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Can Electronic Health Records Be Saved?

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INTRODUCTION

Politicians and policymakers have long dreamed of creating a national system of electronic health records ("EHRs") that would radically transform the delivery of health care.[1] The theoretical advantages of EHRs are tantalizing: among other things, they could reduce medical errors, improve care coordination, limit duplicative testing, and help uncover new public health strategies.[2]

Over the past decade, the United States health care system has made progress toward realizing this vision. Until relatively recently, patients' medical histories were typically transcribed on physical notepads and stored in filing cabinets, which were often difficult for providers and patients to access or understand.[3] Today, by contrast, the vast majority of health care providers utilize EHRs, a sea change that is largely attributable to federal policy.[4]

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[1]*See, e.g.,* President George W. Bush, A New Generation of American Innovation, THE WHITE HOUSE, 7–10 (2004) https://www.cepal.org/iyd/noticias/pais/6/31456/EEUU_doc_1.pdf [https://perma.cc/8XVE-NLQZ].

[2]*See* SHARONA HOFFMAN, ELECTRONIC HEALTH RECORDS AND MEDICAL BIG DATA: LAW AND POLICY 16-23 (2016) (outlining the potential benefits of EHR systems).

[3] *See generally* INSTITUTE OF MEDICINE, THE COMPUTER-BASED PATIENT RECORD: AN ESSENTIAL TECHNOLOGY FOR HEALTH CARE 58–62 (Richard S. Dick et. al eds., rev. ed. 1997) (outlining several types of problems with paper health records).

[4]*See infra* Part II.A.

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Since this transition, there have been occasional glimpses of the benefits of EHRs. For instance, the pediatrician who brought the water crisis in Flint, Michigan to public attention did so by utilizing data from EHRs.[5] Similarly, the data from EHRs led to discovery of abuses of adolescent inmates at Rikers Island and helped to form the basis for a Department of Justice civil rights investigation.[6]

Nevertheless, despite billions of dollars in investments, thousands of pages of regulations, and countless hours spent implementing and adapting to new technology and requirements, EHRs have failed to live up to their promise.[7] Studies exploring the impacts of EHRs have had mixed results, at most finding modest incremental improvements.[8] At the same time, glitches in EHR software and user errors have led to a rash of reported medical errors and even several patient deaths.[9] EHRs have also created onerous administrative burdens for health care providers, which interfere with patient care and increase rates of burnout among clinicians.[10] President Obama himself specifically cited EHRs as the main disappointment of his administration's health care policy, saying, "[w]e put a big slug of money to encouraging everyone to digitalize . . . [a]nd it's proven to be harder than we expected."[11]

Perhaps the most important way in which EHRs have failed to live up to their promise is that they are not "interoperable": they cannot be easily exchanged across systems.[12] Many of the theoretical benefits of EHRs depend on their being

[5]David Wahlberg, *Flint Doctor Used Epic Systems Records to Expose Lead Crisis*, WISCONSIN STATE JOURNAL (Jan. 30, 2016), https://madison.com/wsj/news/local/health-med-fit/flint-doctor-used-epic-systems-records-to-expose-lead-crisis/article_ef462592-f27b-5ed0-a2ff-33232902ab74.html [https://perma.cc/2M39-ZR72].

[6]*Former Physician at Rikers Island Exposes Health Risks of Incarceration*, NPR FRESH AIR (March 18, 2019), https://www.npr.org/transcripts/704424675 [https://perma.cc/P3CR-LM5R]. *See also* U.S. DEPARTMENT OF JUSTICE, CRIPA INVESTIGATION OF THE NEW YORK CITY DEPARTMENT OF CORRECTION JAILS ON RIKERS ISLAND (Aug. 4, 2014).

[7]*See* Fred Schulte & Erika Fry, *Death By 1,000 Clicks: Where Electronic Health Records Went Wrong*, KAISER HEALTH NEWS (Mar. 18, 2019), https://khn.org/news/death-by-a-thousand-clicks/ [https://perma.cc/2FMN-W9CG] ("David Blumenthal, who, as Obama's national coordinator for health information technology, was one of the architects of the EHR initiative, acknowledged to KHN and Fortune that electronic health records 'have not fulfilled their potential. I think few would argue they have.'").

[8]*See* HOFFMAN, ELECTRONIC HEALTH RECORDS AND MEDICAL BIG DATA, *supra* note 2, at 35-37; Sunny C. Lin, Ashish K. Jha, & Julia Adler-Milstein, *Electronic Health Records Associated with Lower Hospital Mortality After Systems Have Time to Mature*, 7 HEALTH AFF. 1128 (2018).

[9]*See, e.g.,* Schulte & Fry, *supra* note 7; Raj. M. Ratwani et al., *Identifying Electronic Health Record Usability and Safety Challenges in Pediatric Settings*, 37 HEALTH AFF. 1752 (2018) (analyzing 9,000 patient safety reports and finding that over one-third of them had an EHR usability issue that contributed to a medication error).

[10]Atul Gawande, *Why Doctors Hate Their Computers*, THE NEW YORKER (Nov. 12, 2018), https://www.newyorker.com/magazine/2018/11/12/why-doctors-hate-their-computers. *See also* Ming Tai-Seale et al., *Electronic Health Record Logs Indicate That Physicians Split Time Evenly Between Seeing Patients and Desktop Medicine*, 36 HEALTH AFF. 655 (2017) (finding that primary care providers are spending at least as much time on their computers as interacting with patients).

[11]Sarah Kliff, *Obama's Surprising Answer on Which Part of Obamacare Has Disappointed Him The Most*, VOX (Jan. 9, 2017), https://www.vox.com/2017/1/9/14211778/obama-electronic-medical-records [https://perma.cc/K2MS-4RPS].

[12]*See* Sharona Hoffman & Andy Podgursky, *E-Health Hazards: Provider Liability and Electronic Health Record Systems*, 24 BERKELEY TECH. L. J. 1523, 1531 (2009) (citing BIOMEDICAL INFORMATICS: COMPUTER APPLICATIONS IN HEALTH CARE AND BIOMEDICINE 952 (Edward H. Shortliffe & James J. Cimino eds., 2006)) ("Interoperability' means the ability of two or more systems to exchange data and to operate in a coordinated fashion.").

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interoperable.[13] For instance, an interoperable EHR system could reduce medical errors by enabling emergency room doctors admitting an unconscious patient to quickly look up the patient's medical history and current medications.[14] It could increase care coordination by allowing multiple providers working in different health systems, yet caring for a single patient, to share notes and records.[15] This would be especially beneficial for economically disadvantaged patients, whose care tends to be fragmented across multiple providers.[16] These advantages rely on being able to easily exchange data across health systems.

Without interoperability, many of the benefits of EHRs cannot be realized. Even though the majority of health care providers now utilize EHRs, patients' health information is still siloed within individual health systems or within specific types of EHR technology.[17] Instead of being stuck in physical filing cabinets, patients' health records are now often stuck in electronic ones.[18]

Although there are both technical and regulatory barriers to interoperability, conflicting financial incentives arguably pose the greatest challenge. EHR vendors and health care systems have little to gain—and much to lose—by making EHRs interoperable. Until quite recently, however, both Congress and federal regulators had done little to directly address this incentive problem.

This article explores why, despite tremendous investment by both the public and private sectors over many years, we still do not have an interoperable EHR system, and whether the promise of EHRs can still be salvaged. Part I describes the barriers to ensuring interoperability, focusing on health care organizations' conflicting incentives. Part II reviews the history of federal efforts to promote EHRs and explores why they failed to achieve interoperability. Part III discusses recently proposed regulations designed to address this problem, what they accomplish, and some areas of concern.

I. BARRIERS TO INTEROPERABILITY

Perhaps the most important barrier to interoperability lies in the lack of incentives to share health data.[19] Because most health care payments are based on the volume of services delivered rather than the value of these services to patients, there is little incentive to share information to improve the quality of medical care.[20] Indeed, EHR vendors have incentives *not* to share health data. Creating an interoperable system would make it easier for providers to switch to a new EHR vendor if they are dissatisfied with their current EHR system.[21] For EHR vendors that are paid based on the number of patient records in their system, transferring those records would reduce

[13] *See* HOFFMAN, ELECTRONIC HEALTH RECORDS AND MEDICAL BIG DATA, *supra* note 2, at 18; Janet Marchibroda, *Health Policy Brief: Interoperability*, HEALTH AFF. (Aug. 11, 2014), https://www.healthaffairs.org/do/10.1377/hpb20140811.761828/full/ [https://perma.cc/Q644-43SQ].

[14] HOFFMAN, ELECTRONIC HEALTH RECORDS AND MEDICAL BIG DATA, *supra* note 2, at 18.

[15] *Id.*

[16] Sharona Hoffman & Andy Podgurski, *Finding a Cure: The Case for Regulation and Oversight of Electronic Health Record Systems*, 22 HARV. J. L. & TECH. 103, 113 (2008).

[17] Marchibroda, *supra* note 13, at 2.

[18] Nicolas P. Terry, *Anticipating Stage Two: Assessing the Development of Meaningful Use and EMR Deployment*, 21 ANN. HEALTH L. 103, 111 (2012).

[19] Marchibroda, *supra* note 13, at 4 ("The primary barrier to electronic information sharing is the lack of a 'business case.'").

[20] *Id*.

[21] Hoffman & Podgurski, *Finding a Cure*, *supra* note 16, at 153-154.

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their profits.[22] Furthermore, because the market value of EHR vendors' data is based on the number of patient records included in the data, improving interoperability would also reduce the value of that data.[23] Providers, who are still primarily paid on a fee-for-service basis, face some similar incentives: they too may be reluctant to improve data sharing since doing so would only make it easier for patients to switch to a different provider.[24]

This is more than just a theoretical concern: actors within the health care system actively subvert efforts to share data.[25] This intentional and unreasonable interference with the exchange of electronic health information is known as "information blocking."[26] Information blocking occurs in different ways, "most commonly when electronic health record software companies purposefully deploy nonstandard technology that cuts off communication with other health systems or charge exorbitant fees for exchanging information."[27]

Survey evidence suggests that such practices are quite prevalent: half of the respondents in one recent survey of leaders on health information exchange efforts attested that EHR vendors routinely engage in information blocking, and 25% of respondents stated that hospitals and health systems routinely do so.[28] Many policymakers and health scholars have thus concluded that market forces will not ensure interoperability on their own, and that it is necessary for regulators to mandate that EHR vendors and health care providers share data and to penalize information blocking.[29]

Of course, incentives are not the only problem: there are also technical and regulatory barriers to creating an interoperable EHR system. In terms of technical challenges, EHR vendors may encode medical information using incompatible representational systems.[30] Further complicating matters, health care providers may also use different terminologies depending on their specialty or the particular provider practice.[31] Ensuring that patients' records are appropriately matched is another problem: sharing health information is only helpful if health care organizations know

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[22]Lucia Savage, Martin Gaynor & Julia Adler-Milstein, *Digital Health Data and Information Sharing: A New Frontier for Health Care Competition?*, 82 ANTITRUST L.J. 593, 605 (2019).

[23]*Id*. at 605–06.

[24]*Id*. at 611; Julia Adler-Milstein, *Moving Past the EHR Interoperability Blame Game*, NEW. ENG. J. MED. CATALYST (July 18, 2017). Of course, clinicians stand to benefit from interoperability to the extent that it improves their ability to care for patients and reduces their workload. *See id*. ("[P]roviders have professional norms and mission statements that should motivate them to pursue interoperability (or at least not actively interfere with it) to benefit their patients."). *See also* Jeffrey Bendix, *Doctors Sound Off About EHR Shortcomings*, MEDICAL ECONOMICS (Oct. 17, 2019), https://www.medicaleconomics.com/ehr/doctors-sound-about-ehr-shortcomings [https://perma.cc/G8PJ-SMMY] (listing lack of interoperability as one of physicians' primary complaints about EHRs systems).

[25]Savage et al., *supra* note 22, at 612.

[26] OFF. OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., REPORT ON HEALTH INFORMATION BLOCKING 11 (2015) [hereinafter ONC REPORT].

[27]Joel C. White, *Administrative delays threaten the promise of the 21st Century Cures Act*, STATNEWS (Sept. 8, 2018), https://www.statnews.com/2018/09/08/21st-century-cures-act-administrative-delays/ [https://perma.cc/Z4TH-HDM2]. *See also* ONC REPORT, *supra* note 26, at 15.

[28]Julia Adler-Milstein & Eric Pfeifer, *Information Blocking: Is It Occurring and What Policy Strategies Can Address It?*, 95 MILBANK QUARTERLY 117, 118 (2017).

[29]*See, e.g.*, ONC REPORT, *supra* note 26, at 24–25; HOFFMAN, ELECTRONIC HEALTH RECORDS AND MEDICAL BIG DATA, *supra* note 2, at 55.

[30]Hoffman & Podgurski, *Finding a Cure*, *supra* note 16, at 152–53.

[31]*Id*. at 152.

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when they are referring to the same person, and when they are not.[32] Imagine, for example, that one large health system, with millions of patients, queries another similar system for the records of John Smith born on a certain date. Assuming there are multiple John Smiths born on that date, transferring the right data to the right people will be hard.

In addition, health information privacy laws are commonly cited as impediments to interoperability.[33] To some extent, this view of privacy laws is warranted. For instance, discrepancies in state privacy laws likely hinder information sharing,[34] as do federal prohibitions that apply to certain types of health information deemed especially sensitive (e.g., substance abuse data).[35] However, other concerns about privacy laws appear to be based on misconceptions regarding legal requirements.[36] For instance, some health care providers act as though the federal Health Insurance Portability and Accountability Act ("HIPAA") always requires them to obtain patients' authorization to share their data, even though the law explicitly authorizes sharing without patient authorization for "treatment, payment, and health care operations."[37] Similarly, health care providers express anxiety about being held liable for data breaches that can be traced back to them, despite the fact that they are not in fact liable under HIPAA for such breaches.[38]

These technical and regulatory barriers are difficult to separate from the economic incentives identified above.[39] For one thing, if EHR vendors had greater incentives to engage in information sharing, it is possible that they would have already developed better technology to share electronic health information.[40] Similarly, perverse economic incentives may also cause providers to overstate the extent to which privacy law prevents them from sharing information.[41] Thus, economic incentives, technological barriers, and regulatory barriers are not mutually exclusive explanations for the current lack of interoperability.[42]

II. FEDERAL EFFORTS TO PROMOTE ELECTRONIC HEALTH RECORDS

Initially, the federal government focused primarily on incentivizing health care providers to adopt EHRs.[43] Only recently—after EHR adoption became

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[32]Ben Moscovitch, *Testimony before the United States Senate Committee on Health, Education, Labor, & Pensions*, PEW TRUSTS 8–9 (March 26, 2019), https://www.pewtrusts.org/-/media/assets/2019/03/ben-moscovitch-help-written-testimony-326.pdf [https://perma.cc/RN74-XP7Y].

[33]Michelle M. Mello et al., *Legal Barriers to the Growth of Health Information Exchange—Boulders or Pebbles?*, 96 MILBANK Q. 110, 111 (2018).

[34]*Id*. at 120–22.

[35]*Id*. at 125–28.

[36]*Id.* at 117–18.

[37]*Id.* at 118. *See also* OFF. OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., & U.S. DEP'T OF HEALTH AND HUMAN SERVICES OFF. FOR CIVIL RIGHTS, PERMITTED USES AND DISCLOSURES: EXCHANGE FOR TREATMENT (2016), https://www.healthit.gov/sites/default/files/exchange_treatment.pdf [https://perma.cc/7KNG-PANR].

[38]Mello et al., *supra* note 33, at 110–11, 118–20.

[39]*See* Sunny C. Lin et al., *Technology, Incentives, or Both? Factors Related to Level of Hospital Health Information Exchange*, 53 HEALTH SERVS. RES. 3285, 3302-03 (2018) (finding that both technological capabilities and incentives were associated with greater health information exchange).

[40]*See* Savage et al., *supra* note 22, at 612.

[41]Mello et al., *supra* note 33, at 118–19.

[42]Lin et al., *supra* note 39 (finding that both technological capabilities and incentives were associated with greater health information exchange).

[43]*See* Savage et. al, *supra* note 22, at 599.

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widespread— did the federal government prioritize addressing the incentives standing in the way of interoperability.[44] This section provides an overview of the main federal initiatives aimed at promoting EHRs and making them interoperable.

A. THE HITECH ACT

Although the federal government has been promoting EHRs since the George W. Bush administration,[45] the first major federal initiative came in 2009 when Congress passed the Health Information Technology for Economic and Clinical Health ("HITECH") Act, as part of the American Recovery and Reinvestment Act.[46] The HITECH Act provided nearly thirty-six billion dollars in subsidies to physicians and hospitals that demonstrated their "meaningful use" of EHR technology.[47] The Centers for Medicare and Medicaid Services ("CMS") implemented these "meaningful use" standards in three regulatory stages, which imposed progressively more stringent requirements on participating providers. In addition, the HITECH Act also required the Department of Health and Human Services ("HHS") to develop procedures for certifying EHRs to ensure they had certain basic capabilities.[48]

The HITECH Act was quite effective in encouraging providers to adopt EHRs. By 2015, almost 84% of hospitals had implemented at least a basic EHR system, up from less than 10% of hospitals in 2008.[49] Similarly, nearly 54% of office-based physicians had a basic EHR system by 2015, up from around 17% in 2008.[50] Empirical research has confirmed that much of this dramatic shift is likely due to the HITECH Act.[51]

Importantly, however, the HITECH Act did not ensure that EHRs were interoperable. Although the Act specified that EHRs be capable of "health information exchange" ("HIE"), CMS and ONC opted not to include HIE in the first stage of the meaningful use regulations.[52] Although the later stages did require that health care providers be able to transmit discharge summaries for some health care transactions, these requirements were too limited to ensure widespread interoperability.[53] By 2015,

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[44] *See Achieving the Promise of Health Information Technology: What Can Providers and the U.S. Department of Health and Human Services Do to Improve the Electronic Health Record User Experience? Before the S. Comm. on Health, Educ., Labor, and Pensions*, 114th Cong. 2, 3 (2017), https://www.govinfo.gov/content/pkg/CHRG-114shrg95269/pdf/CHRG-114shrg95269.pdf [https://perma.cc/XE97-GNHS].

[45] Nicolas P. Terry, *Meaningful Adoption: What We Know or Think We Know about the Financing, Effectiveness, Quality, and Safety of Electronic Medical Records,* 34 J. LEGAL MED. 7, 10 (2013).

[46] Health Information Technology for Economic and Clinical Health Act, Pub. L. No. 111-5, 123 Stat. 226 (2009) [hereinafter "HITECH Act"]; Savage et al., *supra* note 22, at 594.

[47] Savage et al., *supra* note 22, at 599.

[48] HITECH Act, *supra* note 46, at § 3004 (b)(1).

[49] JAWANNA HENRY, YURIY PYLYPCHUK, TALISHA SEARCY, & VAISHALI PATEL, OFFICE OF NAT'L COORDINATOR FOR HEALTH INFO. TECH., ONC DATA BRIEF NO. 35, ADOPTION OF ELECTRONIC HEALTH RECORD SYSTEMS AMONG U.S. NON-FEDERAL ACUTE CARE HOSPITALS: 2008-2015 3 (2016), https://www.healthit.gov/sites/default/files/briefs/2015_hospital_adoption_db_v17.pdf [https://perma.cc/M826-RWAU]

[50] *Office-based Physician Electronic Health Record Adoption*, OFFICE OF NAT'L COORDINATOR FOR HEALTH INFO. TECH, https://dashboard.healthit.gov/quickstats/pages/physician-ehr-adoption-trends.php [https://perma.cc/H2CH-BL85].

[51] *See* Julia Adler-Milstein & Ashish Jha, *HITECH Act Drove Large Gains in Hospital Electronic Health Record Adoption*, 36 HEALTH AFF. 1416, 1416 (2017).

[52] Adler-Milstein, supra note 24.

[53] *See, e.g.,* HOFFMAN, ELECTRONIC HEALTH RECORDS AND MEDICAL BIG DATA, *supra* note 2, at

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less than one-third of hospitals could find, send, receive, and integrate patient information from other health care providers.[54]

Part of the explanation for this lack of emphasis on interoperability was that the Obama administration was concerned about imposing interoperability requirements too early when most health care providers were not even using EHRs.[55] In addition, neither Congress nor the Obama administration adequately appreciated how challenging it would be to overcome health care organizations' incentives *not* to share data.[56] As President Obama himself later explained:

> In some cases, you have economic incentives against making the system better; you have service providers — people make money on keeping people's medical records — so making it easier for everyone to access medical records means that there's some folks who could lose business. And that's turned out to be more complicated than I expected.[57]

B. MACRA

The Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA") contained additional provisions designed to address interoperability. For instance, the Act requires eligible health care providers to attest that they have not "knowingly and willfully taken action . . . to limit or restrict the compatibility or interoperability of certified EHR technology."[58] It also transformed three preexisting Medicare payment formulas into a single formula—the Merit-based Incentive Payment System ("MIPS")—designed to transition from paying for each service rendered to paying for value delivered. As part of its new formula, MIPS conditions physician payments on performance in four categories, including "promoting interoperability."[59]

Unfortunately, however, these new tools did not prove very effective. The attestation standards were criticized as "toothless," [60] while the interoperability requirements in MIPS were flexible and easy to meet.[61] In fact, recently the Medicare Payment Advisory Commission called for scrapping MIPS, concluding that it is

55; Savage et al., *supra* note 22, at 612.

[54] A. Jay Holmgren, Vaishali Patel, & Julia Adler-Milstein, *Progress in Interoperability: Measuring US Hospitals' Engagement in Sharing Patient Data*, 36 HEALTH AFF. 1820, 1820 (2017).

[55] *See* Schulte & Fry, *supra* note 7.

[56] Niam Yaraghi, *Where HITECH's $28 Billion of Investment Has Gone*, BROOKINGS (March 5, 2015), https://www.brookings.edu/blog/techtank/2015/03/05/where-hitechs-28-billion-of-investment-has-gone [https://perma.cc/8648-HFR4]; Schulte & Fry, *supra* note 7; Sarah Kliff, *The Fax of Life: Why American Medicine Still Runs on Fax Machines*, VOX (Jan. 12, 2018), https://www.vox.com/health-care/2017/10/30/16228054/american-medical-system-fax-machines-why [https://perma.cc/92JF-QV65] ("Obama officials believed competing health systems would volunteer to share patient data. They now admit that was naive.").

[57] Kliff, *Obama's Surprising Answer*, *supra* note 11.

[58] Medicare Access and CHIP Reauthorization Act of 2015, Pub. L. No. 114-10 § 106(b)(2)(B).

[59] *Explore Measures*, QUALITY PAYMENT PROGRAM, https://qpp.cms.gov/mips/explore-measures/promoting-interoperability?py=2018#measures [https://perma.cc/PXJ5-4RDS].

[60] Scott Mace, *MACRA's Information Blocking Threat May Be Toothless*, HEALTH LEADERS MEDIA (Nov. 22, 2016), https://www.healthleadersmedia.com/innovation/macras-information-blocking-threat-may-be-toothless [https://perma.cc/5X59-ZTNC].

[61] Savage et al., *supra* note 22, at 613 (noting that to achieve top marks in the "advancing care information" domain, a physician needed only exchange a summary of care record with one other physician).

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"profoundly flawed" and that, among other things, it will not "succeed as an incentive program designed to improve clinician practice patterns."[62]

C. THE 21ST CENTURY CURES ACT

Following the HITECH Act, Congress grew increasingly frustrated with the lack of improvement on interoperability and reports of vendors deliberately blocking the exchange of information.[63] In response, Congress passed the 21st Century Cures Act ("the Cures Act"), which took several steps to promote interoperability, including: penalizing information blocking, imposing health information technology certification requirements on application programming interfaces, and developing a "trusted exchange framework."[64]

First, the Cures Act created new regulatory authority to penalize information blocking. Previously, regulators had little authority to penalize providers or EHR vendors who engage in information blocking.[65] The Act authorizes the HHS Office of Inspector General ("OIG") to investigate claims of information blocking, and impose Civil Monetary Penalties of up to one million dollars per violation.[66] It also authorizes the OIG to penalize providers engaging in information blocking by subjecting them "to appropriate disincentives using authorities under applicable Federal law, as the Secretary sets forth through notice and comment rulemaking."[67] In addition, the Cures Act requires certified health information technology developers to attest that they do not "take any action that constitutes information blocking," and to test the interoperability of their technologies in a "real world" setting.[68]

Second, the Cures Act made some changes to the Health IT Certification Program, most notably imposing new requirements on "application programming interfaces" ("APIs"). Donald Rucker, the National Coordinator for Health Information Technology, has defined APIs as "technology that allow one software program to access the services provided by another software program."[69] The development of APIs is thought to be crucial in health care to create programs that extract data from multiple sources and aggregate them in one place.[70] Among other things, the Cures Act requires:

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[62] MEDICARE PAYMENT ADVISORY COMM'N, REPORT TO THE CONGRESS: MEDICARE PAYMENT POLICY 449 (MAR. 2018).

[63] *Achieving the Promise of Health Information Technology: What Can Providers and the U.S. Department of Health and Human Services Do to Improve the Electronic Health Record User Experience? Before the S. Comm. on Health, Educ., Labor and Pensions*, 114th Cong. 2 (2017) (statement of Sen. Bill Cassidy) (describing the lack of interoperability and information blocking as "inexcusable"). *See also id*. at 3 (statement of Sen. Sheldon Whitehouse) (stating "very much respect my Republican colleague's concerns about the usability of EHRs and remaining barriers to the interoperation of different EHR systems. There is a lot of frustration to go around.").

[64] OFFICE OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., TRUSTED EXCHANGE FRAMEWORK AND COMMON AGREEMENT (TEFCA) DRAFT 2, at 4 (2019) [hereinafter TEFCA (2019)].

[65] Adler-Milstein & Pfeifer, *supra* note 28, at 131.

[66] 21st Century Cures Act, Pub. L. No. 114-255, § 4004, 130 Stat. 1033, 1177-78 (2016).

[67] *Id*.

[68] *Id*. at § 4002.

[69] Don Rucker, *Achieving the Interoperability Promise of 21st Century Cures*, HEALTH AFF. BLOG (June 19, 2018), https://www.healthaffairs.org/do/10.1377/hblog20180618.138568/full/ [https://perma.cc/9BDR-K2RR].

[70] PEW CHARITABLE TRUSTS, ELECTRONIC TOOLS CAN STRENGTHEN HEALTH CARE DATA ACCESS (Sept. 2018), https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2018/09/electronic-tools-can-strengthen-health-care-data-access-sharing [https://perma.cc/KC4S-YTVF].

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> "Health information from such technology to be accessed, exchanged, and used *without special effort* through the use of application programming interfaces or successor technology or standards, as provided for under applicable law, including providing access to all data elements of a patient's electronic health record to the extent permissible under applicable privacy laws."[71]

Third, the Cures Act provides that the Office of the National Coordinator for Health Information Technology ("ONC"), together with the National Institute of Standards and Technology, shall "convene public-private and public-public partnerships to build consensus and develop or support a *trusted exchange framework*, including a common agreement among health information networks nationally."[72]

Still, although the Cures Act took important steps to promote interoperability, regulatory agencies have significant latitude over how to interpret and enforce the Act. For instance, in order to give the information blocking provisions force, the ONC is directed to promulgate a rule that defines "reasonable and necessary activities that do *not* constitute information blocking."[73] Thus, the effectiveness of the Cures Act depends in large part on how aggressively regulators use these tools.[74]

III. THE TRUMP ADMINISTRATION'S APPROACH

A. REGULATORY ACTION

In February 2019, over two years after the passage of the Cures Act, CMS and ONC each proposed new interlocking rules aimed at implementing different interoperability provisions in the Act.[75] The CMS and ONC rules attempt to encourage information sharing in a number of ways, including penalizing information blocking, requiring payers to use open and standardized APIs, and publicly shaming uncooperative providers. Together, these provisions are aimed at making the sharing of electronic health information the default practice in the U.S. health care system. We briefly review some of the most important provisions below.

First, recall that the Cures Act prohibits information blocking, and directs ONC to promulgate a rule that defines activities that do *not* constitute information blocking.[76] ONC implements this provision by outlining seven categories of activities: (1) preventing harm; (2) promoting privacy; (3) promoting security; (4) recovering reasonable costs; (5) responding to infeasible requests; (6) licensing of interoperability

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[71] 21st Century Cures Act § 4002(a).

[72] *Id*. at § 4003(b).

[73] *Id.* at § 4004(a)(3) (emphasis added).

[74] *See* Carolyn T. Lye, Howard P. Forman, Jodi G. Daniel & Harlan M. Krumholz, *The 21st Century Cures Act and Electronic Health Records One Year Later: Will Patients See the Benefits?*, 25 J. AM. MED. INFORMATICS ASS'N. 1218, 1220 (2018).

[75] Press Release, U.S. Department of Health & Human Services, HHS Proposes New Rules to Improve the Interoperability of Electronic Health Information (Feb. 11, 2019), https://www.hhs.gov/about/news/2019/02/11/hhs-proposes-new-rules-improve-interoperability-electronic-health-information.html [https://perma.cc/ZQ46-UNYS]. This article does not discuss the final versions of the rules, which were released after the article was finalized for publication. *See* Press Release, U.S. Department of Health & Human Services, HHS Finalizes Historic Rules to Provide Patients More Control of Their Health Data (March 9, 2020), https://www.hhs.gov/about/news/2020/03/09/hhs-finalizes-historic-rules-to-provide-patients-more-control-of-their-health-data.html.

[76] 21st Century Cures Act § 4004(a)(3) (emphasis added).

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elements on reasonable and non-discriminatory terms; and (7) maintaining and improving health information technology performance.[77] Further, ONC prohibits developers from restricting EHR users from communicating about the EHR product, thus repudiating so-called "gag clauses" developers included in their contracts.[78] These provisions are bolstered by the CMS rule, which proposes to publicly report any eligible clinicians or hospitals in CMS programs that do not attest that they are not engaging in information blocking.[79] CMS argues that doing so "would serve to discourage knowing and willful behavior that limits interoperability and prevents the sharing of information."[80]

Second, both sets of rules promote the use of APIs. ONC requires developers participating in the certification program to base their APIs on the commonly used technical standard known as Fast Healthcare Interoperability Resources ("FHIR").[81] This will promote the ease of data exchange. Such APIs must also be accessible to third-party applications and developers, and provide documentation to ensure that third-party developers can obtain information necessary to develop their apps.[82] ONC also specifies a new data set—the U.S. Core Data for Interoperability—as the new standard for EHRs moving forward.[83] This new data set would assist with incorporation of APIs and incorporate other innovations for specialty practices.

The CMS rule extends the technical standards regarding APIs in the ONC rule to health payers such as Medicare Advantage plans and Medicaid managed care organizations, and imposes additional requirements on both payers and providers to make patient health information accessible.[84] Payers must provide an array of documentation "to ensure that any interested third-party application developer can easily obtain the information needed to develop applications technically compatible with the organization's API."[85] CMS also requires plans to exchange data among itself, at the request of patients,[86] and participate in trusted data exchange frameworks.[87] Certain hospitals are required to send electronic notifications whenever a patient is admitted, discharged, or transferred to providers the patient identifies for follow up care.[88]

Finally, in addition to these rules, ONC also proposed a draft framework for a national health data network, as the Cures Act mandates. In January 2018, ONC released its first draft of a Trusted Exchange Framework and Common Agreement ("TEFCA") and solicited comments, releasing a second draft in April 2019. TEFCA "aim[s] to create technical and legal requirements for sharing EHI [electronic health information] at a nationwide scale across disparate HINs [Health Information

[77]21st Century Cures Act, 84 Fed. Reg. 7424, 7523 (March 4, 2019) (codified at 45 C.F.R. pt. 170 and 171).

[78]*Id.* at 7469.

[79]Protection and Affordable Care Act, 84 Fed. Reg. 7610, 7616 (March 4, 2019) (codified at 45 C.F.R. pt. 156).

[80]*Id.* at 7625.

[81]*Id.*; 21st Century Cures Act, 84 Fed. Reg. 7424, 7427 (March 4, 2019) (codified at 45 C.F.R. pt. 170 and 171).

[82]21st Century Cures Act, 84 Fed. Reg. 7424, 7482.

[83]*Id.* at 7440–41.

[84]Protection and Affordable Care Act, 84 Fed. Reg. at 7610, 7617–18.

[85]*Id.* at 7634.

[86]*Id.* at 7640.

[87]*Id.* at 7642.

[88]*Id.* at 7650.

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Networks]."[89] The April draft provides that "[t]he TEF and the Common Agreement will be distinct components." Each of the components have a separate function: "[t]he TEF describes a common set of principles that facilitate trust between HINs. These principles serve as 'rules of the road' for nationwide electronic health information exchange." ONC will develop the TEF.[90] The Common Agreement, in turn "will provide the governance necessary [for] a functioning system of connected HINs . . . . The architecture will follow a 'network of networks' structure, which allows for multiple points of entry and is inclusive of many different types of health care entities."[91]

The national interconnected network will be separated into large, regional subnetworks of Qualified HINs ("QHINs").[92] All the networks together that will be governed by TEFCA will be administered by "a single, industry-based [Recognized Coordinating Entity ("RCE")]."[93] This RCE has a range of responsibilities. It will onboard organizations onto the network, ensure that the QHINs comply with TEFCA, address non-compliance, and generally carry out daily management.[94]

B. CONCERNS

Although these rules represent the most ambitious regulatory actions to date to improve the interoperability of EHRs, several concerns remain as to whether the rules will be successful. First, the rules, arguably, contain loopholes. For instance, although the Cures Act applies the prohibition against information blocking to developers of "health information technology," the ONC proposed rule only applies only to certified EHR developers, leaving out various other types of health information technology.[95] The national network that TEFCA describes is also a voluntary network. While some certified EHR developers and public insurance plans might have to participate in TEFCA, most healthcare entities will not.

Moreover, it is possible that some of the proposed exemptions could become even broader by the time the rule is finalized. As a general matter, regulations tend to become less stringent from the proposed rule stage to the final rule stage in response to industry pressure.[96] Several powerful industry associations have already raised concerns with the rule. For instance, the American Hospital Association has objected

[89] TEFCA 2019, *supra* note 65, at 4.
[90] *Id.*
[91] *Id.*
[92] *Id.* at 5.
[93] *Id.* at 8.
[94] *See generally id.*
[95] *Implementing the 21st Century Cures Act: Making Electronic Health Information Available to Patients and Providers: Hearing Before the S. Comm. on Health, Educ. Labor & Pensions,* 116th Cong. 2 (2020) (testimony of Lucia C. Savage, Chief Privacy & Regulatory Officer, Omada Health, Inc.), https://www.help.senate.gov/imo/media/doc/Savage2.pdf [https://perma.cc/ZDW4-MJNV].
[96] *See, e.g.*, Jason Webb Yackee & Susan Webb Yackee, *A Bias Towards Business? Assessing Interest Group Influence on the U.S. Bureaucracy*, 68 J. POL. 128, 135 (2006) (examining interest group participation in over 30 regulations and finding that find "[w]hen business commenters are united in their desire to see less regulation in a final rule . . . they will receive less regulation over 90% of the time").

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to CMS's electronic event notification requirement,[97] while American Health Insurance Plans has stated that the 2020 compliance deadline is too soon.[98]

Second, some observers have raised concerns about whether the rules will be enforced strongly enough to sufficiently incentivize health care organizations to share information with one another, or whether instead fines for information blocking will simply be viewed as the "cost of doing business."[99] Whether the rules effectively deter information blocking will depend on both the probability that regulators find and penalize entities engaged in information blocking, as well as the size of the penalties that they levy.[100] Although potential fines of one million dollars per violation might seem to constitute a substantial deterrent, much larger fines levied in other contexts—including in the financial and pharmaceutical sectors—have arguably failed to deter further corporate wrongdoing.[101]

Third, even if the rules are successful in encouraging information sharing, they will not by themselves assure that patients' records are appropriately matched.[102] Theoretically, one way to address this challenge would be to come up with a unique patient identifier ("UPI") for each individual that could be used to match patients to their records.[103] However, because of privacy and security concerns, Congress has long prohibited HHS from adopting this approach.[104] Instead, ONC and CMS requested information on "patient matching"—a process where EHRs use pieces of information about patients (name, birthday, gender, etc.) to match health information that refer to the same individual.[105] However, patient matching can be less accurate than using a UPI,[106] and ONC and CMS are still seeking information as to how to improve current patient matching technology.[107]

Finally, another related challenge for APIs in health care is that different EHR systems may use different representational systems to encode medical information.[108]

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[97]Press Release, Ashley Thompson, Am. Hosp. Ass'n Senior Vice President for Pub. Policy Analysis & Dev., AHA Statement on Proposed Electronic Health Information Rule (Feb. 11, 2019), https://www.aha.org/press-releases/2019-02-12-aha-statement-proposed-electronic-health-information-rule [https://perma.cc/X7V5-PXF3].

[98]Mike Miliard, *AHIP Says Proposed Interoperability Rules Push Payers Too Far, Too Fast*, HEALTHCARE IT NEWS (Mar. 27, 2019, 12:59 PM), https://www.healthcareitnews.com/news/ahip-says-proposed-interoperability-rules-push-payers-too-far-too-fast [https://perma.cc/HM5L-ZXHV].

[99]Jennifer Bresnick, *CMS Sparks Mixed Reactions with Interoperability, Data Blocking Rules*, HEALTH IT ANALYTIC (Feb. 15, 2019) https://healthitanalytics.com/features/cms-sparks-mixed-reactions-with-interoperability-data-blocking-rules [https://perma.cc/MN45-BY7G].

[100]*See generally* Gary S. Becker, *Crime and Punishment: An Economic Approach*, 76 J. POL. ECON. 169 (1968).

[101] *See, e.g.*, *Fine and Punishment*, ECONOMIST (July 21, 2012), https://www.economist.com/finance-and-economics/2012/07/21/fine-and-punishment [https://perma.cc/CG4T-DEZM].

[102]Protection and Affordable Care Act, 84 Fed. Reg. at 7610, 7614 (March 4, 2019) (codified at 45 C.F.R. pt. 156).

[103]*Id.* In June 2019, the House of Representatives voted to repeal this prohibition, but as of August 2019, the bill's fate in the Senate is uncertain. Susannah Luthi & Jessica Kim Cohen, *House Votes to Overturn Ban on National Patient Identifier*, MODERN HEALTHCARE (June 13, 2019), https://www.modernhealthcare.com/politics-policy/house-votes-overturn-ban-national-patient-identifier [https://perma.cc/4GHK-H723].

[104]Protection and Affordable Care Act, 84 Fed. Reg. at 7610, 7614-7615.

[105]*Id.* at 7615.

[106]*Id.*

[107]ONC REPORT, *supra* note 26; Centers for Medicare & Medicaid Services, 84 Fed. Reg. 7615 (March 4, 2019).

[108]*See supra* note 30 and accompanying text.

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To address this challenge, the rules require that the use of the FHIR standard for APIs—a standard that is designed to "build a base set of resources that, either by themselves or when combined, satisfy the majority of common use cases."[109] Whereas previous standards enabled providers to share too much irrelevant information, FHIR is designed to enable providers "to obtain only relevant information through an API."[110] FHIR, however, still tolerates a certain amount of variation in terms of how data elements such as medication names and diagnoses are represented, and which ones are included.[111]

CONCLUSION

The story of EHRs in the United States is one of both market failure and government failure. Health care organizations have strong incentives to withhold data from one another, and federal policymakers did not initially recognize or adequately address these incentives. Now, regulators are trying to correct their earlier missteps by imposing new regulatory mandates and penalties designed to promote interoperability. Whether they succeed will depend on whether they can do what previous efforts have failed to do: change private health care organizations' incentives so that it is in their own interest to share health data. If the rules are successful in translating into actual norms of generally respected behavior, then they will go a long ways toward achieving the promise of EHRs.

[109] FAST HEALTHCARE INTEROPERABILITY RESOURCES, https://www.hl7.org/fhir/overview.html [https://perma.cc/KZJ6-JHSQ].

[110] *Electronic Tools Can Strengthen Health Care Data Access, Sharing*, THE PEW CHARITABLE TRUSTS (Sept. 19, 2018), https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2018/09/electronic-tools-can-strengthen-health-care-data-access-sharing [https://perma.cc/UWM4-K69B].

[111] *Hearings before the Comm. on Health, Education, Labor & Pensions* (2019) (statement of Ben Moscovitch, Project Director of Health Information Technology, The Pew Charitable Trusts); *Electronic Tools Can Strengthen Health Care Data Access, Sharing*, THE PEW CHARITABLE TRUSTS (Sept. 19, 2018), https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2018/09/electronic-tools-can-strengthen-health-care-data-access-sharing [https://perma.cc/2T42-AWDM].

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