How Blockchain Fused with Public Policy can Create Accountability for the Opioid Epidemic in the United States

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June 27, 2018

BIT Healthcare Information Technology 5564

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Abstract

Abuse of prescription opioids and the high availability of illegal street drugs such as heroin have plunged the US into an opioid epidemic. This crisis has worsened in the US each year with exponential growth in the last ten years. The CDC has released guidelines for safe prescribing to educate doctors and patients on the risks of narcotic prescription painkiller addiction (Centers for Disease Control, 2017). These measures do not provide the necessary oversight to hold prescribers and pharmacists accountable for the number of opioids released into circulation. RxMe modernizes the pharmaceutical model using blockchain technology, artificial intelligence, and smart contracts to move prescriptions into the 21st century.

Section 1.0: Introduction

Each day in America, 115 people die of opioid overdoses, and these numbers have been rising exponentially throughout the 2010's (Centers for Disease Control, 2018b). We will discuss the tragic opioid crisis in America, blockchain technology, blockchain prescription startup companies, plus our proposed blockchain and distributed application solution called RxMe. We also propose a public policy change requiring a new, national prescription blockchain. To combat the opioid crisis, we propose requiring a blockchain to track all opioid prescriptions. By using an Ethereum-based blockchain, an append-only data structure is realized, prohibiting an entity from altering the transaction data. The result is an immutable, historical ledger that provides the auditing and regulatory oversight required for true opioid control. The blockchain data structure includes accessibility by four end-user types: opioid prescribers, patients, pharmacies, and researchers/enforcement investigators. We propose blockchain access through four distributed applications matching the classes of users above. Further, we propose all prescribers tokenize prescriptions that patients later redeem at pharmacies for medication. We present evidence showing blockchain data analytics and

machine learning components deter nefarious physicians, pharmacists, and patients who fuel to the opioid crisis.

Section 2.0: Opioid Crisis Overview

Section 2.1: Opioid Overdose and Mortality Statistics

Opioids are potent medicines intended for patients in active cancer treatment, palliative care, or end-stage illnesses. Many opioids are prescribed for chronic pain or injury en masse leading down a slippery slope, frequently resulting in opioid addiction or illegal street drug addiction. The National Institute on Drug Abuse reports 80 percent of all heroin users began by using legally prescribed opioids before graduating to stronger street drugs (National Institute on Drug Abuse, 2018). Of the 63,600 drug overdose deaths in 2016, 66 percent were opioid-related (Centers for Disease Control, 2018b). The CDC also notes approximately 115 people per day die of an opioid overdose, meaning nearly every 26 days as many people die of opioid overdoses as were killed on September 11, 2001, in New York. Figure 1 shows the prescription opioid deaths adjusted per 100,000 of the population from 2015 to 2016:

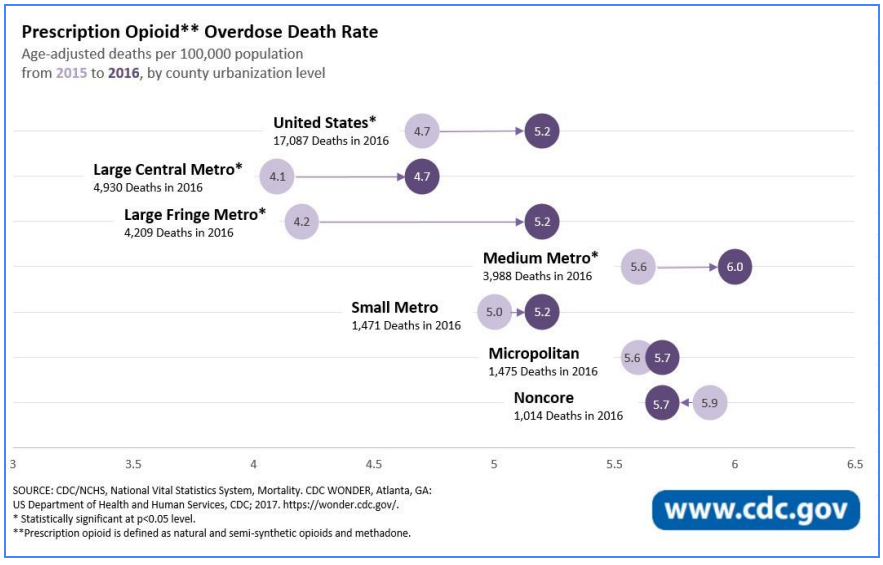

Figure 1: CDC: https://www.cdc.gov/drugoverdose/data/overdose.html

Drug overdose deaths by opioid type have worsened in recent years, as shown in Figure 2 below, “Overdose Deaths Involving Opioids, by Type of Opioid.” The distinction between ‘opioid,’ a synthetic drug intended to mimic opium and ‘opiate,’ the drug derived from the opium poppy plant. Both ‘opioid’ and ‘opiate’ are highly addictive and have serious side effects. The rates of drug overdose deaths involving synthetic opioids other than methadone (drugs such as fentanyl, fentanyl analogs, and tramadol) doubled in a single year from 3.1 per 100,000 in 2015 to 6.2 in 2016. Rates of drug overdose deaths involving heroin have increased from 4.1 in 2015 to 4.9 in 2016, while rates of drug overdose deaths involving natural opiate and semisynthetic opioids increased from 3.9 in 2015 to 4.4 in 2016 (Centers for Disease Control, 2018b).

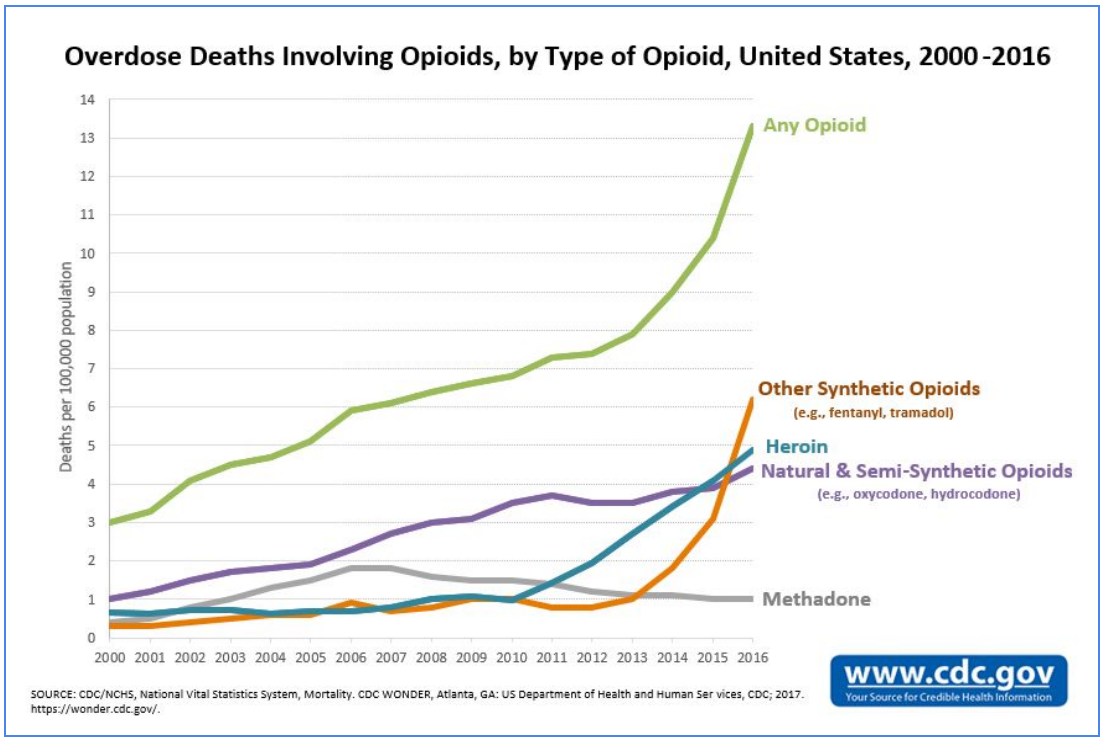

Figure 2: CDC: https://www.cdc.gov/drugoverdose/epidemic/index.html

Section 2.2: Progression of Addiction

The progression of addiction is the central factor for many individuals who slip into chemical dependency, leading to usage of street drugs such as heroin. The progression of

addiction is unique for each of the 63,000 people who died from an overdose in 2016, but many have the same origin: an opioid prescription for an injury or pain. Many people take opioids without long-term addiction, but a chance exists for narcotic addiction. There are four stages of addiction: Experimentation, Regular Use, Risky Use/Abuse, and Drug Addiction and Dependency. Opioids enter the brain through the bloodstream, flooding it with artificial endorphins and dopamine to create feelings of pleasure, satisfaction, and euphoria. This feeling exceeds the average levels of euphoria produced by the brain which is why the user wants to experience it again by taking another dose. The brain then stops creating dopamine and endorphins naturally, requiring another dose of opioids to produce the dopamine and endorphins. The body develops tolerance to the dosage level, and the user must increase the dosage or the intensity of the drug. At the same time, the body becomes dependent on the drug, and withdrawal will occur if the patient tries to stop taking medicine. When the patient lacks the means to continue receiving prescriptions, many seek street drugs to fill the void. This slide into addiction and dependency can happen over months or even weeks, in some cases.

Section 2.3: Opioids are Over Prescribed

In 2013, physicians prescribed one-quarter of a billion opioids, enough opioids for every adult American to have a 30 dose bottle (Centers for Disease Control, 2017). The same CDC study reveals numerous states prescribed three times as many opioids as Hawaii, the state that prescribed opioids the least. The CDC studies note that relevant population health issues data cannot explain regional prescription discrepancies. The CDC reports that the most commonly abused opioids are: Methadone, Oxycodone (OxyContin®), and Hydrocodone (Vicodin®). Figure 3 shows opioid prescriptions by state based on data from the National Prescription Audit (NPA):

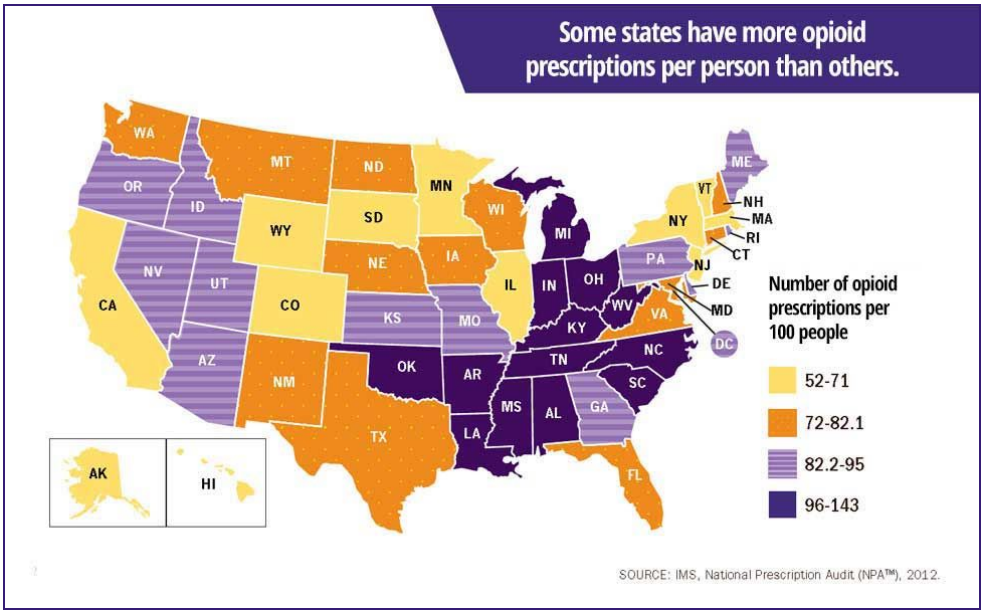

Figure 3: CDC: https://www.cdc.gov/drugoverdose/data/prescribing.html

The CDC has released guidelines for prescribing opioids for pain including a plan for prescribing only the necessary amounts, discussions of the risks of dependencies, and non-opioid therapies as alternatives (Center for Disease Control, 2017).

Section 2.4: Reasons Physicians Overprescribe

Why would a trained physician prescribe a dangerous opioid when a non-addictive medication or physical therapy with an over the counter medication would suffice? Some corrupt prescribers break their Hippocratic oath for financial gain. However, the majority of the prescribers are subject to a complex web of factors. For example, Sara Gorman, Ph.D., Public Health Specialist, and Jack Gorman, MD, Psychiatrist, liken overprescribing opioids to overprescribing antibiotics (Gorman & Gorman, 2018). They conclude patients are exerting pressure on physicians cause the overprescription of antibiotics in situations where antibiotics will not help. The patient pressure for opioids for pain is often exerted by patients when a less addictive drug or physical therapy is a better alternative. The guidelines provided by the CDC for pain management are intended to educate physicians who have previously received little or no

training on pain management and the highly addictive nature of certain medications (Suzuki, 2016). Lack of sufficient training and patient pressure explains why Family Medicine practitioners prescribe over 22 percent of all opioids (Figure 4 below).

The Dartmouth Atlas of Healthcare project in the 1970s showed that physicians in small geographic areas, or communities, tended to prescribe and treat illnesses and symptoms based on the approach of other physicians in the same area (Wennberg & Gittelsohn, 1973). The like-minded prescription pattern is real even when the medical evidence did not necessarily support the original or subsequent treatment. Research shows when physicians are merely informed they prescribe in unusual ways, their prescription rates for the outlier drugs drop dramatically (Meeker et al., 2016). Figure 4 shows the top 10 medical specialties by opioid prescription.

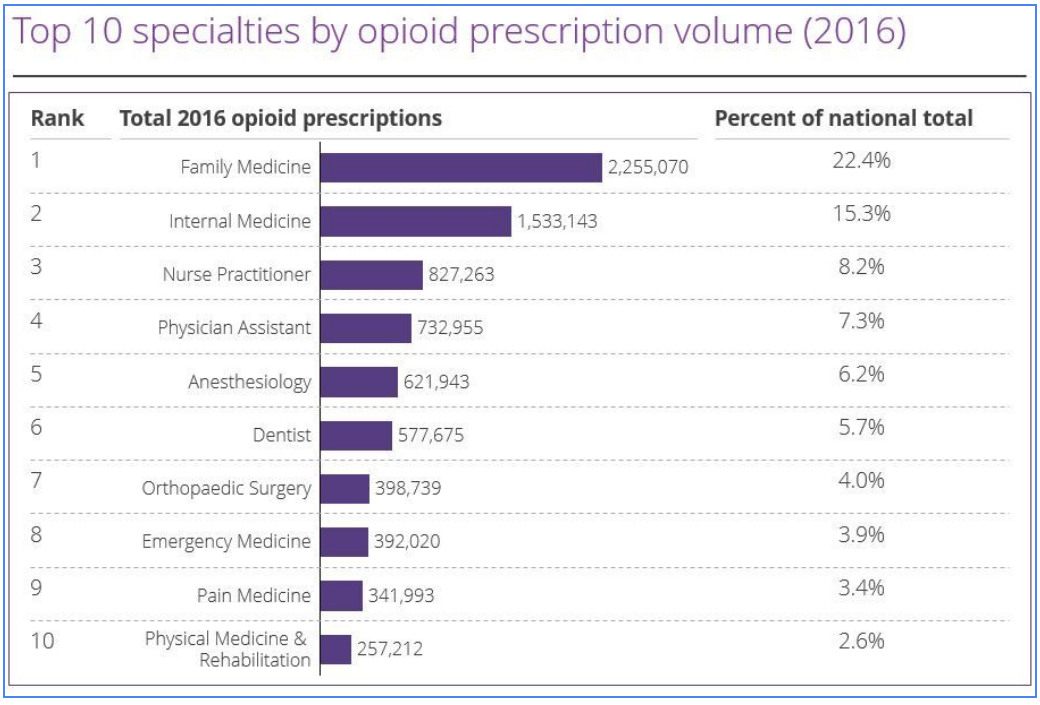

Figure 4: https://news.aetna.com/2017/06/aetna-sets-five-year-goals-fight-opioid-epidemic/

Section 3.0: Blockchain Overview

Section 3.1: Blockchain as a Data Structure

The most literal definition of “blockchain” is transactions bundled into blocks that are linked by a cryptographic hash (Brakeville, 2018). Although transaction details in each block are implementation specific, typical transaction details include a transaction ID, an originator ID, the digital signature of the sender, a timestamp, the previous block’s hash, the current block’s hash, and some payload data that serves as the purpose the blockchain exists.

Section 3.2: Nodes and the Distributed Ledger

A blockchain is stored on a peer to peer network. Each “peer,” also known as a “node,” presents a portion of its computing resources to other nodes in the network. Each node stores a copy of the entire blockchain providing integrity and ensuring blockchain distribution. If undermining the system and altering the data in a previous block is a goal, an actor must change the block data on every node before the next block writes by any node. Blockchain as a decentralized data structure is known as a distributed ledger. Nodes mine or forge data consistent with the blockchain’s purpose.

Section 3.3: Cryptography and Hashing

The blockchain typically relies on public key cryptography (public/private keys) to prevent modifications to previous transactions (“Blockchain Cryptography Explained” n.d.). Digital signatures are created with the sender’s private key, thus securing the identity of a transaction’s sender. Although blockchain implementations vary, many blockchains send transactions to the public key of the recipient. The private key is used to “unlock” or access data in the blockchain (BitCoins, privileged data, etcetera).

Hashing applies a mathematical algorithm to data generating a fixed length character

sequence. Blocks in the blockchain are linked together by their hashes. Each transaction is hashed together in a Merkle Tree hierarchy until one hash remains for the entire block. As with any tree data structure, the bottom row contains the leaves, but the root entry is the final hash of the block. Thus, it is possible to verify a single transaction without downloading the entire blockchain.

Section 3.4: Consensus Algorithms

With copies of the blockchain distributed across numerous nodes, how can the nodes collectively "agree" on the state of the data? Consensus algorithms provide ways for the nodes to synchronize and converge on the "truth." Each consensus algorithm or protocol described below validates the next block written to the chain.

Section 3.4.1: Proof of Work (PoW) Versus Proof of Stake (PoS)

Proof of Work (PoW) makes sense in the context of cryptocurrency where limited quantities drive value through scarcity (i.e., BitCoin). To write the next block, the miner must solve a mathematical or computational problem (Tosh, Shetty, Liang, & Kamhoua, 2017). The problem is challenging to solve but easy for other nodes to verify (Tosh et al., 2017). Other nodes reject any attempt for a bad actor node to write the next block unless the node is the first to solve the problem (Tosh et al., 2017). The downside to PoW is the enormous amount of processing power and energy required to validate blocks.

Like Proof of Work, Proof of Stake (PoS) validates blocks but with less energy and higher efficiency. Rather than solving a computational problem, Proof of Stake recognizes the percent of the cryptocurrency owned by a node (Tosh et al., 2017). The higher the ownership, or stake, the higher the number of transactions the node can mine (Tosh et al., 2017).

Section 3.4.2: Delegated Proof of Stake (DPoS)

Delegates are node operators responsible for maintaining their node. These operators engage in “real-time voting combined with a social system of reputation to achieve consensus” (“Blockchain Cryptography Explained” n.d.). Token holders vote on delegates, and their vote weighs according to their total token ownership. Elected delegates must keep their node online, process transactions, broadcast validated transactions and broadcast blocks to all nodes on the network. DPoS affords all token owners control over the network while incentivizing good behavior with commitments to the network.

Section 3.5: Permission-based Versus Permissionless Networks

Some security concerns described in the previous section regarding consensus algorithms are avoidable in a permission-based network. A permission-based network requires nodes to prove their identity to the blockchain ledger. Only approved nodes can join the network. Since all nodes are known in a permission-based network, the network need not waste computational power to achieve consensus. Most blockchain healthcare use cases involve a permission-based network. Only authorized entities such as hospitals, physicians, pharmacists, pharmaceutical companies write transactions to the blockchain (Alhadhrami, Alghfeli, Alghfeli, Abedlla, & Shuaib, 2017).

Section 3.6: Cryptocurrencies, Coins, and Tokens

BitCoin and alternative coins, known as alt-coins, are built-in to the structure of an underlying blockchain and are viewed as a valued medium of exchange (i.e., traditional currency). For most coins, the exchange of that specific coin is the point of the blockchain. The underlying protocol must be adapted to meet the coin’s specific needs. Multiple tokens can append on top of an existing blockchain with standard templates instead of requiring large

structural changes to the blockchain. Tokens typically represent a utility or an asset (possibly secondary), in a blockchain environment, which pairs well with smart contracts (“Cryptocurrency Coins and Tokens,” 2018).

Section 4.0: Prescription Blockchain Competitor Analysis

Though many companies play a part in the microcosm of the pharmaceutical world, the companies relevant to RxMe are startups seeking to integrate prescription blockchain: BlockMedX, ScalaMed, and BlockRx. Table 1 below provides an overview and comparison of companies beginning to work on blockchain based prescription solutions.

Competitor Solution Summary	
BLOCKMEDX	BlockMedx seeks to provide a secure e-prescription blockchain platform with full accountability through the usage of the distributed ledger and identity verification to record a full record of prescriptions (BlockMedx, 2018). **Problems To Be Solved:** ● Overprescribing medicine ● Prescription fraud ● Lack of prescription transparency
ScalaMed	ScalaMed aims to use blockchain technology to keep patient data private and secure. In doing so, the patients have more control in receiving personalized treatment. This entire process is automated through the use of smart contracts and IoT devices which can monitor the patient’s health, update prescriptions, automatically make payments, reducing bottlenecks and administrative overhead (ScalaMed, 2018). **Problems To Be Solved:** ● Improved EHR interoperability ● Prevent counterfeit pharmaceuticals ● Helps secure clinical trial data ● Using Smart contracts to help facilitate outcome-linked healthcare

	BlockRX aims to build a platform across legacy systems in the pharmaceutical supply chain space. By facilitating the transfer of information between these systems, BlockRx aims to create a network of "Trusted Partners" who are further incentivized by the BlockRx Tokens (BlockRx, 2017). **Problems To Be Solved:** ● Supply chain reform ● Growth of counterfeit drugs ● Rising cost of healthcare

Table 1: Competitor Solution Summary

Section 5.0: Technical Solution: RxMe

Section 5.1: Mission Statement

RxMe modernizes the pharmaceutical model using blockchain technology, artificial intelligence, and smart contracts to move prescriptions into the 21st century.

Section 5.2: Vision

Using blockchain with smart contracts allows us to create a single source of trust for prescriptions. This model creates a secure prescription data repository using blockchain to prevent opioid leakage in the prescriber-pharmacy-patient triangle. By using blockchain, RxMe utilizes an append-only data structure, and one entity cannot alter the transaction data. The result is an immutable, historical ledger that provides the auditing and regulatory oversight necessary for opioid data mining and enforcement.

Section 5.3: Current Process Workflow and New Process Workflow

Section 5.3.1: Current Process Workflow

As one pharmacist noted, "there is no authoritative source of truth when it comes to the data layer for pharma prescriptions" (Diaz, 2018). Subjective guidelines for pharmacists include whether the patient appears "suspicious," the patient is too far from home, the prescriber's

handwriting is too legible, or the physical condition of the prescription or the dosage is high. Additional considerations include how well does the pharmacist know the prescriber or the patient or whether the patient is in a hurry (Ontario College of Pharmacists, 2013). Faxed or voicemail prescriptions are also subject to forgeries and pharmacists are encouraged to verify the origin of the prescriptions if possible with the doctor or doctor's office. Poly-pharmacy, or doctor shopping, represents an issue that pharmacists cannot solve in the current system. Figure 6 provides an overview of the current system process workflow, where patients approach multiple prescribers who issue either handwritten prescriptions (2b in Figure 5) or e-prescriptions (2a in Figure 5). Pharmacies attempt to determine the legitimacy of patient prescriptions as shown in Figure 5 below.

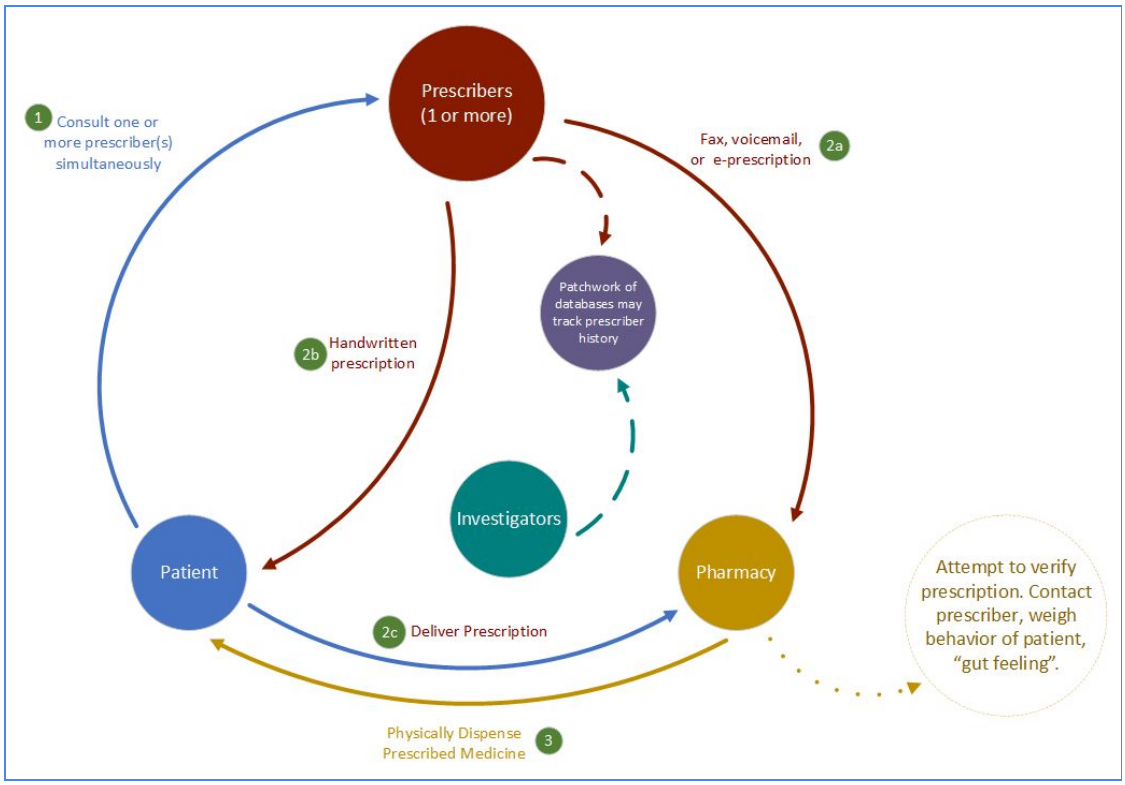

Figure 5: Current Process Workflow

Section 5.3.2: New Process Workflow Proposed

Trust, or a single source of easily verifiable truth, is the revolutionary component in the proposed process workflow. In Figure 6 below, blockchain is the single source of prescription truth for the prescriber, patient, and pharmacy. All opioid prescriptions can be seen in one location, thus preventing patient poly-pharmacy and discouraging physician over-prescribing. Blockchain touches all aspects of the prescription workflow, ensuring proper visibility and synchronization within the process.

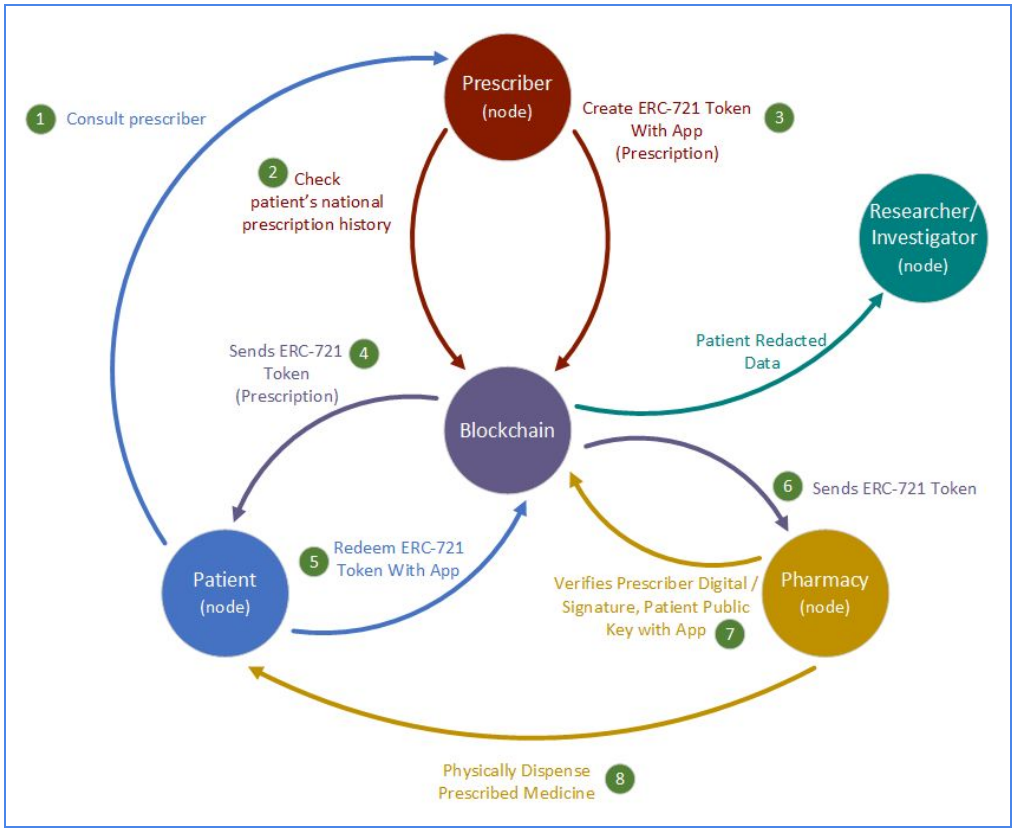

Figure 6: Proposed Process Workflow with Blockchain Trust

Section 5.4: Underlying Technology Platform: Ethereum

RxMe utilizes the Ethereum smart economy platform as the foundation for prescription technology. Ethereum is the most highly utilized blockchain platform in the world. RxMe utilizes

an ERC-721 token, compatible with trusted Ethereum based wallets such as MyEtherWallet, Ledger, and Trezor. Unlike currency based ERC-20 tokens, ERC-721 are unique and non-interchangeable tokens that are used to represent the actual prescriptions. Several Ethereum based distributed applications (dApps) currently exist as options for the RxMe model as growth dictates. Ethereum provides a trusted, decentralized, and highly utilized network with easy access to exchanges and hardware wallets providing token holders with multiple benefits and options.

Section 5.5: Distributed Apps

Due to the structure of the Ethereum network, Distributed Apps (Dapps) can be used to help solve real-world problems. We propose a Dapp aimed at each of our four user roles: prescribers, patients, pharmacy, and researcher/investigator, which are discussed further in Section 5.7, “User Roles.” Dapps will service these users’ needs, provide a platform to facilitate the writing of prescriptions, and track as prescriptions are redeemed.

Distributed Apps have three essential fundamental characteristics:

- Open Source: Our code base resides on GitHub, with routine updates that follow our regular agile cadences. RxMe will expose an API ensuring new developers, and healthcare providers access to build on top of our platform.
- Decentralized: RxMe will run on a permission-based, decentralized blockchain to hold the utmost security and integrity of all prescription records.
- Protocol: Ethereum platform supports Proof of Work (PoW) which is the current RxMe consensus algorithm (Section 3.4.1). Since RxMe is using a Private Ethereum Consortium Network architecture instead of the Public MainNet, RxMe may consider forking Ethereum to produce the Proof of Interoperability consensus algorithm proposed in Section 5.8, “Consensus Algorithm.”

Distributed Apps allow multiple user roles to have different access to the blockchain. RxMe empowers patients by allowing them to view their prescription history as well as active tokens for current prescriptions. Patients have a unique private key linked to their identity for privacy and security. Physicians view a patient's full prescription history for transparency and prevent overprescribing with potentially harmful side effects. Pharmacies match and validate prescription tokens with the private key of the patient to reduce prescription fraud. Researchers and investigators cannot see patient identities and HIPPA protected Personal Health Information such as the day and month of prescription or identity of the patient.

Section 5.6: ERC-721 Prescription Tokens

Prescriptions are represented as ERC-721 tokens with a solidity contract standard. This non-fungible token contains metadata including prescriber's digital signature, patient's public key, medication ID, expiration date, unit quantity, Primary Diagnosis Code (ICD), and dosage quantity to be dispensed. We will create a custom metadata ERC-721 token for each opioid. Physicians prescribe or provide refills by issuing a token to the patient's public key address. The RxMe equivalent of a prescription with three refills might be three tokens, regardless of whether the tokens are issued all at once or distributed electronically with an interval of time between them (such as 30 days). When the patient redeems the token at a pharmacy, the pharmacy destroys (or "burns," to use Ethereum's terminology) the token to prevent duplicate prescription or double spending. The ERC-721 solidity contract prevents the token from being transferred to a third party who is not a pharmacy.

Section 5.7: User Roles

The initial RxMe system includes four individual user role use cases:

- **Prescriber**: Executes a smart contract to prescribe medication, generating a token for the medication to be prescribed with the diagnosis code.
- **Patient**: Receives a prescription encapsulated as a token into the patient's wallet. The patient can transform the electronic token into a prescription through a pharmacy. The patient sends the token to the pharmacy's public wallet.
- **Pharmacy**: Fills the prescription after receiving the token by validating the signature between the physician and the patient.
- **Researcher/Investigator:** Include academics, regulatory bodies, and law enforcement officials which are discussed further in Section 5: "Blockchain Data Analytics and Machine Learning."

Section 5.8: Network Permission, Nodes, Miners, Consensus Algorithm

Physician-patient and pharmacy-patient comprise the transaction relationships, allowing the network to be permission-based, requiring each node's authentication and approval by a central authority. This authentication boosts security and allows for usage of different consensus algorithms that Ethereum later implements, since not anyone from the public can become a node. Nodes include physicians and pharmacies who are responsible for verifying and processing (mining) transactions presented to the network.

Ethereum currently supports only Proof of Work, as noted in Section 5.5, "Distributed Apps." As Ethereum evolves, RxMe will change consensus algorithms to avoid the inefficiency of Proof of Work. Our preferred consensus algorithm proposal borrows from Peterson, Deeduvanu, Kanjamala, and Boles of the Mayo Clinic who proposed "Proof of Interoperability" in their blockchain white paper submitted to the Office of the National Coordinator for Health Information Technology (Peterson, Deeduvanu, Kanjamala, & Boles, 2016). Proof of Interoperability requires nodes to contribute "something intrinsically valuable" rather than

computational solutions that serve only to make writing new blocks difficult (BitCoin's Proof of Work) or basing network control on ownership (Proof of Stake). In our solution, the intrinsic value is the validation of tokens and validity of prescription data written to the blockchain. The Mayo Clinic researchers propose "structural and semantic" validation. Applied to our solution, this might include the validity of the medical diagnosis, the validity of the physician's digital signature, and whether any required data is missing. Fast Healthcare Interoperability Resources (FHIR) could be used to partially implement the constraints (Peterson et al., 2016).

Section 5.9: Structure of the Blockchain and Transactions

The RxMe blockchain and transaction structure are shown in Figure 7. The transaction is written to the blockchain after the patient redeems the ERC-721 token (see Section 5.6).

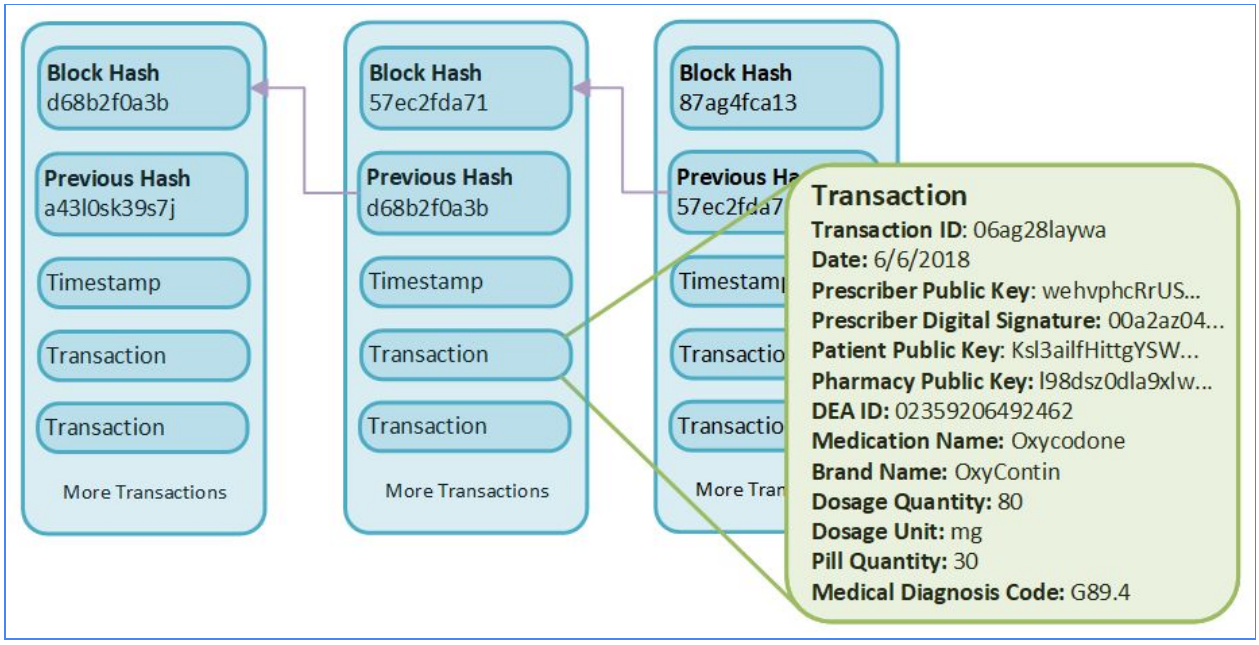

Figure 7: RxMe Blockchain and Transaction Structure

Each Transaction has a unique identifier, the prescription date, and the prescribers Drug Enforcement Agency (DEA) ID. The transaction also includes the fulfilling pharmacy's public key, medication name (scientific name), medication brand name, dosage quantity, dosage unit,

and pill quantity. RxMe also requires the medical diagnosis code, which uses the medical classification list from International Statistical Classification of Diseases and Related Health Problems, or ICD-9 / ICD-10.

The prescriber digitizes a prescription with an ERC-721 token and sends the token to the patient's public key address. When a patient redeems the token at a pharmacy, the RxMe creates an entry of the pharmacy's fulfillment in the blockchain. Each party can view confidential data with their private key. For example, physicians can view their prescribing history, patients can view their prescription history, and a pharmacy can view their dispensed prescriptions.

Section 5.10: RxMe Blockchain Data Analytics and Machine Learning

RxMe will perform data analytics providing intelligence data and charts generated below. The charts below are implemented using standard Python algorithms mining the dataset from the United States Centers for Medicare and Medicaid Services (CMS) instead of the RxMe blockchain data. Figure 8 below shows a mock-up of a RxMe Research Interface, with drugs shown by prescription occurrence:

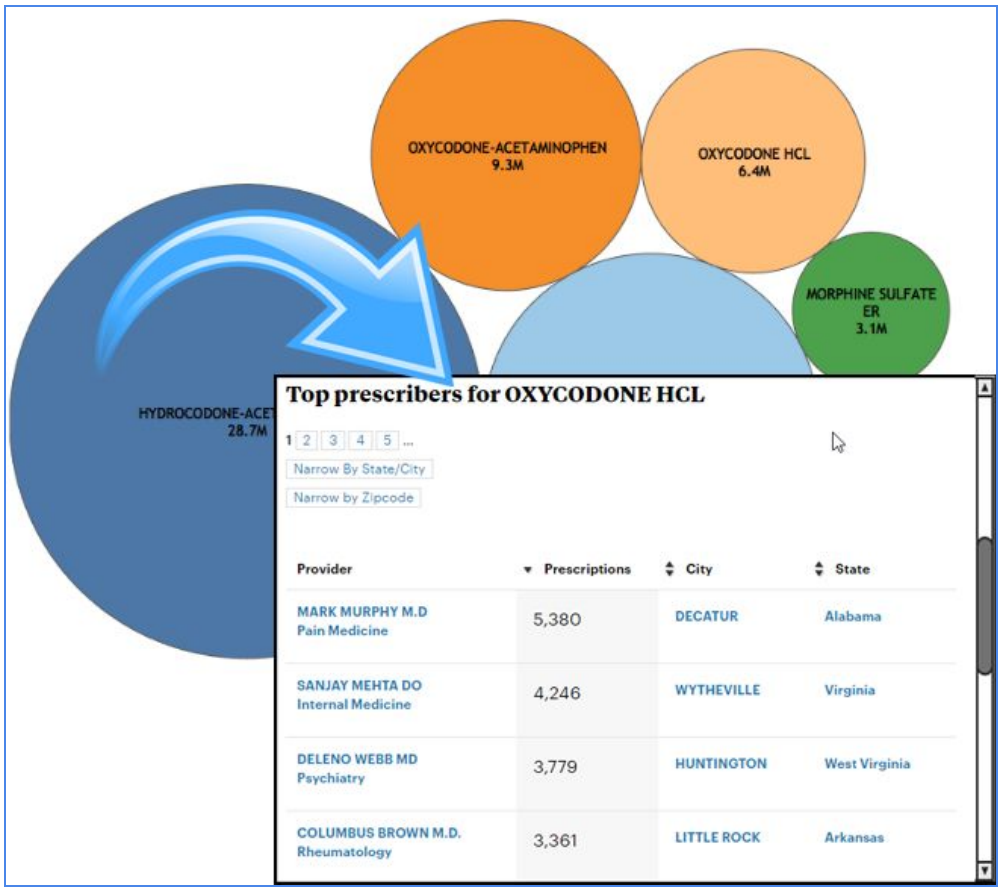

Figure 8: Example of how RxMe User Interface may appear. Researcher clicks on a drug bubble to see top prescribing physicians in a given geographic area.

An analyst viewing the above screen in RxMe selects a drug bubble then selects a state or geographic location. The next screen shows the top prescribing physicians, health networks, or hospitals would appear pop-up. RxMe blockchain data analytics tool provides an interface such as Figure 9 below allowing the analyst to show the top prescribing physicians by specialty.

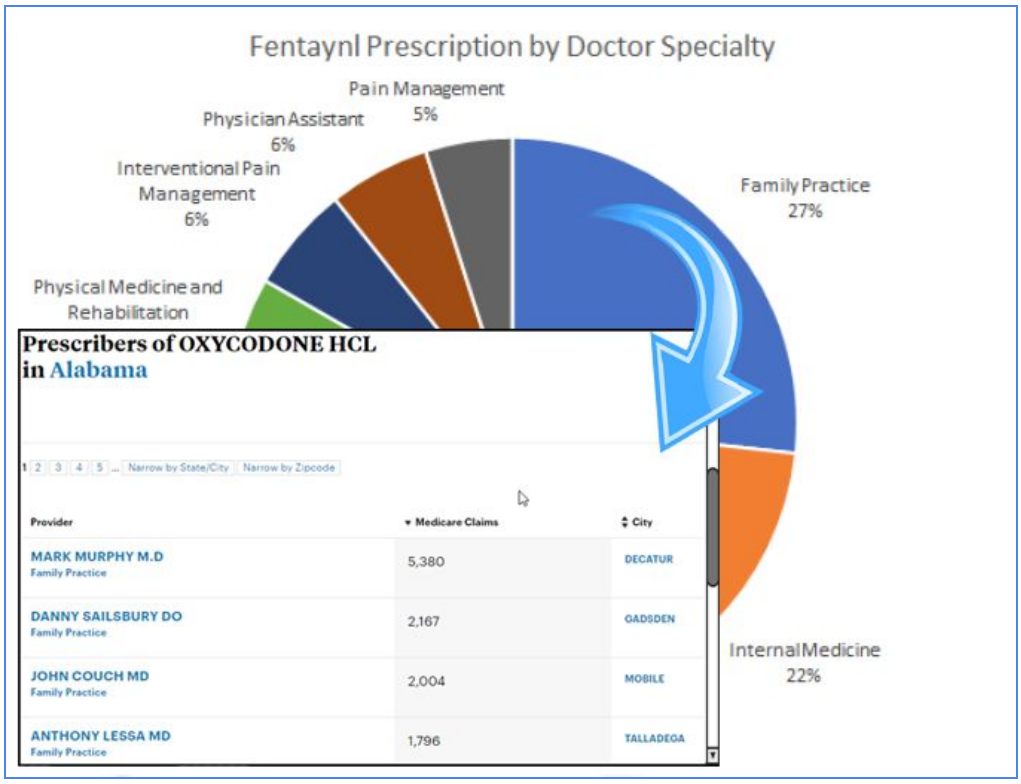

Figure 9: Another way we envision the user interface so that researchers can view top prescribing physicians by specialty.

RxMe's data analytics tool displays individual physicians, physicians grouped by health organization, by health organization, or a pharmacy. Detection of anomalies in narcotic prescriptions across multiple transaction points is possible by analysts or artificial intelligence tools using blockchain data. A key advantage of the RxMe blockchain is the integrated data analytic charts produced from fundamental data analysis, like the ones above. RxMe does not restrict data analytics to just one data source from a government agency or regional research project. Instead, the RxMe analytic tools and API data would include all medication prescribed through pharmacies in the United States and their prescription purpose codes.

Section 5.10.1: RxMe Impact of Physician Prescribing Rank

A physician's prescribing rank for specific drugs or classes of drugs could be deduced from the RxMe blockchain and presented to the physician via a clinical decision support system. Previous studies demonstrated when physicians were shown they overprescribed medication relative to their peers, their prescription rates dramatically dropped (Meeker et al. 2016). In the same study, when physicians sought to prescribe drugs in a way that exceeded decision support medical guidelines for a patient, and the system required a brief justification from the physician, the physician was less likely to prescribe the drug. Meeker also showed the justification requirement works exceptionally well when the physician knows other physicians can review the justification.

Section 5.10.2: RxMe Predictions of Patients Likely to Abuse Opioids

Another dimension of data analysis involves predicting a patient's likelihood of abusing an opioid prescription from EHR and blockchain prescription history. Machine learning classification algorithms such as Logistic Regression, Random Forest, Gradient Boosting, Support Vector Machine, and various neural networks continuously analyze the datasets. Researchers from the University of Southern California and The Mayo Clinic used data from over 100,000 patients in the Rochester Epidemiology Project. Using a Deep Feed-Forward Neural Network Model and Recurrent Neural Network Model, researchers predicted opioid abuse according to specific risk factors. For example, anxiety and other mental health disorders were substantially more likely to be correlated with opioid abuse and addiction (Che, St Sauver, Liu, & Liu, 2017). This new endeavor was successful despite the researchers having access to only a smart fraction of the nation's prescriptions. Similar research on the entire blockchain of

the nation's prescriptions would enable an even more profound understanding of opioid risk factors.

Section 6.0: Public Policy Solution: National Prescription Blockchain

While the concept of creating a centralized or national Electronic Health Record is not new for better overall EHR interoperability (Kohane, Greenspun, Fackler, Cimino, & Szolovits, 1996), prescription records are presented as an auxiliary benefit. We propose the US government mandate a distributed data structure, like the RxMe implementation of blockchain, to track the physicians who prescribe prescriptions, the patients who receive them, and the pharmacies that fulfill them. Later, a parallel blockchain could be set up for pharmaceutical supply chain management to prevent illegal and fraudulent activity (Alexander, Kruszewski, & Webster, 2012) outside of the prescriber-patient-pharmacy triangle.

Section 6.1: EHR Fragmentation Issues Foreshadow Prescription Blockchain Issues

The RxMe technical solution proposed in Section 5 may fail if the healthcare industry develops fragmented technical solutions, such as competing blockchains that track the same types of prescription data. Fragmented solutions that defy the goals of the intended solution is not without precedent in the Health Information Technology sector. For example, the Health Insurance Portability and Accountability Act (HIPAA) of 1996 sought to protect the "exchange and use of electronic health information" ("Information Blocking," 2017). Later in 2004, the Health Information Technology (ONC) planned the National Health Information Network (NHIN) to support healthcare data exchange between healthcare providers and Health Information Exchange (HIE). The NHIN was later changed in the Obama era as the focus was again on EHR interoperability through The Health Information Technology for Economic and Clinical

Health (HITECH) act. Despite all the investment to promote interoperability, the 21st Century Cures Act of 2016 and the rules promulgated since (by the Act's authority) acknowledge that information blocking undermines interoperability. The tendency of providers and fragmented vendors to engage in information blocking is the exact opposite of the government's goals for healthcare interoperability. The American Bar Association (Pechette, Niecko-Najjum, & Schmit, 2018) and the National Law Review (Thomas, 2015) both cite information blocking as a problem and caution healthcare providers and HIT vendors against the practice. Both organizations describe a competitive climate between opposing hospitals and networks that promote information blocking to prevent patients from switching to a competing organization or network. HIT vendors also have an interest in information blocking to appease their customers (clinicians) and to prevent their market share loss when an organization seeks to change its underlying EMR system (Thomas, 2015).

Section 6.2: Fragmentation Causes Problems in EHRs and Blockchain

We argue a fragmented EHR system causes the "information hoarding" described by the American Bar Association (Pechette et al., 2018). There is every reason to believe that a fragmented prescription blockchain solution would fail because it is fragmented. More specifically, competing for blockchain solutions would merely mean that patients who abuse (or sell) prescription drugs (and opioids specifically) would then shop between physicians of competing blockchains for prescriptions instead of merely seeking different physicians. As noted previously in this paper, the government made significant investments (billions of US dollars) in stopping the Opioid crisis, yet the CDC reports the problem is worsening (Centers for Disease Control, 2018a).

Section 6.3: Benefits of a National Blockchain for Prescription Drugs

A government-mandated blockchain with usage required for prescription or fulfillment of a prescription would prevent potential opioid leakage in the prescriber-patient-pharmacy triangle. Patients who attempt to engage in poly-pharmacy (, or “doctor-shopping”) would be ineligible to receive subsequent prescriptions as the prescribing physician can view the prescription history across all prescribers for that patient. Narcotic prescription data residing in a centralized location affords RxMe and independent machine learning analysis an opportunity to detect physicians who overprescribe, whether out of indifference or corruption. We propose the understanding that analysis is being continually run on prescription decisions would diminish opioid overprescription tendencies, regardless of the underlying motivation of the tendencies. Studies have revealed that physicians shown to overprescribe medication relative to their peers will decrease their prescriptions after being made aware (Meeker et al. 2016).

The RxMe initial implementation is a starting point to combat an American crisis. RxMe second phase would expand to include the entire narcotic industry supply chain including tools to counter opioid leakage and counterfeit issues (Alexander et al., 2012). Ultimately, the solution to the opioid crisis is a technical architecture like blockchain fused with a public policy mandate that prevents circumvention.

Section 7.0: Conclusion

RxMe is required to stop opioid leakage in the prescriber-pharmacy-patient triangle. The United States is in an opioid crisis, senselessly costing lives every day. The government’s money spent to address the problem has not been successful enough to keep pace with the growing epidemic. Just as government regulations have curbed the growth of tobacco usage, America must take regulatory action against the opioid crisis with blockchain technology.

The biggest short-term obstacle for our solution is getting buy-in from prescribers, pharmacists, and patients. The long-term obstacle is working with Congress to pass legislation requiring prescription purpose codes for all narcotics prescriptions, along with an underlying blockchain to establish prescription trust and legitimacy. Blockchain's use of public key cryptography likely violates the Health Insurance Portability and Accountability Act (HIPPA), Privacy Rule. HIPAA's Privacy Rule does not allow the use of pseudonyms to represent de-identified information because of the concern that the de-identified information could be re-identified. Future regulatory action must address HIPPA compliance with blockchain to reduce the corporate regulatory risk of developing blockchain solutions for healthcare.

While most of the proposed RxMe components are not new to academia, a single product with all the original functionality (prescription blockchain, medical/prescription purpose codes, and data analytics with machine learning) does not yet exist. Based on our research, a national prescription blockchain to address the opioid crisis is unproposed in academia. Our call for a national prescription blockchain for all opioid prescriptions is a novel idea to stop all types of opioid leakage in the prescriber-pharmacy-patient relationship. Cited research verifies that reckless prescribing slows in an environment where prescription decisions require justification and may be subject to oversight. Equally important, the immutable and central history of the proposed mandatory prescription blockchain prevents poly-pharmacy or doctor shopping. The government must decide when to end the suffering caused by the opioid epidemic, which kills more people every 26 days than those who died in the World Trade Center attack on September 11, 2001.

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