INTEROPERABILITY AND THE PATH TO COMPREHENSIVE HEALTH INFORMATION EXCHANGE

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At the Health Datapalooza conference in 2016, in light of the passage of the 21st Century Cures Act,[1] Joe Biden took to the stage to share the story of his son Beau's unsuccessful battle with brain cancer.[2] Biden recounted how his family struggled to have Beau's health records sent between the Walter Reed National Military Medical Center and the University of Texas MD Anderson Cancer Center, where Beau was receiving treatment from a world class team of oncologists.[3] Ultimately, the brain scans had to be flown from Maryland to Texas.[4] Biden lamented that in 2015, even with the influence of the Vice President of the United States, something as seemingly simple as electronically transmitting an image from one hospital to another was impossible to accomplish.[5] Biden called the state of affairs a "matter of life and death," saying that the industry must eliminate technical roadblocks that prevent patients from obtaining their own medical records.[6] In reality, successful exchange of a patient's electronic medical records between different providers faces more than just technical roadblocks; privacy, security, and – importantly – economic incentives all stand in the way of a healthcare system in which a patient's medical information can flow seamlessly from one provider to the next.

The American healthcare industry's transition from paper medical records to digital medical records is effectively complete, but the full potential of electronic records to improve patient outcomes and reduce spending has not yet been reached. As it stands today, real-time, robust exchange of medical records between different healthcare providers is still an elusive goal, partly due to economic disincentives to share patient information. This Note argues

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[1] 21st Century Cures Act, Pub. L. No. 114-255, 130 Stat. 1033 (2016).

[2] Dan Bowman, *Joe Biden: Sharing of Health Data 'a Matter of Life and Death'*, FIERCEHEALTHCARE (May 10, 2016, 11:18 AM), https://www.fiercehealthcare.com/it/joe-biden-sharing-health-data-a-matter-life-and-death [https://perma.cc/H37A-84RE].

[3] *Id.*

[4] *Id.*

[5] *Id.*

[6] *Id.*

that economic roadblocks to information exchange can be resolved through regulation that builds upon the incentives of patients and health insurance providers to ensure that information flows readily.

Part I will provide background on healthcare Information Technology (IT), describing the history of electronic health record adoption and the need for interoperability between electronic health record databases. Part II discusses the state of health information exchange, including the regulatory landscape and current rates of information exchange. Part III evaluates the various obstacles that stand in the way of information exchange, with a particular focus on economic incentives. Part IV argues that regulations that focus on patients and payers as key stakeholders in health information exchange will be the best way to drive information exchange going forward.

I.

INTRODUCTION TO INTEROPERABILITY

A. Health IT Adoption and Interoperability

Healthcare systems across the United States began implementing electronic health record (EHR) platforms in substantial numbers in the 2000s.[7] EHRs serve both as data repositories for medical records and as workflow tools for healthcare professionals, providing valuable safety protections such as matching the medication barcoding[8] and drug interaction checking based on the information in the patient's chart. The benefits associated with EHRs include increased accuracy, quick access to patient data, and efficient reporting capabilities.[9] Increasingly, EHR vendors are introducing artificial intelligence and machine learning functionality capable of delivering valuable clinical insights based on the vast amounts of data contained within their systems.[10]

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[7] John Jay Kenagy, *The Evolution of EHR Regulation*, 31 NO. 4 HEALTH LAW. 14, 15 (2019).

[8] Medication barcoding is a means of ensuring that a hospital patient receives the correct medication and dose at the time of administration. When the hospital pharmacy prepares a medication for a patient, an EHR will generate a unique barcode that can be printed and attached to the medication. When a nurse administers the drug, he or she scans the printed barcode. If the scanned barcode does not match the medication order that was originally placed in the patient's chart, the EHR will alert the nurse.

[9] *Clinical Advantages of Electronic Health Records*, ATHENAHEALTH, https://www.athenahealth.com/knowledge-hub/ehr/what-is-ehr/advantages [https://perma.cc/3MXG-E9VS].

[10] Thomas H. Davenport et al., *Using AI to Improve Electronic Health Records*, HARVARD BUSINESS REVIEW (Dec. 13, 2018), https://hbr.org/2018/12/using-ai-to-

Despite the existence of adequate technology as early as the 1970s, EHR adoption was still (to some) surprisingly low in the mid-2000s. Commentators attributed the lack of technology diffusion to prohibitive adoption costs, including the upfront price of the software, licensing fees, maintenance expenses, and time spent in training.[11] In 2009, with the passage of the HITECH Act,[12] the federal government began to incentivize EHR implementation through subsidies that added up to $19 billion.[13] Following the passage of HITECH, the percentage of U.S. hospitals using EHRs skyrocketed from 9.4 to 75.5 percent by 2014, marking a paradigm shift from paper to electronic records.[14] As of 2019, 97% of hospitals in the United States utilized electronic health records.[15]

Although EHRs are now ubiquitous, the EHR systems installed by hospitals, clinics, and other entities are proprietary products developed by a variety of vendors. Healthcare systems may even purchase individual software applications from different vendors in order to meet needs across departments. Each healthcare system uses its EHR to create and maintain its own isolated database of medical records regarding the care it provides to patients. As patients receive care from providers who are associated with different entities, health information must be exchanged between the siloed databases in order for provider A to receive the medical information documented in provider B's EHR. The information exchanged could be as comprehensive as the entire record of care from provider B's organization, including self-reported medical history, or as limited as a list of the patient's allergies.

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improve-electronic-health-records [https://perma.cc/3PTY-74SD] ("AI is being applied in EHR systems principally to improve data discovery and extraction and personalize treatment recommendations . . . .").

[11] Ashish K. Jha et al., *Use of Electronic Health Records in U.S. Hospitals*, 360 NEW ENG. J. MED. 1628, 1628 (2009).

[12] Health Information Technology for Economic and Clinical Health Act (HITECH), Pub. L. No. 111-5, §13001, 123 Stat. 227 (2009). The HITECH Act was passed as part of the American Recovery and Reinvestment Act of 2009. It was enacted to promote the adoption and use of health information technology.

[13] Amalia R. Miller & Catherine Tucker, *Health Information Exchange, System Size and Information Silos*, 33 J. HEALTH ECON. 28, 29 (2014).

[14] OFFICE OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., ADOPTION OF ELECTRONIC HEALTH RECORD SYSTEMS AMONG U.S. NON-FEDERAL ACUTE CARE HOSPITALS: 2008-2014 1, 1 (2015).

[15] Anna Wilde Mathews, *New Rules Could Ease Patients' Access to Their Own Health Records*, WALL ST. J., https://www.wsj.com/articles/new-rules-could-ease-patients-access-to-their-own-health-records-11549892701 [https://perma.cc/9YZF-VG5G] (last updated Feb. 11, 2019, 12:45 PM).

The Health Information Management Systems Society (HIMSS) defines interoperability of health information technology (health IT) as "the ability of different information systems, devices, and applications ('systems') to access, exchange, integrate and cooperatively use data in a coordinated manner, within and across organizational, regional and national boundaries, to provide timely and seamless portability of information and optimize the health of individuals and populations globally."[16] Industry experts generally agree that interoperability can take forms that vary in sophistication and outcome because data must first be transmitted effectively and then put to use in the recipient's EHR. Accordingly, HIMSS defines four increasing levels of interoperability: foundational - two systems have the requisite connectivity to communicate data; structural - including defined format of data exchange for interpretation; semantic - providing for common data elements with standardized and publicly available sets; and organizational - including governance, policy, and legal considerations to facilitate communication and use of data.[17] "Interoperability" refers to the capability of participation in "health information exchange" (HIE) - the "electronic sharing of health-related data between two or more organizations facilitated by applied standards for use by a variety of stakeholders to inform health and care."[18] Both interoperability and HIE are imperative in the modern era as Americans navigate the healthcare system with increasing mobility.

B. The Value of Health Information Exchange

Widespread HIE (facilitated by interoperability) is a necessary condition for unlocking the full social and economic benefits of ubiquitous EHR adoption. The majority of Americans receive their care from more than one provider, and without HIE, the information collected and created by each of a patient's providers remains isolated.[19] With a more complete picture of a patient's health supplied by HIE, health care providers can deliver higher quality care. A cost-effective national healthcare system depends upon accessible information regarding quality and use of services. HIE can also improve public health reporting, bioterrorism surveillance, quality

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[16] *What is Interoperability?*, HEALTH INFO. MGMT. SYS. SOC'Y, https://www.himss.org/what-interoperability [https://perma.cc/E7W7-ZE2P].

[17] *Id.*

[18] *Id.*

[19] David J. Brailer, *Interoperability: The Key to the Future Health Care System*, 24 HEALTH AFF., W5.19, W5-19 (2005) https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.W5.19 [https://perma.cc/4CHP-PHTB].

monitoring, and clinical trial advancements.[20] In a 2013 white paper laying out a 10-year vision for national interoperability, the Office of the National Coordinator for Health Information Technology (ONC) described a "learning health system" in which "an array of interoperable health IT products" would make continuous quality of care improvement feasible through analysis of aggregated data.[21] ONC predicted that a learning health system would lower costs, improve population health, empower consumers, and drive innovation by the year 2024.[22]

A considerable amount of research has aimed to estimate and measure the value of interoperability and HIE. "HIE has been associated with 50% reduction in rates of hospital readmission, 35% reduction in rates of repeat imaging procedures, 26% reduction in the rates of emergency department admissions, and 10% lower 30-day readmission rates among Medicare fee-for-service beneficiaries."[23] A 2005 conceptual study estimated that fully implemented interoperability would yield a net value of $77.8 billion annual savings in the U.S. healthcare system, representing about 5% of projected annual healthcare expenditures at the time.[24] On average, a medium sized hospital would save $1.3 million annually.[25] This estimate was low, as the methodology did not attempt to quantify potential clinical benefits and instead limited conclusions to ascertainable savings resulting from reduced administrative time and redundancies.[26] Another well-cited RAND report estimated that "effective EHR implementation could save more than $81 billion annually."[27]

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[20] *Id.* at W5-20.

[21] OFFICE OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., CONNECTING HEALTH AND CARE FOR THE NATION: A 10-YEAR VISION TO ACHIEVE AN INTEROPERABLE HEALTH IT INFRASTRUCTURE 2–3 (2014).

[22] *Id.* at 1.

[23] N.Y. EHEALTH COLLABORATIVE, ANALYSIS ESTIMATES VALUE ASSOCIATED WITH USE OF THE STATEWIDE HEALTH INFORMATION NETWORK FOR NEW YORK 1 (Nov. 12, 2019), http://www.nyehealth.org/nyec16/wp-content/uploads/2019/11/White-Paper_Analysis-Estimates-SHIN-NY-Value_11.12.19.pdf [https://perma.cc/ZT4N-BEFK].

[24] Jan Walker et al., *The Value of Health Care Information Exchange and Interoperability*, 24 HEALTH AFF. W5-10, W5-10, W5-16 (2005), https://www.healthaffairs.org/doi/10.1377/hlthaff.W5.10 [https://perma.cc/85YM-Y3FN].

[25] *Id.*

[26] *Id.*

[27] Daniel J. Gilman & James C. Cooper, *There is a Time to Keep Silent and a Time to Speak, the Hard Part is Knowing Which is Which: Striking the Balance Between Privacy Protection and the Flow of Health Care Information*, 16 MICH. TELECOMM. TECH. L. REV. 279, 291 (2010).

Despite a clear consensus among policy makers, academics, and industry experts that public policy favors robust health information exchange, HIE has been slow to take hold in the United States. Even with CMS reimbursement levels tied to measures of interoperability, success of HIE has been lurching at best. Although technical standardization remains to be fully realized and concerns regarding privacy and security have slowed the overall adoption of HIE, economic disincentives to engage in HIE remain the most stubborn barrier to increasing levels of clinical data exchange.

II.

OVERVIEW OF CURRENT STATE OF HEALTH INFORMATION EXCHANGE

A. *Relevant Legislation and Regulation*

In addition to incentivizing EHR implementation, HITECH introduced the State Health Information Exchange (State HIE) Cooperative Agreement Program, which granted awards totaling over $500 million to 56 states, territories, and eligible entities to implement plans to advance HIE in their regions.[28] The efforts spurred by the State HIE Cooperative Program are the dominant facilitators of medical record exchange in the U.S.[29]

Also pursuant to HITECH, CMS established the Medicare and Medicaid EHR Incentive Programs, which tied the level of Medicare and Medicaid reimbursements received by healthcare providers to demonstrated "meaningful use" of EHRs.[30] There were three stages to the Meaningful Use Program – each with progressively more challenging criteria related to sophisticated use of EHR technology. Interoperability was incorporated in the Meaningful Use measures, but the bar was set low for providers to meet the requirements of Stage 1 and Stage 2. For example, Stage 2 could be satisfied by electronically transmitting a summary of care record for just 10 percent of transitions of care. In order to maximize payments from CMS, a health care system would have reached Stage 1 by

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[28] *State Health Information Exchange*, HEALTHIT.GOV (Apr. 29, 2019), https://www.healthit.gov/topic/onc-hitech-programs/state-health-information-exchange [https://perma.cc/HFZ6-WT8Q].

[29] OFFICE OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., 2018 REPORT TO CONGRESS: ANNUAL UPDATE ON THE ADOPTION OF A NATIONWIDE SYSTEM FOR THE ELECTRONIC USE AND EXCHANGE OF HEALTH INFORMATION (2018).

[30] *Meaningful Use of Electronic Health Records*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/cancer/npcr/meaningful_use.htm [https://perma.cc/T5B6-3WUU] (last reviewed Dec. 11, 2018).

2011, Stage 2 by 2015, and Stage 3 by 2019.[31] Since interoperability was not prioritized at the beginning of the Meaningful Use program, many health care systems implemented EHR systems with limited interoperability functionality in the early 2010s and gave little consideration to incorporating HIE into provider workflows. CMS changed the name of the Medicare and Medicaid EHR Incentives Programs to "Promoting Interoperability Programs" in 2018, signaling a shift in focus from basic EHR functionality to interoperability and patient access to health information.[32] Now that an entire HIT ecosystem developed without regard for interoperability, retrofitting EHR systems and workflows to incorporate significant HIE will present considerable challenges.

Since the passage of the 21st Century Cures Act, the Department of Health and Human Services (HHS) has promulgated and proposed several significant regulations which affect health information exchange. In 2018, CMS announced the MyHealthEData Initiative, which aimed to "empower patients by ensuring that they control their healthcare data and can decide how their data is going to be used, all while keeping that information safe and secure."[33] Among other things, the MyHealthEData Initiative included the "BlueButton 2.0" tool – a service which will make Medicare patients' claims data available to developers of patient-facing applications.[34] In the MyHealthEData Initiative press release, CMS urged private payers to take similar steps to make claims data available to their patients.[35] As a payer that serves over 130 million individuals in the U.S., CMS is uniquely positioned to put pressure on private payers to conform to best practices.[36]

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[31] *Stages of Promoting Interoperability Programs: First Year Demonstrating Meaningful Use*, CTRS. FOR MEDICARE & MEDICAID SERVS. 2, https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/Stages_of MeaningfulUseTable.pdf [https://perma.cc/27H4-Y5MK].

[32] *Promoting Interoperability Programs*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Sept. 24, 2019), https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index?redirect=/ehrincentiveprograms/ [https://perma.cc/SUN8-YQDP].

[33] *Trump Administration Announces MyHealthEData Initiative at HIMSS18*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Mar. 6, 2018), https://www.cms.gov/newsroom/fact-sheets/trump-administration-announces-myhealthedata-initiative-himss18 [https://perma.cc/FW6M-Y793].

[34] *Id.*

[35] CTRS. FOR MEDICARE & MEDICAID SERVS, *supra* note 33.

[36] *Id.*

B. Health Information Exchange Models & Policy Directives

While the term "health information exchange" often refers to the actions of sending and

receiving electronic health information (EHI), a "Health Information Exchange" or "HIE" can also refer to an organized effort to facilitate exchange through sets of technical, legal, and business standards.[37] In somewhat overlapping terminology, a Health Information Exchange Organization (HIO) is an entity which provides oversight and governance over an HIE.[38] There are state-wide HIEs, private HIEs, hybrid HIEs, and regional HIEs.[39] Providers may need to connect to multiple HIEs in order to achieve the desired level of interoperability in their community, state, or region. In practice, most hospitals use more than one electronic method to routinely send and receive post-discharge summary of care records with unaffiliated organizations.[40] The methods employed include multi-EHR vendor networks, eHealth Exchange (a national network), regional HIOs, and custom interfaces between EHR systems. About 70% of hospitals sent summary of care records using mail or fax in 2017.[41] The more methods needed to ensure access to electronic information, the more cost and complexity is associated with health information exchange.

Regional Health Information Exchanges spurred by the HITECH Act and State HIE Cooperative Program are the dominant facilitators of medical record exchange in the U.S.[42] All 50 states now have some form of HIE services available to support providers at the point of care.[43] ONC emphasized its goal of transitioning to a nationwide health information network through the development of common standards, services, and policies.[44] The stakeholders of

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[37] *Interoperability in Healthcare*, HIMSS (Oct. 29, 2014), https://www.himss.org/library/health-information-exchange/FAQ [https://perma.cc/7FT3-VAAV].

[38] *Id.*

[39] *Id.*

[40] OFFICE OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., METHODS USED TO ENABLE INTEROPERABILITY AMONG U.S. NON-FEDERAL ACUTE CARE HOSPITALS IN 2017 1 (2018).

[41] *Id.*

[42] Sarah R. Rupp, *Making Room for Patient Autonomy in Health Information Exchange: The Role of Informed Consent*, 56 ST. LOUIS U.L.J. 885, 888 (2012).

[43] OFFICE OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., *supra* note 14, at 2.

[44] OFFICE OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., GET THE FACTS ABOUT THE NATIONWIDE HEALTH INFORMATION NETWORK, DIRECT PROJECT, AND CONNECT SOFTWARE 1 (2010).

HIE include those within the treatment context (hospitals, primary care providers, specialists, patients, and HIE vendors) and those outside of the treatment context (payers, researchers, and public health analysts).[45] However, most HIE efforts have focused their design, value creation, and business propositions around the providers', rather than the patients', point-of-view.

In addition to state and regional HIOs, vendor networks also play a significant role in the landscape of health information exchange. For example, Epic Systems, the EHR vendor with the largest market share in U.S., developed a proprietary exchange platform for its customers called Care Everywhere.[46] Several platform-independent organizations operate at the national level to facilitate health information exchange. Carewell and eHealth Exchange are examples of such entities. As part of its vision for a nationally integrated HIT system, ONC released the Trusted Exchange Framework and Common Agreement (TEFCA), which is intended to provide a "single on ramp" to national connectivity.[47] TEFCA lays out the standards for Qualified Health Information Networks, which will then be eligible to participate within the relevant framework.

Certain state laws may encourage or discourage participation in HIEs, many of which are administered or funded by state-sponsored entities. Combinations of legislation and regulations typically include participation incentives, privacy and security standards, and governance rules.[48] Some legal scholars have suggested that the complex web of regulations surrounding HIE has delayed implementation as organizations struggle to make sense of their legal obligations and ensure compliance with potentially conflicting legal requirements, particularly when operating across jurisdictional boundaries.[49] One nationwide study found that the character of

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[45] Rupp, *supra note* 42, at 888–89.

[46] *Care Everywhere*, HIMSS, https://www.himss.org/resource-environmental-scan/care-everywhere [https://perma.cc/Z77N-4FPB]

[47] Don Rucker, *Moving Beyond Closed Networks – An Update on Trusted Exchange of Health Information*, HEALTH IT BUZZ (Apr. 19, 2019), https://www.healthit.gov/buzz-blog/interoperability/moving-beyond-closed-networks-an-update-on-trusted-exchange-of-health-information [https://perma.cc/4V3J-VKUW].

[48] Brittany L. Brown-Podgorski et al., *The Association Between State-Level Health Information Exchange Laws and Hospital Participation in Community Health Information Organizations*, 2018 AMIA ANN. SYMP. PROC. 313, 313, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6371387/ [https://perma.cc/3JY5-8WS4].

[49] *See generally*, Cason Schmit et al., *Transitioning from Paper to Digital: State Statutory and Regulatory Frameworks for Health Information Technology*, 5 PUB. HEALTH REP. 585 (2017).

state legislation impacted the likelihood of hospital engagement in community HIOs.[50] The results showed that three different aspects of state law were associated with increased community HIO participation: authorization of a state HIO, maintaining a combination of financial and non-financial participation incentives, and structuring patient consent as an opt-out model.[51] Surprisingly, the same study found that state funding for health information exchange was negatively correlated with hospital participation. The authors posited that this finding could be attributed to the volatility of government funding and the increased regulations that often accompany government funds.[52]

C. Empirical Success

As of 2017, about 70% of hospitals in the United States were participating in at least one nationwide Health Information Exchange.[53] Excluding participation in Surescripts, the nation's dominant e-prescribing network, the figure was closer to 50%.[54] ONC statistics indicate that 32% of individuals who saw a doctor in 2018 experienced a gap in information exchange.[55] Approximately 7 in 10 hospitals sent or received summary of care records by fax or mail in 2017.[56]

New York's state HIO published a report in November 2019 announcing that it saves the state's healthcare system between $160 million and $195 million per year.[57] Although such savings are impressive, the report suggested that if the system were leveraged to its full capacity, annual savings could reach about $1 billion, indicating that healthcare systems are not participating in health information exchange to the extent made possible by interoperability.[58]

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[50] Brown-Podgorski, *supra* note 48, at 313.

[51] *Id.*

[52] *Id.* at 318.

[53] OFFICE OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., *supra* note 40, at 8.

[54] *Id.*

[55] *Gaps in Individuals' Information Exchange*, HEALTHIT.GOV (June 2019), https://dashboard.healthit.gov/quickstats/pages/consumers-gaps-in-information-exchange.php [https://perma.cc/GZB6-2XYE].

[56] OFFICE OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., *supra* note 40, at 2.

[57] N.Y. EHEALTH COLLABORATIVE, *supra* note 23, at 1.

[58] *Id.*

The Surescripts e-prescribing network facilitated 17.7 billion secure transactions in 2018[59] and has been dubbed "the single greatest success in interoperability since the widespread adoption of EHRs."[60] Surescripts is an alliance of pharmacies and pharmacy benefit managers, which joined together in 2001 to create what would become the nation's dominant e-prescribing network.[61] The success of Surescripts' business model may be attributable to commodification of a service. The ability to transmit prescriptions electronically has become a valuable function of EHRs and pharmacy systems, saving time and administrative costs for doctors, pharmacists, and patients alike. Interestingly, the e-prescribing enablement rate in pharmacies is considerably higher than that in providers' offices,[62] suggesting that e-prescribing capabilities are more economically valuable to pharmacies than to providers. Recently, Surescripts has been leveraging the power of its network to maintain a record locator and exchange service that allows clinicians to query the Surescripts Master Patient Index to receive a summary of where a patient previously received care.[63] As the 2018 Surescripts National Progress Report stated, massive adoption is enabling Surescripts to shift its attention to improving the quality of its intelligence.[64]

The patient access component of health information exchange has seen considerable improvement. In 2013, half of individuals were able to access some of their health information electronically.[65] A report published by the American Hospital Association

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[59] *2018 National Progress Report*, SURESCRIPTS, https://surescripts.com/news-center/national-progress-report-2018/#/better-healthcare-for-all [https://perma.cc/9NN3-6J2H].

[60] Rajiv Leventhal, *Micky Tripathi on Surescripts' E-Prescribing: "A Great Interoperability Success"*, HEALTHCARE INNOVATION GROUP (July 5, 2017), https://www.hcinnovationgroup.com/interoperability-hie/article/13028858/micky-tripathi-on-surescripts-eprescribing-a-great-interoperability-success [https://perma.cc/H87C-6WWU].

[61] Zina Moukheiber, *How Surescripts Became the Dominant Electronic Prescribing Network*, FORBES (Apr. 22, 2014, 11:32 AM), https://www.forbes.com/sites/zinamoukheiber/2014/04/22/how-surescripts-became-the-dominant-electronic-prescribing-network/#4e1403ae5aa0 [https://perma.cc/V2MV-CQN5].

[62] *2018 National Progress Report*, *supra* note 59.

[63] Kate Monica, *Surescripts Continues to Expand Health Data Exchange Nationwide*, EHRINTELLIGENCE (Apr. 23, 2019), https://ehrintelligence.com/news/surescripts-continues-to-expand-health-data-exchange-nationwide [https://perma.cc/QY4S-8EKN].

[64] *2018 National Progress Report*, *supra* note 59.

[65] OFFICE OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., *supra* note 14, at 2.

found that 93% of hospitals provided online patient access to EHRs in 2016.[66] However, the same report found a disparity between the access provided by small and large hospitals.[67] Access has surely increased due to Meaningful Use provisions which specify that healthcare providers must ensure access to electronic health information. The concept of patient access has also expanded beyond mere visibility to include the ability to download records, designate a proxy to view records, and to modify or supplement the electronic records.[68] CMS's Blue Button tool alone will make significant inroads toward increasing the potential for Americans to make use of their own health data.[69]

In sum, although interoperability in the United States has been improving over the past five to ten years, levels of health information exchange are not as high as experts would like. Functionally speaking, patients are not regularly seeing a flow of information between their healthcare providers.

III.

CHALLENGES AND OBSTACLES IN HEALTH INFORMATION EXCHANGE

A. *Technical barriers*

The first and most foundational barrier to health information exchange is technical – mostly due to lack of standardization. As healthcare stakeholders implemented disparate health IT systems in isolation, there were a variety of competing technical specifications, requiring stakeholders to make costly investments in order to achieve the desired interoperability. In particular, "semantic interoperability" relies upon a shared set of established terms and associated meanings, but existing EHR systems developed differing proprietary representations of medical information that could not be easily reconciled.[70] The ONC rule, finalized in June 2020, makes

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[66] Kate Monica, *93 Percent of Hospitals Allow Online Patient Access to EHRs*, EHRINTELLIGENCE (Mar. 5, 2018), https://ehrintelligence.com/news/93-percent-of-hospitals-allow-online-patient-access-to-ehrs [https://perma.cc/VXE2-8BGM].

[67] *Id.*

[68] *Id.*

[69] CMS's Blue Button tool is an application programming interface (API), which allows third party application developers to connect to Medicare and Medicaid claims data. CMS BLUE BUTTON 2.0, https://bluebutton.cms.gov/ [https://perma.cc/BWT8-WQD2].

[70] Sharona Hoffman & Andy Podgurski, *Finding a Care: The Case for Regulation and Oversight of Election Health Record Systems*, 22 HARV. J.L. & TECH. 103, 152 (2008).

strides toward unification by replacing the common clinical data set with USCDI, which defines a set of data classes and their constituent elements, such as clinical notes, medications, vital signs, and immunizations.[71]

Furthermore, the proposed rules mandate the use of FHIR, or Fast Healthcare Interoperability Resources. FHIR is a standard developed by Health Level 7, an international organization dedicated to creating and building consensus for healthcare standards.[72] "The embrace of FHIR APIs means that we're not going to have a Betamax-VHS fight in healthcare," said Aneesh Chopra, the first CTO of the United States.[73] "We now have an approach to adding more content on the data model. We're done with the fight."[74] As Chopra's remarks suggest, the solution to disparate technical specifications is a matter of facilitating uniformity.

The breadth of existing health information exchange efforts currently in place in the United States presents an additional challenge. The patchwork of networks must be interoperable with each other in order to serve effectively as a nationwide health information network. A 2014 report by the JASON group at the MITRE Corporation stressed that interoperability challenges could only be overcome by establishing a "comprehensive, transparent, and overarching software architecture . . ."[75] To that end, HHS released the TEFCA in 2018 to define standards of interoperability as mandated by the 21st Century Cures Act.[76] TEFCA seeks to establish a single on-ramp for HIE that will allow any health information network to connect to a national information exchange. A Recognized Coordinating Entity – the Sequoia Project – will administer TEFCA and

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[71] 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program, 45 C.F.R. §170 (2021).

[72] *About Fhir.org*, HL7 FHIR FOUNDATION, http://fhir.org/about.html [https://perma.cc/7CAG-KZEX].

[73] Tom Sullivan, *HIMSS19 Keynoters Challenge Private Sector to Keep Pace with FHIR, Open APIs*, HEALTHCARE IT NEWS (Feb. 12, 2019, 4:13 PM), https://www.healthcareitnews.com/news/himss19-keynoters-challenge-private-sector-keep-pace-fhir-open-apis [https://perma.cc/NDM2-AD52]. Chopra's reference to the Betamax-VHS fight calls back to the competition between Betamax and VHS in the 1980s, in which VHS emerged as the dominant videotaping format for consumers.

[74] *Id.*

[75] *A Robust Health Data Infrastructure*, THE MITRE CORP. 6 (2014), https://www.healthit.gov/sites/default/files/ptp13-700hhs_white.pdf [https://perma.cc/NR9W-TCTS].

[76] *See* OFFICE OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., DRAFT TRUSTED EXCHANGE FRAMEWORK 3–4 (2018) [https://perma.cc/76H3-68XC].

serve as its governing body.[77] However, industry members given the opportunity to comment on TEFCA expressed concern that timelines are too hasty and that incentives will be insufficient to induce voluntary participation.[78]

ONC also proposed to increase standardization of the HIE industry through updates to the conditions of certifications for health IT products.[79] The rule requires that certified EHRs implement standards-based application programming interfaces (APIs) that will make structured patient data available upon submission of a standardized request.[80] It also specifies the instances in which API suppliers and API data providers are permitted to charge fees.[81] The new API requirement is an important step toward creating an HIT ecosystem with room for new players to innovate and create connections among the stakeholders in the health care system.

B. Privacy and Security Concerns

Justifiable concerns regarding privacy and security present another significant challenge to HIE and have shaped health information exchange through consumer pressure and regulatory measures. The healthcare industry is very conservative with respect to privacy, perhaps slowing adoption of novel technologies. Scholars exploring privacy and security in HIE have noted that "the inherent tension in this process between the need to share and desire to protect health information has impacted the achievement of greater interoperability."[82] There will be some tradeoff between

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[77] Press Release, Dep't of Health & Human Servs., ONC Awards the Sequoia Project a Cooperative Agreement for the Trusted Exchange Framework and Common Agreement to Support Advancing Nationwide Interoperability of Electronic Health Information (Sept. 3, 2019).

[78] Rebecca Pifer, *Industry Interoperability Concerns Plague TEFCA Draft*, HEALTHCARE DIVE (June 20, 2019), https://www.healthcaredive.com/news/industry-interoperability-concerns-plague-tefca-draft/557208/ [https://perma.cc/J3XF-ACTR].

[79] *Notice of Proposed Rulemaking to Improve the Interoperability of Health Information*, HEALTHIT.GOV (June 5, 2019), https://www.healthit.gov/topic/laws-regulation-and-policy/notice-proposed-rulemaking-improve-interoperability-health [https://perma.cc/5MDB-QNWW].

[80] *Id.*

[81] OFFICE OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., APPLICATION PROGRAMMING INTERFACE (API) CONDITION OF CERTIFICATION: PERMITTED FEES CONDITION, 12 (2019), https://www.healthit.gov/sites/default/files/facas/2019-02-20_HITAC_Posnack_API_CoC_FeesIB_508_1.pdf [https://perma.cc/MAT9-PA8K].

[82] Chad Anderson et al., *A Framework for Evaluating the Tension Between Sharing and Protecting Health Information*, HAWAII INT'L. CONF. ON SYS. SCI. 3638, 3646

protecting privacy interests and achieving the goal of sharing helpful medical information among clinicians.

The most important legislation addressing privacy and security of electronic health information is the Health Insurance Portability and Accountability Act (HIPAA).[83] HIPAA's protections apply to personally identifiable medical information maintained or transferred by "covered entities," which include health plans, healthcare clearinghouses, healthcare providers, and their business associates.[84] Covered entities generally may use or disclose personally identifiable health information, without authorization, as follows: (1) to the individual subject of that information; (2) for treatment, payment, and health care operations; (3) incident to an otherwise permitted use and disclosure; (4) for certain public interest and benefit activities; and (5) as limited data sets for research, health care operations, or public health purposes.[85] When use or disclosure is not expressly permitted, the covered entity must first obtain written authorization from the individual.[86]

HIPAA's mandates with respect to personally identifiable health information are carried out in two distinct rules: the Privacy Rule and the Security Rule, effective in 2003 and 2005 respectively.[87] The Privacy Rule was the first regulation to set out national standards for protection of personal health information.[88] In promulgating the Privacy Rule, HHS sought to strike a balance which would allow the necessary flow of health information while protecting the privacy of patients.[89] The rule protects all "individually identifiable health information," which is data that relates to an individual's medical conditions, the provision of care to an individual, or the payment for care by an individual.[90] De-identified data is not subjected to the constraints of the Privacy Rule, but de-identification is becoming less effective as a privacy protection measure

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(2017), https://aisel.aisnet.org/cgi/viewcontent.cgi?article=1462&context=hicss-50 [https://perma.cc/2W3L-EZSD].

[83] *See* Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936.

[84] Applicability, 45 C.F.R. § 160.102 (2013).

[85] Uses and Disclosures of Protected Health Information: General Rules, 45 C.F.R. § 164.502(a)(1) (2013).

[86] Uses and Disclosures for which an Authorization is Required, 45 C.F.R. § 164.508 (2019).

[87] Daniel J. Solove, *HIPAA Turns 10: Analyzing the Past, Present and Future Impact*, 84 J. AHIMA 22, 23 (2013).

[88] U.S. DEP'T OF HEALTH & HUMAN SERVS. OFFICE OF CIVIL RIGHTS, SUMMARY OF THE HIPAA PRIVACY RULE 1 (2003).

[89] *Id.*

[90] *Id.*

due to modern techniques that can be used to re-identify the individual.[91] Future regulations may need to revisit the criteria for qualification as "de-identified," but the existence of re-identification methods will likely have significant implications for the use of medical data in research and population health.

The Security Rule operationalizes the privacy rule through physical, administrative, and technical requirements intended to ensure the integrity and confidentiality of electronic protected health information (PHI).[92] Covered entities must "ensure the "confidentiality, integrity, and availability" of all electronic PHI they "create, receive, maintain, or transmit."[93] Under the Security Rule, "confidentiality" means that electronic PHI is not disclosed to "unauthorized persons."[94]

While HIPAA established a federal floor for privacy regulation, states are free to build upon the federal regulations with stronger safeguards for patient data.[95] Many individual hospitals have also developed privacy policies that go further than HIPAA or state laws and can inhibit HIE within a network.[96] HIOs must also develop their own privacy and security policies. Experts advise that security policies for an HIO should "balance the requirements of ensuring interoperability and availability of information to authorized parties, while at the same time ensuring confidentiality, integrity and overall security."[97]

Lack of clarity around applicable privacy law also inhibits the flow of information because stakeholders share conservatively in order to avoid violating a confusing set of restrictions. Industry experts have noted that selectively sharing information and citing HIPAA as the justification accounts for a large portion of data blocking,[98] despite that fact that HIPAA permits two covered entities to share PHI about a person who they are both treating without obtaining prior consent.

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[91] President's Council of Advisors on Sci. & Tech., Big Data and Privacy: A Technological Perspective (2014).

[92] Gilman, *supra* note 27, at 302.

[93] *Summary of the HIPAA Security Rule*, U.S. Dep't of Health & Human Servs. (last reviewed July 26, 2013), https://www.hhs.gov/hipaa/for-professionals/security/laws-regulations/index.html [https://perma.cc/72GA-HYWJ].

[94] *Id.*

[95] Gilman, *supra* note 27, at 354.

[96] Anderson et al., *supra* note 82, at 3643.

[97] *Id.* at 3641.

[98] Julia Adler-Milstein & Eric Pfeifer, *Information Blocking: Is it Occurring and What Policy Strategies Can Address it?*, 95 Milbank Q. 117, 129 (2017).

Privacy regulation can take one of three forms: (1) consent requirements, (2) breach notification requirements, or (3) data security requirements.[99] Privacy regulations have been shown to suppress the network benefits of EHR adoption by as much as 24%.[100] Hospitals in states with laws that further restricted the ability to share patient information beyond federal requirements were significantly less likely to invest in implementing an EHR, perhaps because of the lost benefit of sharing information with neighboring healthcare systems.[101] There is a trade-off between strong privacy protection and health information exchange. However, privacy protections can also function to increase network benefits by providing reassurance to patients, thereby increasing network participation. Privacy concerns can be thought of as relating to either security or confidentiality.[102] Policy experts recommend opting for security requirements over consent requirements or breach notification requirements, concluding that if HIT can reduce losses from breach by reducing the probability of an occurrence, then HIT can function as a more efficient safeguard of privacy.[103]

There is competing evidence on the inherent value of privacy to consumers and the threat of data breaches. According to HHS, more than 113 million health records were compromised in 2015, making the healthcare sector the second highest target of data breaches of any U.S. industry that year.[104] In 2018, there were at least 221 breaches – impacting the data of about 6 million patients –reported to HHS Office of Civil Rights.[105] Patients appear to be troubled by the security of their data.[106] Consumer apprehension can affect adoption rates of HIT products; patients avoid consumer-oriented products if they do not trust the security and privacy measures put in place to protect their information.[107] However, some

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[99] Gilman, *supra* note 27, at 327.

[100] Amalia R. Miller & Catherine Tucker, *Privacy Protection and Technology Diffusion: The Case of Electronic Medical Records*, 55(7) MGMT. SCI. 1077, 1077 (2009).

[101] *Id.* at 1081.

[102] *Id.*

[103] Gilman, *supra* note 27, at 325.

[104] Nsikan Akpan, *Has Health Care Hacking Become an Epidemic?*, PBS (Mar. 23, 2016, 6:19 PM), https://www.pbs.org/newshour/science/has-health-care-hacking-become-an-epidemic [https://perma.cc/KZ6C-ES3D].

[105] *July 2018 Healthcare Data Breach Report*, HIPAA J. (Aug. 24, 2018), https://www.hipaajournal.com/july-2018-healthcare-data-breach-report/ [https://perma.cc/EV3T-LJHV].

[106] Gilman, *supra* note 27, at 315.

[107] *Id.* at 297.

evidence shows that patients' privacy preferences are actually distributed widely across a spectrum.[108]

The current discourse surrounding big tech has stoked fears around data collection and confidentiality.[109] Given the recent forays of big tech into healthcare, patients may be especially wary of commercial entities gaining access to their medical records, particularly outside of the traditional boundaries of the healthcare industry. In November 2019, several news outlets reported on Project Nightingale, a collaboration between Google and Ascension, the second largest healthcare provider in the U.S.[110] Ascension agreed to transfer the data of 50 million people from its EHR to Google without warning its patients or providers ahead of time.[111] According to a whistleblower, the transfer was set to occur without de-identification, and a number of Google employees would have access to the information.[112] Google and Ascension released statements asserting that the transfer was in full compliance with HIPAA and that the patient data would be protected, but the specter of Google's artificial intelligence capabilities and the vast troves of personal data already in its possession caused public outcry, sparking an HHS probe into the project.[113] One commentator observed, "the medical industry is notoriously sensitive when it comes to privacy and security, and Google faces an uphill battle to prove that it can be trusted when it makes the bulk of its money through advertisement."[114]

Big tech health projects aside, health data mining (compiling patient records from multiple sources and selling the conclusions to other businesses) is a very large commercial enterprise within the

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[108] *Id.* at 318.

[109] Farhad Manjoo, *We Hate Data Collection. That Doesn't Mean We Can Stop it.*, N.Y. TIMES (Nov. 15, 2019), https://www.nytimes.com/2019/11/15/opinion/privacy-facebook-pew-survey.html [https://perma.cc/6HQX-JAU4].

[110] Ed Pilkington, *Google's Secret Cache of Medical Data Includes Names and Full Details of Millions – Whistleblower*, GUARDIAN (Nov. 12, 2019), https://www.theguardian.com/technology/2019/nov/12/google-medical-data-project-nightingale-secret-transfer-us-health-information [https://perma.cc/J7W8-3CHX].

[111] *Id.*

[112] *Id.*

[113] Christina Farr & Jennifer Elias, *Google's Hospital Data-sharing Deal Raises Privacy Fears – Here's What's Really Going on*, CNBC (Nov. 12, 2019), https://www.cnbc.com/2019/11/12/google-project-nightingale-hospital-data-deal-raises-privacy-fears.html [https://perma.cc/R4XU-W32C].

[114] *Id.*

healthcare industry.[115] The insights that can be harvested from such data are an extremely valuable commodity. For example, Pfizer spends about $12 million per year to purchase health data.[116] However, compared to the attention garnered by Project Nightingale, the practice of regular data mining is relatively obscure, and many patients and providers are unaware of its existence. Patients are rarely given the opportunity to opt into data sharing for medical and research purposes while simultaneously opting out of data sharing for commercial purposes.[117]

The tangible harms and actual fraud resulting from data breaches are less certain, but medical identity theft appears to be somewhat rare. "[F]rom 2001 to 2005, about 0.111% of the adult population suffered medical insurance account misuse (defined as the use of personal information to obtain or receive payment for medical treatment, services or goods), and only 0.0148% of the adult population had their personal data used to create a new health insurance policy."[118] An FTC survey found that three percent of those whose personal health data was misused reported fraudulent use of their medical insurance, while 0.4% of all identity fraud victims reported that their personal data was used to create a new medical insurance policy.[119] However, despite the fact that medical insurance misuse appears to be low, medical records are excellent targets for comprehensive demographic information that can be used for illicit purposes beyond the context of healthcare.[120] An individual's credit information can be sold for about $0.10-$0.15 on the black market, while stolen medical records may garner as much as $30 to $1000.[121] Although medical theft identity appears rare in practice, there is significant potential for profit.

There are several different consent models which can be incorporated into health information exchange, but generally, the more

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[115] Adam Tanner, *How Data Brokers Make Money Off Your Medical Records*, SCI. AM. (Feb. 1, 2016), https://www.scientificamerican.com/article/how-data-brokers-make-money-off-your-medical-records/ [https://perma.cc/P5UA-3HHW].

[116] *Id.*

[117] *See* Sam Thielman, *Your Private Medical Data is for Sale – and it's Driving a Business Worth Billions*, GUARDIAN (Jan. 10, 2017, 5:00 AM), https://www.theguardian.com/technology/2017/jan/10/medical-data-multibillion-dollar-business-report-warns [https://perma.cc/7EEB-YG46].

[118] Gilman, *supra* note 27, at 284.

[119] *Id.* at 320.

[120] Akpan, *supra* note 104.

[121] Mariya Yao, *Your Electronic Medical Records Could be Worth $1,000 to Hackers*, FORBES (Apr. 14, 2017, 10:15 PM), https://www.forbes.com/sites/mariyayao/2017/04/14/your-electronic-medical-records-can-be-worth-1000-to-hackers/#526db8f650cf [https://perma.cc/3YFT-BNED].

granular the choices provided to patients with respect to information sharing, the more expensive it is to design and administer a system of patient consent. An opt-in or opt-out choice at the provider level might optimize the balance between securing adequate patient consent and minimizing the burden of doing so.[122] Additionally, an opt-out model may increase the percentage of patients who consent, despite providing the same choice as an opt-in model.[123] Another model would be to offer patient privacy packages as "bundles" which represent common sets of privacy selections, simplifying the process for patients.

A federally funded nonprofit research organization called MITRE has released a model patient data use agreement in which a patient agrees to allow a "patient data manager"—any entity compiling an individual's longitudinal health record—to "request, acquire, receive, aggregate, maintain, curate, secure, share, and delete" data on the patient's behalf.[124] The patient can designate any portion of the health record for one of the above actions, and the agreement contemplates aggregating data from non-clinical sources and patient-generated sources.[125] In contrast with existing legal defaults, the agreement also grants complete control over the aggregated record to the patient, including the destruction of the data.[126] Once the individual signs and submits a standing release to each provider, a patient data receipt is sent to the patient or patient data manager following each healthcare encounter.[127] The patient data manager model would help to reduce the costs of obtaining consent since the data manager would serve as a centralized facilitator.

Successful implementations of HIE have demonstrated that privacy and security can be achieved even as networks scale. Examples include Surescripts, regional HIE efforts around the U.S., and networks in other nations.[128] The healthcare industry might also look to other industries such as financial services to determine best practices. Despite the gravity of the issues surrounding privacy and security in the healthcare context, it is important not to allow stake-

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[122] Gilman, *supra* note 27, at 340.

[123] *Id.*

[124] MITRE CORP., *Patient Data Use Agreement*, GITHUB (July 1, 2019), https://github.com/patient-data-manager/pdua/blob/master/patient-data-use-agreement.md [https://perma.cc/DZP8-ADQJ].

[125] *Id.*

[126] *Id.*

[127] *Id.*

[128] *See generally* Thomas H. Payne et al., *Status of Health Information Exchange: A Comparison of Six Countries*, 9 J. GLOB. HEALTH 3 (2019).

holders in HIE to use privacy and security concerns as a convenient pretext for opting out of health information exchange when, in fact, other motivations are at play.

C. Business Models and Incentives

While technical standards and privacy concerns are still being ironed out to achieve a robust HIT infrastructure, individual providers and health care systems have had ample opportunity to engage in HIE through a variety of offerings that provide broad geographic coverage.[129] The slow uptick in provider participation suggests that even as the infrastructure is refined from a technical perspective, HIE engagement may not continue to grow at a significant pace for largely nontechnical reasons.

Data from other countries provides some evidence that economic incentives in the American HIE context are inhibiting the flow of information. A recent Commonwealth Fund survey which examined physician's attitudes towards care coordination found that Americans receive less information from their colleagues than physicians in other countries. While 84% of Dutch doctors said they received notifications when their patients were treated in the Emergency Department, only 48% of American doctors reported that they received the same information.[130] The healthcare systems in other nations have been able to achieve greater flow of patient information despite facing the same obstacles related to technical feasibility and privacy. The competitive nature of the American healthcare system and prevalent reimbursement models present barriers to the sharing of information which are nonexistent in countries that have a national healthcare system.

Health Information Exchange Organizations in the United States have struggled to remain economically viable, with 74% of HIOs surveyed in 2012 reporting that they were having difficulty developing a business model.[131] Grants and contracts were the most substantial funding sources for just over half of HIOs, and approximately one quarter of HIOs stated that they would be unable to

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[129] Julia Adler-Milstein et al., *The Number of Health Information Exchange Efforts is Declining, Leaving the Viability of Broad Clinical Data Exchange Uncertain*, 35 HEALTH AFF. 1278, 1280–81 (2016).

[130] Michelle M. Doty et al., *Primary Care Physicians' Role in Coordinating Medical and Health-related Social Needs in Eleven Countries*, 39 HEALTH AFF. 115, 118 (2020).

[131] Julia Adler-Milstein et al., *Operational Health Information Exchanges Show Substantial Growth, but Long-Term Funding Remains a Concern*, 32 HEALTH AFF. 1486, 1489 (2013).

sustain their operations with revenues from participation fees.[132] The researchers who conducted the survey predicted that existing efforts would fail once government funding ran out,[133] and, in a follow up survey conducted in 2014, confirmed that the number of HIE efforts had begun to decline.[134] When initially allocating funds to kickstart HIE efforts, policymakers believed that such efforts would generate value that was obvious to stakeholders, who would in turn be willing to pay to continue to benefit from that value.[135] The decline in operational HIE efforts indicates that either the efforts have not sustained high enough engagement to produce value, or that stakeholders do not perceive significant value. The benefits of interoperability are in fact highly dispersed across stakeholders, creating a collective action problem that stands in the way of comprehensive interoperability.[136] The limited success of HIE initiatives following HITECH signifies a need to focus on manners in which to make HIE economically viable.[137]

HIOs typically charge membership fees based on the participating organizations' revenues.[138] HIOs mostly rely on providers to support their operations financially, but in a fee-for-service reimbursement system in which the benefits of better overall outcomes and reduced redundancy accrue to the payers, it might be unreasonable to expect that providers will bear the entire cost of HIE.[139] However, payers participate less often than providers in HIE efforts in the United States.[140] HIOs have sought financial support from payers, expecting that they would be willing to fund efforts that promised returns in the form of efficiency. Yet payers have been resistant, in part because the value created by provider driven HIE is uncertain, difficult to measure, and not immediate.[141]

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[132] *Id.*

[133] *Id.*

[134] Adler-Milstein et al., *supra* note 129, at 1280.

[135] *Id.* at 1278.

[136] Brailer, *supra* note 19, at W5-21.

[137] Anderson et al., *supra* note 82, at 3639.

[138] Jessica Kim Cohen, *Interoperability Proposals Could Push HIEs Toward New Services*, MOD. HEALTHCARE (Oct. 28, 2019, 11:37 AM), https://www.modernhealthcare.com/information-technology/interoperability-proposals-could-push-hies-toward-new-services [https://perma.cc/9H85-GM84].

[139] *See generally* David C. Kaelber et al., *Use and Perceived Value of Health Information Exchange: One Public Healthcare System's Experience*, 19 AM. J. MANAGED CARE 337 (2013).

[140] *See generally* Julia Adler-Milstein et. al, *supra* note 129.

[141] *See generally* Dori A. Cross et al, *Assessing Payer Perspectives on Health Information Exchange*, 23 J. AM. MED. INFORMATICS ASS'N 297(2016).

The most cited barriers to HIE in relevant scholarship between 1990 and 2015 were incomplete information, inefficient workflows, and reports that the information exchanged did not meet user needs.[142] Notably, incomplete information was a common theme in the U.S., but was not mentioned in studies focused on other countries that take collective approaches to healthcare.[143] Healthcare delivery in the United States is relatively fragmented, and individual healthcare providers or systems may not have the capability to exchange outside of an insular group or may choose not to participate in HIE altogether.

The HIE industry experiences network effects because the value of the product (HIE membership) increases with the number of other users. First movers' disadvantages and negative network externalities discourage early adoption of HIE.[144] Network effects may impact the development, production, and competition among vendors. Where firms have created incompatible products, the collective incentives for compatibility are lower than the prospective social benefits. State laws that stringently guard EHI privacy have been associated with suppression of network benefits for HIE, resulting in lower rates of HIT adoption.[145] A systematic review of barriers to HIE found that "[i]ndividual patients and practices in the US may exercise the right to participate in (or [abstain from]) HIE which affects the completeness of patient information available to be exchanged."[146] On a more granular level, rates of HIE have been shown to vary by patient, tracking attributes such as comorbidity and type of insurance coverage.[147] A study conducted by MetroHealth System in Ohio found that HIE occurred least often among commercially insured patients.[148] Given the prevalence of fee-for-service reimbursement, this statistic may confirm that the financial incentive to reduce redundant testing and procedures was insufficient or lacking altogether when providers treated patients with private coverage.

Rates of exchange within HIEs can be affected by certain entities' unwillingness to share information. Healthcare providers and EHR vendors have been accused of data blocking due to economic

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[142] Karen B. Eden et al., *Barriers and Facilitators to Exchanging Health Information: A Systematic Review*, 88 INT'L J. MED. INFORMATICS 44, 45, 47 (2016).

[143] *Id.*

[144] Brailer, *supra* note 19, at W5-21.

[145] Gilman, *supra* note 27, at 337.

[146] Eden et al., *supra* note 142142, at 44.

[147] Kaelber et al., *supra* note 139, at 341.

[148] *Id.* at 338.

and market conditions which create business incentives to exert exclusive control over information.[149] EHR vendors with large market shares can use lack of interoperability with other propriety systems to their advantage by making it difficult for smaller competitors to offer network benefits to potential customers, making their software more attractive by comparison.[150] They may also engage in opportunistic pricing practices by charging very high fees that are disproportionate to the effort required to ensure interoperability.

The business incentives of providers and healthcare organizations also run counter to the goals of HIE. Providers may not recognize clinical value in HIE and, to the extent they are concerned about losing business, may be hesitant to facilitate transitions of care to competitors.[151] Alternatively, health care organizations may strategically implement HIE in order to control referrals. In a survey of HIE leaders, 85% of respondents believed that EHR vendors routinely or occasionally engage in data blocking and 60% believed that health systems do the same.[152]

Evidence suggests that concerns over information blocking are well-founded. Competitive incentives have been shown to impact levels of HIE engagement in the United States. One study concluded that "both hospital and EHR vendor dynamics are associated with whether a market has an HIO as well as the level of hospital participation in HIOs."[153] Specifically, a higher number of hospitals and higher EHR vendor competition in a particular market were associated with lower participation in HIOs.[154] Levels of HIE also vary according to hospital ownership, with government and non-profit hospitals exchanging more information than hospitals with for-profit ownership.[155]

Already dominant healthcare enterprises can maintain a comparative advantage in the healthcare market by imposing high costs on consumer switchover and by exercising market leverage over

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[149] OFFICE OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., DEP'T OF HEALTH & HUM. SERVS., REPORT TO CONGRESS ON HEALTH INFORMATION BLOCKING 8 (2015).

[150] Brailer, *supra* note 19, at W5-20.

[151] Gilman, *supra* note 27, at 298.

[152] Lucia Savage et al., *Digital Health Data and Information Sharing: A New Frontier for Health Care Competition?*, 82 ANTITRUST L.J. 593, 603 (2019).

[153] Sunny C. Lin & Julia Adler-Milstein, *The Relationship Between Hospital and EHR Vendor Market Dynamics on Health Information Organization Presence and Participation*, 18 BMC MED. INFORMATICS & DECISION MAKING 28, 28 (2018).

[154] *Id.*

[155] Sunny C. Lin et al., *Technology, Incentives, or Both? Factors Related to Level of Hospital Health Information Exchange*, 53 HEALTH SERVS. RES. 3285, 3285 (2018).

smaller players.[156] Studies show that large healthcare systems are more likely to exchange patient information internally, but less likely to exchange EHI externally with unaffiliated organizations. Researchers posit that the disparity is driven by the desire to maintain a competitive advantage by maintaining exclusive possession of the patient's medical information and have noted that the often-used strategy of luring in "marquee users" as first adopters of health IT may result in information silos. Economic incentives aside, some reluctance to exchange EHI may stem from the notion that the records are the property of the hospital. This empirical observation demonstrates that regulation focusing on interoperability (i.e., capability) may be misplaced, and that regulation will need to incentivize actual instances of HIE.[157]

The 21st Century Cures Act addressed various issues in the healthcare industry and included the practice of information blocking.[158] The Act imposes civil penalties of up to $1 million for violations of its information blocking provisions.[159] The ability to levy penalties was much needed, as most data blocking practices were previously beyond the purview of any federal agency to address.

ONC promulgated the Cures Act Final Rule in 2020, which gave teeth to the anti-data blocking provisions of the 21st Century Cures Act.[160] It defines data blocking as a practice that is "likely to interfere with access, exchange, or use of electronic health information."[161] The rule carves out eight types of "reasonable and necessary" practices which might otherwise meet the definition of data blocking but are exempt under the Act: preventing physical harm, promoting the privacy of EHI, promoting the security of EHI, charging fees to recover costs incurred, responding to infeasible requests, responding with information that differs from the scope of the request, licensing of interoperability elements, and maintaining or improving HIT performance.[162] The exceptions are vague and provide little concrete guidance to healthcare organizations. Under the exceptions, it would not be information blocking for an actor to

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[156] Brailer, *supra* note 19, at W5-20.

[157] Miller & Tucker, *supra* note 13, at 35.

[158] 21st Century Cures Act, Pub. L. 114-255.

[159] Kenagy, *supra* note 7, at 19–20.

[160] Cures Act Final Rule, 85 Fed. Reg. 25,642 (May 1, 2020) (to be codified at 45 C.F.R. pt.170-71).

[161] 45 C.F.R. § 171.103 (2020).

[162] Cures Act Final Rule: Information Blocking Exceptions, OFFICE OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH. (2020), https://www.healthit.gov/sites/default/files/cures/2020-03/InformationBlockingExceptions.pdf [https://perma.cc/3VET-X3CB].

refrain from sharing information as long as they were complying with internal policies or procedures, allowing organizations to easily escape the reach of regulators by clinging to elusive – and possibly pretextual – privacy concerns. Although the anti-data blocking provisions will probably have some deterrent effect, actual enforcement will only involve the most egregious offenses, especially given the wide breadth of the exceptions. Another regulatory option to directly address information blocking would be to promote transparency by requiring EHR vendors to make their pricing practices publicly available, thereby reducing information blocking by vendors in the form of prohibitively high prices for basic interoperability. Regulatory intervention is justifiable in this area because health care organizations appear to be applying insufficient pressure to obtain the information from vendors in advance of purchasing software.

The economic incentives discussed above suggest that in addition to setting clear policy that information blocking is illegal and punishable, regulations need to be formulated to create an environment in which the underlying incentive problem is resolved. Banning information blocking may have an effect on organizations' willingness to send information, but it will not increase demand for EHI. In the current healthcare climate, the best way to flip the incentives is to promote value-based contracting in which providers are reimbursed on the basis of providing quality healthcare, as opposed to the current fee-for-service system which compensates for each procedure and test. With value-based contracting, hoarding patient data will no longer be seen as a competitive advantage. Rather, organizations will compete to create value from the same data.

IV.

ENGAGING PATIENTS AND PAYERS AS STAKEHOLDERS IN INFORMATION EXCHANGE

Since the widespread adoption of EHRs, interoperability legislation and regulations focused on utilizing carrot and stick approaches to induce institutions in the healthcare system (i.e., providers and EHR vendors) to develop the capability to communicate the valuable health information that could otherwise be hoarded within their organizations. Success has been lurching, but as of 2019, the national health IT network is approaching a state in which interoperability has been achieved. Prevailing technical standards have come to the forefront and consensus built around common structures and meaning of the clinical data exchanged.

However, compatibility alone will be insufficient to ensure that information is actually shared.[163] Experts who have studied the matter suggest that, "to succeed in ensuring comprehensive meaningful use, the federal government will have to address the fact that larger hospital systems that may be producing the best health outputs may also be less willing to exchange information."[164]

In fact, the actual rates of exchange are far from ideal. Anecdotally, patients are not experiencing seamless flows of information from provider to provider, from provider to patient, or from payer to patient. Network costs, unsustainable business models, perverse economic incentives, and privacy concerns are threatening continued expansion of HIE. In order to make the leap to the next level of connectivity and flow of data, regulatory and business efforts will need to recognize the importance of payers and patients as stakeholders in HIE.

A. *Payer-driven HIE*

Given the economic incentives of health care organizations and EHR vendors and the fragile business models of HIOs, engaging the conspicuously absent payers in HIE efforts is a promising way to drive HIE participation. Two possible methods of achieving greater payer engagement are: (1) promoting value-based contracts; and (2) redefining HIE infrastructure to fulfill payer needs.

Historically, American healthcare reimbursement has operated on a fee-for-service basis, meaning that providers have economic incentives to perform more tests and procedures. Many onlookers in recent decades have called for a shift to reimbursement models that prioritize patient outcomes rather than the number of diagnostic and treatment measures taken. The underlying notion is that healthcare could be provided with higher quality at lower cost and that a value-based payment model will align financial incentives with the value of care.

With the passage of the Affordable Care Act, CMS began to reform its reimbursement models to induce better outcomes and has introduced a host of value-based care models for Medicare and Medicaid over the past 10 years.[165] Under a prospective based reimbursement model, hospitals receive flat payments for each diagno-

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[163] Miller & Tucker, *supra* note 13, at 29.

[164] *Id.*

[165] Andrew Meola, *How and Why the Value Based Payment (Pay for Performance) Model is Trending in the Healthcare Industry*, BUS. INSIDER (last updated Feb. 26, 2021, 8:44 PM), https://www.businessinsider.com/value-based-care-pay-for-performance-healthcare-model [https://perma.cc/Y5M6-S64M].

sis group, incentivizing a reduction in expensive duplicate tests and procedures.[166] Alternatively, another model employed by CMS is to assign scores to hospitals relative to certain baseline metrics and to either supplement or reduce Medicare payments on that basis.[167] Data sharing across organizations that care for the same patients will allow providers to coordinate care for patients with chronic diseases, who generally see multiple providers and specialists.[168] Metrics such as hospital readmission rates, immunization rates, and even patient feedback on the hospital experience are crucial in order to deliver and measure the value of care.[169]

Value-based payments models are inextricably linked to HIE. Without adequate information exchange, providers will be unable to deliver the most efficient care and will suffer economic loss. As value-based reimbursement becomes popularized, the underlying incentives related to provider-to-provider information exchange will shift and the demand for information will increase significantly. However, value-based models may not become widespread until HIE is occurring at a baseline level that allows for real-time monitoring across the care continuum. HHS has acknowledged the relationship between interoperability and value-based care, writing that "[i]nteroperability will help ensure the success of new payment models that pay for value. All of the providers in a patient's network will need to coordinate their care for a value-based system to work. That requires data and information to be exchanged in a secure format."[170]

As payers begin to experiment with different value-based models, survey results have confirmed that technology is hampering progress because payers have insufficient information to create a full picture of a clinician's performance.[171] Overall, private payers have been slow to follow CMS's lead in implementing new types of reimbursement models. Most healthcare professionals surveyed in 2019 reported that less than 20% of their population was covered

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[166] *Id.*

[167] *Id.*

[168] Jessica Kent, *74% of Execs Say Interoperability is Critical for Value-based Care*, HEALTH IT ANALYTICS (Feb. 21, 2018), https://healthitanalytics.com/news/74-of-execs-say-interoperability-is-critical-for-value-based-care [https://perma.cc/Z2SX-M3A2].

[169] Meola, *supra* note 165.

[170] CTRS. FOR MEDICARE & MEDICAID SERVS., s*upra* note 33.

[171] Les Masterson, *Payers Divided over Best Value-based Payment Model, Survey Finds*, HEALTHCARE DIVE (Feb. 14, 2019), https://www.healthcaredive.com/news/payers-divided-over-best-value-based-payment-model-survey-finds/548388/ [https://perma.cc/J4W5-39DW].

by a risk-based model.[172] Access to timely data was reported as one of two major barriers to implementation of such contracts.[173] HIE and value-based contracting will have to grow in tandem in order to see strides in either area. The most important way that the federal government can ensure that value-based models continue to gain traction is to demonstrate success through Medicare.

Another way to increase payer engagement in HIE is to open up HIEs to additional use cases. Since HIEs were created with provider-to-provider exchange as the top priority, not much consideration was given to the business needs of payers. When surveyed, payers reported that they wanted to actively participate in HIE rather than merely fund provider-to-provider exchange.[174] Participation would allow payers to boost their own analytics with bidirectional data flow in addition to receiving the downstream efficiency benefits of provider-centric HIE. Payers were interested in utilizing HIE to lead case management, population health analytics, quality reporting, and patient and provider profiling.[175]

There are a couple of significant challenges to overcome in order to increase payer involvement. One is providing an easy connection to a network of networks to allow payers to capture all pertinent data for their customers. The other is overcoming provider resistance to payer participation. Due to the nature of the business relationship between payers and providers, there is a certain level of distrust of payers among providers. An added benefit of transitioning to a value-based system is that providers may be less hesitant to accept payer participation in HIE. Under the fee-for-service model in which contracts are frequently renegotiated,[176] allowing payers to access clinical data would give them a new advantage in the negotiation process.

While overall payer participation is low, there have been some recent instances of payers becoming more involved in HIE efforts. For example, Blue Shield of California required its network to exchange data through the state HIE. In western New York, BlueCross BlueShield signed on with a regional HIE in a deal that will allow

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[172] Robert King, *Survey: Hospital, Health System Leaders Slow to Adopt Risk-based Payment Arrangements*, FIERCE HEALTHCARE (Sept. 17, 2019, 12:19 PM), https://www.fiercehealthcare.com/hospitals-health-systems/survey-hospital-health-system-leaders-slow-to-adopt-risk-based-payment [https://perma.cc/S26N-ARYV].

[173] *Id.*

[174] Cross et al., *supra* note 141, at 297.

[175] *Id.* at 301.

[176] *Id.* at 302.

physicians to access claims data.[177] To the extent that HIEs can support payers' use cases for health data, this trend is likely to continue.

B. Patient-centric HIE Frameworks

The major actors in today's dominant HIE infrastructure are healthcare institutions and the organizations that provide governance over HIE – payers were an afterthought and patients were excluded altogether (notwithstanding giving consent to their provider). Institutions decide whether to join various HIEs according to regulatory requirements and business imperatives. HIOs define the technical specifications and privacy policies of the network. Within this framework, providers decide when and how to attempt to access external health information. However, the incentives of patients with respect to HIE have the potential to close the gap between technical interoperability and actual comprehensive health information exchange. If patient demand for health information exchange ramps up, providers will recognize additional economic value in information exchange and in turn will begin to demand widespread health information exchange.[178]

Changes to the existing technical infrastructure could enable the patient and provider to bypass the traditional HIE. BlueButton 2.0 and similar efforts such as Share Everywhere, developed by Epic Systems,[179] allow patients to display a summary of their health information on demand, which they can show to a new healthcare provider no matter where they seek treatment. In a world of ever-present smartphones, this is an efficient and readily available means of sharing health information that affords easy identification and authentication. More access to health information also means that patients' knowledge of their own health will improve, allowing them to take more active roles in their own care. Patients have a significant interest in ensuring that their providers have a complete picture of their medical history.

The patient (or the patient's proxy) is often best positioned to identify the sources of EHI that need to be consolidated. One of the most cited barriers to HIE is incomplete information. Where

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[177] Chuck Green, *BlueCross BlueShield Strikes Deal to Improve Health Data Exchange*, HEALTHPAYERINTELLIGENCE (Dec. 13, 2018), https://healthpayerintelligence.com/news/bluecross-blueshield-strikes-deal-to-improve-health-data-exchange [https://perma.cc/RHU9-G63A].

[178] Julia Adler-Milstein et al., *supra* note 131, at 1491.

[179] *Share Everywhere*, EPIC, https://shareeverywhere.epic.com/ [https://perma.cc/CJ9L-VFF5].

the patient is given more control over their longitudinal health record, this problem can be reduced. Given the current fragmentation of the HIE efforts across the nation, providers often need to know specific information about when and where a patient had received care in order to query for results. While a patient might be able to help their provider from memory, a comprehensive longitudinal record that can be accessed on the patient's phone or from any internet browser is a much more reliable source of information. An additional issue presented with the physician query method is ensuring that the systems are communicating about the same patient – a deceptively difficult task for HIE efforts and EHR systems alike. The Government Accountability Office reported that in 2017, 45% of large hospitals expressed that difficulties with patient matching inhibited useful health information exchange.[180] However, when the patient controls the flow of information, this problem is nonexistent.

In general, a conception of electronic health information as belonging to the patient is more consonant with HIE than the conception of the medical record as belonging to the healthcare system in which the information was generated. Regardless of regulatory pressures, the patient has incentives to achieve an optimal balance of data liquidity and security. HIPAA does not specify ownership.[181] Of the state laws that address the issue, one grants the right to medical records to the patient, while the remaining twenty grant ownership to the providers that generate the records.[182]

Some commentators have suggested that individuals should have a property right in their health information.[183] Those who have advocated for a property system in personal data – health data or otherwise – often promote propertization as a means of allowing individuals to profit from use of their data.[184] A property system would serve to protect the privacy of patients by giving them legal tools to safeguard the information that they wish to keep private. It

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[180] U.S. GOV'T ACCOUNTABILITY OFF., GAO-19-197, HEALTH INFORMATION TECHNOLOGY: APPROACHES AND CHALLENGES TO ELECTRONICALLY MATCHING PATIENTS' RECORDS ACROSS PROVIDERS 2 (2019).

[181] *Patient Records: The Struggle for Ownership*, MED. ECON. (Dec. 10, 2015), https://www.medicaleconomics.com/health-law-policy/patient-records-struggle-ownership [https://perma.cc/X2V7-DDJ3].

[182] *Id.*

[183] ERIC TOPOL, THE PATIENT WILL SEE YOU NOW 281 (2016).

[184] *Exploring Implications for Data Privacy Rights and Valuation: Hearing on Data Ownership Before the S. Comm. On Banking, Housing, and Urban Affairs*, 116th Cong. (2019) (statement of Will Rinehart, Director of Tech. & Innovation Pol'y, American Action Forum).

might also weaken the notion that patient data rightfully belongs to the organization that originally captured the data to use to its competitive advantage.

However, creation of a property right in health data would represent a departure from existing U.S. common law, which does not recognize a property interest in objective information or facts.[185] Scholars who have explored the wisdom of implementing a property system have rejected the idea for a variety of reasons.[186] Importantly, some believe that any policy which seeks to redirect some of the value back to the patient is economically inefficient.[187] Furthermore, a property system in health data could impeded biomedical research and public health by imposing barriers to amassing large amounts of data. A property right is not necessary to achieve privacy protection; policy efforts would be better spent attempting to safeguard privacy and security through regulation while simultaneously establishing an environment which creates value by connecting patients to their own health information.

Despite the lack of a property system in EHI, existing regulatory frameworks have long prioritized patient access to medical information, at least abstractly. Department of Health and Human Services (HHS) Office of Civil Rights interpretations of HIPAA extend the right to access to the right to transmit PHI to a designated third party.[188] HIPAA gives providers a window of 30 to 60 days to deliver the information to the patient, a length of time that now seems inordinate. Only with the recently proposed rules have regulations begun to operationalize requirements to make patient information readily available.

C. Patient Demand

Even in today's consumer-oriented environment in which individuals put a premium on convenience and connectivity, we have yet to see that demand flow into the medical record space. Patients still face obstacles with respect to accessing their own medical infor-

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[185] Int'l News Serv. v. Associated Press, 248 U.S. 215, 234 (1918).

[186] *See* Jorge L. Contreras, *The False Promise of Health Data Ownership*, 94 N.Y.U.L. Rev. 624, 632 (2019) (noting that legal scholars have expressed concerns over commodification of the individual, impact on public health, and lack of necessity).

[187] *Exploring Implications for Data Privacy Rights and Valuation*, *supra* note 184.

[188] *Can an Individual, Through the HIPAA Right of Access, Have His or Her Health Care Provider or Health Plan Send the Individual's PHI to a Third Party?*, DEP'T OF HEALTH & HUMAN SERVS. (June 24, 2016), https://www.hhs.gov/hipaa/for-professionals/faq/2036/can-an-individual-through-the-hipaa-right/index.html [https://perma.cc/LT5B-DF93].

mation.[189] However, there are some indications that patients are beginning to take more control over their healthcare experiences. In 2018, patients opted for high-deductible health plans at unprecedented rates, perhaps demonstrating a desire to get the most out of the money they spend on healthcare.[190] The traditional dynamics of the doctor-patient relationship are changing as patients begin to take on a more consumer-oriented approach to their own healthcare. Patients are relying less upon a single provider who has treated them over the course of many years and are experiencing a more fragmented version of the healthcare system, which requires increased agency in order to navigate successfully. As generations who are more comfortable with digital technology begin to interact more with the health care system as they age, expectations of connectivity will increase.

Some companies are beginning to take note of this phenomenon and are developing patient-facing products which will aggregate an individual's medical information from multiple sources. In January 2018, Apple debuted integration between its Health app and healthcare institutions' EHRs.[191] The app leverages FHIR APIs to display several discrete types of medical record data alongside user-generated health data. Apple does not charge fees to healthcare providers.[192] Finding a profitable business model for patient data management services will present a challenge to these companies. Existing services like ZocDoc provide important functionality to patients in the form of scheduling, which adds tangible value in terms of convenience and time saved. Incorporating such functionality would allow for charging subscription fees to patients. Alternatively, patients may demand that their providers subscribe to such services, and providers can pass on the costs to patients. Payers are well-positioned to serve as patient data managers because they receive real-time updates via claims, making it easier for them to track patients across the care continuum.

As a prerequisite to desirability of health information exchange, patients need reassurance of security and control over their medical records. MITRE's patient data use agreement model dis-

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[189] Mathews, *supra* note 15.

[190] *2018 National Progress Report*, *supra* note 59.

[191] *Apple Announces Effortless Solution Bringing Health Records to iPhone*, APPLE (Jan. 24, 2018), https://www.apple.com/newsroom/2018/01/apple-announces-effortless-solution-bringing-health-records-to-iPhone/ [https://perma.cc/RS5P-GJ2L].

[192] *Apple Health Records*, APPLE https://www.apple.com/healthcare/health-records/ (last visited March 30, 2021) [https://perma.cc/FNV9-NC2B].

cussed above provides a good starting point for thinking about how to formulate an arrangement between a patient and a patient data manager.[193] It will be important to balance the costs of implementing granular control over the information with the benefits of providing full authority to the patient. Perhaps even more important than privacy policies will be security measures. If security is compromised, privacy policies will do little to assuage patients' concerns over the exposure of their data.

From a regulatory standpoint, it is important to encourage architecture which will create opportunities for innovation that will redefine the patient's relationship to the healthcare system. The API requirements adopted by ONC in 2020 reflect a focus on patient centered HIE, since APIs provide a hook for external systems (including patient-facing applications) to request information pertaining to a particular patient that would otherwise remain siloed in an EHR. APIs create an open-source mechanism for retrieving data that does not require participation in an existing network. As part of the rule, CMS expanded its own BlueButton 2.0 tool to additional CMS-backed health plans. The rule also requires that patients be able to access their EHI at no cost and that EHI be exportable into a computable format.[194] At a HIMSS conference in 2019, when discussing the rules, former national coordinator Dr. Karen DeSalvo noted how the industry is now "looking at how consumers are going to drive this shift to new models of care."[195] In the same discussion, CMS Administrator Seema Verma said that, "the rule is about insurance companies" and opening up the "reams of claims data" in their systems.[196] The API regulations could open up new business opportunities for HIEs, becoming the middleware for mandated APIs. HIEs have the infrastructure in place to bring in data from disparate sources and then standardize it as a FHIR resource. In this manner, HIT could outsource the standardization work to HIEs.[197]

Via the API requirements, downloadable EHI requirements, and mandated patient access, the HHS regulations should support

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[193] *See* MITRE CORP., *supra* note 124.

[194] ELECTRONIC HEALTH INFORMATION (EHI) EXPORT CERTIFICATION CRITERION AND ASSOCIATED REQUIREMENTS, THE U.S. CORE DATA FOR INTEROPERABILITY (2019).

[195] Tom Sullivan, *HIMSS19 Keynoters Challenge Private Sector to Keep Pace with FHIR, Open APIs*, HEALTHCARE IT NEWS (Feb. 12, 2019, 4:13 PM), https://www.healthcareitnews.com/news/himss19-keynoters-challenge-private-sector-keep-pace-fhir-open-apis [https://perma.cc/49XZ-W9ZX].

[196] *Id.*

[197] Cohen, *supra* note 138.

efforts to make longitudinal health information available to patients.[198] Perhaps even more influential will be the CMS BlueButton Tool. As is often the case in the adoption of consumer products, once a substantial percentage of the population has experienced the convenience and advantages of having their health data available at their fingertips, other entities such as payers and accountable care organizations will be pressured to provide similar services. Patient access to longitudinal health information will also push providers to engage in HIE to stay fully informed and meet patient expectations.

V.

CONCLUSION

Electronic Health Records – and health IT in general – have had an enormous impact on the healthcare industry over the past ten years, fundamentally changing the way that healthcare is delivered. Now that EHR adoption is almost complete among U.S. hospitals, reaching full interoperability and leveraging that potential to get to a state of seamless and secure information flow stands as the next big challenge in developing a national health IT network. Regulations should focus on leveraging the incentives of patients and payers to construct a more robust national infrastructure and accelerate rates of HIE. This can be achieved by the prioritization of patient access to information, value-based reimbursement models, and HIE functionality that creates tangible value for payers.

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[198] Press Release, U.S. Dep't of Health & Human Servs., HHS Proposes New Rules to Improve the Interoperability of Electronic Health Information (Feb. 11, 2019).