera to scan the barcode on the drug container (iv). By using the blockchain-based telehealth app, the patient can verify the integrity of the drug using the hash and record this final transfer of ownership in a new block. Once the block for the final transfer of ownership is generated, the telehealth app can share this record with the telehealth and/or primary care provider (PCP) to prevent the loss of prescription information (v). Theoretically, the record could also be shared with payers for fast verification of prescription coverage.
NASSS-CAT Framework Analysis

**TECHNOLOGY**
- Blockchain can support DSCSA compliance for telehealth
- Telehealth platforms must include a DSCSA-compliant blockchain network
- Blockchain scalability is currently limited

**ADOPTERS**
- Personal mobile devices

**ORGANIZATIONS**
- A patchwork of patient consent policies across states and institutions
- Nonuniform requirements for Prescription Drug Monitoring Programs (PDMPs) across states

**WIDER SYSTEM**
- Recent phased interoperability and patient access rules
- A lack of interoperability between PDMPs, electronic health records (EHRs), state HIEs, and pharmacy dispensing software is complicated by telehealth

**EMBEDDING/ADAPTATION OVER TIME**
- Limited state action addressing the role of blockchain in health care
  - Virginia founded the Health Care Provider Credentials Data Solution Fund to solicit blockchain-based proposals for healthcare provider credentialing
  - Oregon established a “Task Force on Protecting Health Information” that includes a blockchain-expert member
Next Steps: Applied Feasibility Framework

Mayo Clinic Advanced Care-at-Home Model
Conclusions

• Technically, blockchain can support DSCSA compliance for telehealth when telehealth platforms are integrated into a DSCSA blockchain network
• Blockchain’s scalability is currently limited
• Rapid adoption of blockchain architecture in healthcare is unlikely due to current industry barriers
• The standardization of smart contracts in healthcare could expedite the blockchain adoption process
• The duration of mandated telehealth reimbursement for a range of services is unknown; however, many Medicare reforms are expected to remain permanent
• Nursing homes and at-home care/hospital-at-home services present unique challenges for DSCSA compliance with and without telehealth
• While the need to prevent the distribution of counterfeit therapies imported from abroad during the PHE is critical, DSCSA compliance is costly, and updated regulatory strategies that consider new, post-pandemic supply chain models are necessary
• Additional research and guidance are necessary to understand the scale of blockchain’s feasibility for telehealth prescription data tracking to understand how best to apply blockchain for DSCSA compliance after the PHE and before the 2023 deadline
Thank You!

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• Oxford Tutors: Trisha Greenhalgh, M.D. and Chrysanthi Papoutsi, Ph.D.
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Slide 9
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