HEALTH DATA FEDERALISM

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ABSTRACT

Federalism scholarship abounds on nearly all aspects of healthcare: on the Affordable Care Act, public health powers, licensing, and drug and device regulation. Yet it overlooks a healthcare resource as essential as money or drugs: health data. Individual-level records contain intimate details of patients' entire lives and drive their diagnoses, treatments, and billing. Big data drives public health efforts like gun, opioid, and COVID-19 control. And groundbreaking regulation on the question of health data federalism is ongoing. This Article tells this overlooked federalism story.

Historically, states took the lead in (1) collecting health data, (2) creating networks to transmit data, and (3) curbing inappropriate data release through privacy law. However, in the last five years, the federal government has intruded into these spaces. But it does not just displace state law. Rather, as part of a general policy in this space that favors private entities, the federal government has shifted control from states to private firms. Federal law now mandates that private contracts displace state law in setting the rules of data collection. The federal government has given private entities a lead in developing data networks by shifting incentives to them from states. And it has favored allowing a private entity to preempt state privacy laws that regulated that very entity and its industry.

While health law scholars have considered bilateral tugs-of-war between the federal and state governments in other areas of healthcare, health data federalism shows how a third actor—the private sector—has entered the mix. I explore the problems this raises and offer solutions. The solutions are modeled

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on federalist healthcare structures like Medicaid and the Affordable Care Act that balance state, federal, and private power. First, the federal government should give states the first option to develop health networks and data collection in conformance with federal guidelines before turning to private entities. Second, the federal government should include states in consultative capacities to direct network development, privacy, and data collection efforts. And third, the federal government should delegate to states the power to carry out enforcement actions against private entities that misbehave. This federalist approach will offer an integrated, balanced solution to health data regulation.

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INTRODUCTION

Imagine that you are a patient in a large health system. Information about your biometrics (heart rate, blood pressure, temperature), ailments (sleep disorders, COVID-19 history, cancer), demographics (age, sex, address), sexual and reproductive history (sexually transmitted infections, tests, pregnancies, and pregnancy terminations), medications, insurance coverage, allergies, genetic and family history, and vaccinations is all stored in your electronic health record ("EHR").[1] Your healthcare system, insurance company, and related EHR vendors can all access this data.[2] These firms use your data not just for their own analyses but also to sell to the highest bidder.[3] That said, the firms are also subject to long-standing state regulation, requiring that they share data for the public good while at the same time maintaining privacy.[4] Further imagine that the federal government intervenes not just to rein in states but to *hand* those reins over to private entities. Private firms then would control a new national data network and could determine when and whether to follow *any* state rules with respect to your most intimate medical details over the course of your entire life. Such control over data would allow them to engage in price manipulation, stymie research, and create risks for individual consumers, including discrimination, blackmail, and identity theft.[5] This scenario implicates the future of health data—and of federalism.

In healthcare law, federalism has always been in vogue. Healthcare federalism scholarship explores conflict and cooperation between the state and federal governments in administering nearly all resources important for healthcare: money, drugs and devices, and medical personnel. Thus, since 2010, articles on health insurance have proliferated, largely focused on the Affordable Care Act

[1] Off. of the Nat'l Coordinator for Health Info. Tech., *What Information Does an Electronic Health Record (EHR) Contain?*, HEALTHIT.GOV, https://www.healthit.gov/faq/what-information-does-electronic-health-record-ehr-contain [https://perma.cc/EA8V-KS7C] (last updated Apr. 9, 2019).

[2] Providers may disclose data for "payment" to insurance companies, 45 C.F.R. § 164.506(a) (2021), and to EHR vendors as business associates, 45 C.F.R. § 164.504(e) (2021). *See* Marla Durben Hirsch, *Editor's Corner: EHR Vendor Business Associate Agreements Still Skewed Against Providers*, FIERCE HEALTHCARE (Oct. 11, 2016, 11:05 AM), https://www.fiercehealthcare.com/it/ehr-vendor-business-associate-agreements-still-skewed-against-providers [https://perma.cc/G2NG-2ULC].

[3] *See infra* Section IV.A.1.

[4] *See infra* Part II.

[5] *See, e.g.*, Carissa Véliz, *Medical Privacy and Big Data: A Further Reason in Favour of Public Universal Health-Care Coverage*, *in* PHILOSOPHICAL FOUNDATIONS OF MEDICAL LAW 306, 306-18 (Andelka M. Phillips, Thana C. de Campos & Jonathan Herring eds., 2019). As the author explains, individuals can suffer from medical discrimination in the workplace, insurance discrimination, and price discrimination by pharmaceutical companies. *Id.* Véliz also describes incidents of identity theft and a specific incident where criminals blackmailed clients of a cosmetic surgery clinic and published private information. *Id.*

("ACA") and Medicaid.[6] Drug and device issues have long raised federalism concerns,[7] as have the training and licensing of health professionals.[8] Most recently, the COVID-19 pandemic has raised significant federalism concerns regarding the limits of state public health powers, the allocation of medical resources, and financial assistance (or in the alternative, bankruptcy) of state and municipal entities.[9]

[6] *See, e.g.*, Abbe R. Gluck & Nicole Huberfeld, *What Is Federalism in Healthcare For?*, 70 STAN. L. REV. 1689, 1690 (2018) (discussing ACA's federalism, stating "the ACA's implementation is clearly a story about state leverage, intrastate democracy, and state policy autonomy within, not apart from, a national statutory scheme"); Abbe R. Gluck, *Intrastatutory Federalism and Statutory Interpretation: State Implementation of Federal Law in Health Reform and Beyond*, 121 YALE L.J. 534, 576-77 (2011) (exploring ACA as an example of various federalism theories; noting within ACA there are multiple visions of role of states); Nicole Huberfeld, *Federalizing Medicaid*, 14 U. PA. J. CONST. L. 431, 435 (2011) (discussing Medicaid's cooperative federalism approach); Alan Weil, *The Value of Federalism in Defining Essential Health Benefits*, 366 NEW ENG. J. MED. 679, 679-80 (2012) (discussing how states will define essential health benefits under ACA); Nicholas Bagley, *Federalism and the End of Obamacare*, 127 YALE L.J.F. 1, 15-25 (2017) (examining how to allocate responsibilities between states and federal government under ACA).

[7] Myrisha S. Lewis, *Innovating Federalism in the Life Sciences*, 92 TEMP. L. REV. 383, 398-410 (2020); Catherine M. Sharkey, *States Versus FDA*, 83 GEO. WASH. L. REV. 1609, 1613-15 (2015); Catherine M. Sharkey, *Federalism Accountability: "Agency-Forcing" Measures*, 58 DUKE L.J. 2125, 2131-40 (2009) (using Food and Drug Administration ("FDA") as case study of federal agency asserting preemptive authority through regulation); Catherine M. Sharkey, *Inside Agency Preemption*, 110 MICH. L. REV. 521, 546-53 (2012) (continuing discussion of FDA as case study); *see also* Christine H. Kim, Note, *The Case for Preemption of Prescription Drug Failure-to-Warn Claims*, 62 FOOD & DRUG L.J. 399, 399 (2007) ("The Food and Drug Administration (FDA) has become a favorite target in attacks on administrative preemption."); Catherine M. Sharkey, *What* Riegel *Portends for FDA Preemption of State Law Products Liability Claims*, 103 NW. U. L. REV. 437, 437-41 (2009) (discussing effect of *Riegel v. Medtronic, Inc.*, on state products liability claims).

[8] Patricia J. Zettler, *Toward Coherent Federal Oversight of Medicine*, 52 SAN DIEGO L. REV. 427, 434-53 (2015); Lars Noah, *Ambivalent Commitments to Federalism in Controlling the Practice of Medicine*, 53 KAN. L. REV. 149, 149-54 (2004); Abigail R. Moncrieff, *Federalization Snowballs: The Need for National Action in Medical Malpractice Reform*, 109 COLUM. L. REV. 844, 857-61 (2009); *see also* Collin Sult, Note, *Questionable Medicine—Why Federal Medical Malpractice Reform May Be Unconstitutional*, 47 ARIZ. L. REV. 195, 205-20 (2005) (examining HEALTH Act as example of whether medical malpractice reform is constitutional); Lawrence S. Lewin & Robert A. Derzon, *Health Professions Education: State Responsibilities Under the New Federalism*, 1 HEALTH AFFS. 69, 72-83 (1982) (discussing state and federal efforts to support health education both financially and institutionally); Gabriel Scheffler, *Unlocking Access to Health Care: A Federalist Approach to Reforming Occupational Licensing*, 29 HEALTH MATRIX 293, 299 (2019) (arguing for federalist approach to reforming occupational licensing).

[9] *See, e.g.*, Rebecca L. Haffajee & Michelle M. Mello, *Thinking Globally, Acting Locally—The U.S. Response to Covid-19*, 382 NEW ENG. J. MED. e75(1), e75(1) (2020); Carl Hulse, *McConnell Wants States to Consider Bankruptcy*, N.Y. TIMES, Apr. 23, 2020, at A14.

But when it comes to a key healthcare resource—health data—federalism scholarship is elusive, apart from scattered articles on privacy law.[10] This Article tells the story of the shift away from states' control over the vast quantities of patient health data that have permeated the medical system across the nation in the last five years. It also explains the harms this shift causes and proposes solutions based on existing models of cooperative federalism such as the ACA. It also shows how health data regulation, because of its novelty, implicates new forms of federalism in which the struggle involves not just federal and state governments but also *private* entities as arbiters between the two.

The lacuna that this Article fills is important for three reasons. First, data is as essential as any other healthcare resource—finances, personnel, drugs—that has been the subject of federalism scholarship. Without health data, the healthcare system would fail: doctors could not diagnose or treat, drugs could not be developed, insurance could not be paid, and public health conditions like COVID-19 could not be tracked.[11] Research combines, compiles, and analyzes millions of records to help understand how humans tick and how best to treat novel diseases.[12] Indeed, the lacuna is particularly puzzling as scholars have repeatedly emphasized the importance of health data and have considered a

[10] These articles concern a single set of federal privacy rules. *See* Barbara J. Evans, *Institutional Competence to Balance Privacy and Competing Values: The Forgotten Third Prong of HIPAA Preemption Analysis*, 46 U.C. DAVIS L. REV. 1175, 1190-1205 (2013); Ani B. Satz, *The Federalism Challenges of Protecting Medical Privacy in Workers' Compensation*, 94 IND. L.J. 1555, 1570-81 (2019); Grace Ko, Note, *Partial Preemption Under the Health Insurance Portability and Accountability Act*, 79 S. CAL. L. REV. 497, 500-01 (2006). The one exception I have found is Wendy Netter Epstein, *Bottoms Up: A Toast to the Success of Health Care Collaboratives . . . What Can We Learn?*, 56 ADMIN. L. REV. 739, 747-48 (2004), which also focuses on data standards—just not on privacy provisions.

[11] *See* Yale Univ., *Obama Administration Pumped $27 Billion into Electronic Health Records—Doctors Give an 'F,'* SCITECHDAILY (Nov. 17, 2019), https://scitechdaily.com/obama-administration-pumped-27-billion-into-electronic-health-records-doctors-give-an-f/ [https://perma.cc/F99A-3SK8] ("[EHR systems] were developed to improve patient care by making health information easy for healthcare providers to access and share, reducing medical error."); Heather Landi, *Global EHR Market Hits $31B but Faces Usability, Interoperability Challenges*, FIERCE HEALTHCARE (July 8, 2019, 1:17 PM), https://www.fiercehealthcare.com/tech/global-ehr-market-hits-31-billion-but-faces-usability-interoperability-challenges [https://perma.cc/33DF-KSAM] ("Over the last 30 years, medical institutions have encouraged the shift toward computerization to help manage patient information. . . . But the EHR industry has faced mounting criticism about lack of usability, inefficiency and associations with physician burnout.").

[12] *See* Craig Konnoth, *Data Collection, EHRs, and Poverty Determinations*, 46 J.L. MED. & ETHICS 622, 625-27 (2018).

range of issues, including equity,[13] efficiency,[14] privacy,[15] malfeasance,[16] and agency competence[17]—but not the question of who *controls* the regulation in this space.

Second, the federalism changes in this space are ongoing. The federal government is in the process of writing new rules for the nation's health system that wrest control from states and transfer it to private entities.[18] These rules were triggered by congressional intervention, and unlike other areas of health law in which there is often gridlock, Congress regularly legislates in this field on a bipartisan basis, including in 2009, 2015, and 2016;[19] thus, following past patterns, Congress may soon step in.

Third, the question of health data federalism is particularly novel because of the particular form it has taken. Unlike other areas, the federal government has not just taken power from states for itself—it has delegated power to private entities in *lieu* of states.[20] This is part of a broader phenomenon of federal regulation in the health space in the last fifteen years, which has tended to

[13] *Id.*; Craig Konnoth, *Health Information Equity*, 165 U. PA. L. REV. 1317, 1323-33 (2017) [hereinafter Konnoth, *Health Information*].

[14] *See* Craig Konnoth, *Regulatory De-Arbitrage in Twenty-First Century Cures Act's Health Information Regulation*, 29 ANNALS HEALTH L. & LIFE SCIS. 135, 135-36 (2020) [hereinafter Konnoth, *Regulatory De-Arbitrage*]; Sharona Hoffman & Andy Podgurski, *Balancing Privacy, Autonomy, and Scientific Needs in Electronic Health Records Research*, 65 SMU L. REV. 85, 129-30 (2012).

[15] *See* Konnoth, *Health Information*, *supra* note 13, at 1334-38; Nicolas P. Terry, *Regulatory Disruption and Arbitrage in Health-Care Data Protection*, 17 YALE J. HEALTH POL'Y L. & ETHICS 143, 148-49 (2017).

[16] *See* Julia Adler-Milstein & Eric Pfeifer, *Information Blocking: Is It Occurring and What Policy Strategies Can Address It?*, 95 MILBANK Q. 117, 119 (2017); Konnoth, *Regulatory De-Arbitrage*, *supra* note 14, at 138.

[17] Craig Konnoth, *Are Electronic Health Records Medical Devices?*, *in* THE FUTURE OF MEDICAL DEVICE REGULATION: BALANCING INNOVATION AND PROTECTION (I. Glenn Cohen et al. eds., forthcoming 2021) (manuscript at 6-8) (on file with author) [hereinafter Konnoth, *Electronic Health Records*].

[18] There was particular concern over privatization of data sources in the context of COVID-19. However, that involved diminishing the role of federal agencies in favor of private entities. Liz Essley Whyte, *New, Secretive Data System Shaping Federal Pandemic Response*, CTR. FOR PUB. INTEGRITY (Sept. 22, 2020), https://publicintegrity.org/health/coronavirus-and-inequality/secretive-data-system-shaping-pandemic-response-hhs-protect/ [https://perma.cc/45X6-JAPZ] (discussing how HHS Protect "became a source of controversy . . . when officials told hospitals to stop reporting information on [hospital] beds and patients to a well-known and revered CDC system . . . and instead send it to Teletracking, a private contractor").

[19] *See* Craig Konnoth & Gabriel Scheffler, *Can Electronic Health Records Be Saved?*, 46 AM. J.L. & MED. 7, 11-14 (2020) (describing HITECH Act, MACRA, and 21st Century Cures Act).

[20] *See infra* Part III.

promote the interests of private entities.[21] But unlike other areas of health regulation that had well-entrenched government programs, health *data* technology and its regulation is a relatively recent phenomenon, and has borne the brunt of the privatization trend, with private players rather than the federal government displacing state laws and programs. This phenomenon does not fall into any of the traditional federalism buckets that health federalism scholarship has studied, and thus offers a useful case study for the increasing intersection of federalism and privatization.

The Article proceeds as follows. Part I briefly describes the traditional federalism categories that healthcare scholarship has offered with respect to the resources that scholars have already explored. I refer to these categories as separate spheres, cooperative, and interstitial federalism. For example, states regulate medical personnel and their medical practice, the federal government regulates drugs and devices that go into medical treatment, and both, jointly, regulate medical financing.[22] Health data federalism falls into none of these conceptual categories.

Part II begins by explaining the importance of health data regulation and describing the first decades of state-dominated regulation from the 1980s to the early 2000s. Such regulation covered the life cycle of health data—collection, transmission, and protection. First, states passed regulations to collect health data. Analysis of this data at a population level informed public policy and healthcare regulation more generally. In a second phase, states created health data networks so that data could be transmitted across the state. Such data transmission supported public health goals but also, for example, supported billing and allowed data to follow individual patients when they moved providers. Finally, to limit transmissions to permissible contexts, states passed privacy laws. The state regulation thus reflected two goals of health regulation—promote data exchange in contexts that promote health but limit exchange where privacy concerns should be dominant.

Starting in 2002, we see a shift away from states going it alone.[23] The federal government began to intervene with the application of federal data privacy and security rules.[24] But these rules allowed significant state regulation: the rules set

[21] *See infra* notes 229-236. For a general description of this phenomenon, see Craig Konnoth, *Privatization's Preemptive Effects*, 134 HARV. L. REV. 1937, 1940-47 (2021) [hereinafter Konnoth, *Privatization*].

[22] *See supra* notes 7, 8, and accompanying text.

[23] Under the authority of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), the federal government issued Privacy and Security Rules in 2002 to protect patient healthcare data. 45 C.F.R. pts. 160, 164 (2021); *see also* Sarah C. Rispin, *Cooperative Federalism and Constructive Waiver of State Sovereign Immunity*, 70 U. CHI. L. REV. 1639, 1642 (2003).

[24] These rules set a series of standards on how individually identifiable health information can be used and disclosed to prevent abuse and fraud in the healthcare system. 45 C.F.R. pts. 160, 164 (2021).

a "floor," and states were free to protect health data privacy above this floor.[25] Further, in 2009, the federal government took steps to assist state networks' health data exchanges.[26] But while the states were no longer solo actors, they largely remained the stars; the federal government would often defer to, or support, state efforts.

Part III describes how the true displacement of state law has occurred only in the last five years. It begins by explaining how federal regulation of health data has tended to favor the interests of private entities. That general approach to health data has affected the federalism aspects of health data regulation across the areas of collection, transmission, and privacy protection.

First, when it comes to data collection, the Supreme Court has read federal law to preempt state activities.[27] While this looks like straightforward preemption, the ruling effectively lets firms decide by contract whether to displace state rules regarding data collection—what I call *contractual* displacement.[28] Next, in the field of data transmission, the federal government, through recent regulation, has shifted its focus from assisting *state* health data networks to assisting *private* networks.[29] As private and state health data exchanges compete for customers, the federal government gives private firms a leg up by allowing them to displace state entities. I call this *incentivized* displacement.[30] Finally, in the privacy arena, the federal government proposed delegating to a private contractor the power to determine the rules for a national health data network. That power would have included the ability to displace state privacy laws with respect to the network. While the regulation was beaten back after significant opposition, I analyze the proposal in detail to show how it would have allowed a firm to veto state laws that regulated the firm itself, which I refer to as *delegated* displacement.[31]

The ongoing shifting of power in this field away from states is remarkable in its own right. What is even more remarkable is *how* this shift has occurred: rather than straightforwardly preempt the law, the federal government has created room for *private* firms to displace the law through contracts, incentives, and delegations. This phenomenon occurs throughout the administrative state.[32] But

[25] U.S. Dep't of Health & Hum. Servs., *Does the HIPAA Privacy Rule Preempt State Laws?*, HHS.GOV, https://www.hhs.gov/hipaa/for-professionals/faq/399/does-hipaa-preempt-state-laws/index.html [https://perma.cc/8BCU-VVHK] (last reviewed July 26, 2013).

[26] Health Information Technology for Economic and Clinical Health Act, Pub. L. No. 111-5, 123 Stat. 226 (2009) (codified as amended in scattered sections of 42 U.S.C.).

[27] Gobeille v. Liberty Mut. Ins. Co., 136 S. Ct. 936, 947 (2016) (holding that ERISA preempted Vermont state law).

[28] *See infra* Section III.A.

[29] *Infra* Section III.B.

[30] *Infra* Section III.B.

[31] *Infra* Section III.C.

[32] Konnoth, *Privatization*, *supra* note 21, at 1940-47 (offering examples ranging from education, to utilities administration, to consumer rights).

in part because of its novelty, health data regulation is the only field I know of that exhibits all three kinds of preemptive effects. This is a new phenomenon in healthcare federalism.

Part IV first explains why this privatized displacement of state law is problematic. While privatization may sometimes be desirable, privatization in health data regulation is not. When it comes to health data, the incentives of firms are inverted. Where society wants to promote data exchange to further research and collaboration, as well as patient treatment, firms are incentivized to hold on to research data and deny data transmission that will enable patient mobility to preserve bottom lines, limit collaborative research, and enable price manipulation.[33] On the flip side, firms have incentives to sell patient data outside the health system for marketing and other purposes—which, in turn, can lead to insurance discrimination, price discrimination, and even blackmail.[34] More importantly, history shows firms *acting* on those incentives, which, indeed, prompted some of the regulation in this area. It is unclear how successful federal regulation would be at curbing such behavior.

The rules of national health data exchange are being made as this Article is being written, so the problem I identify is ripe for a solution. I thus turn to existing examples of healthcare federalism that scholars have explored and use them as a blueprint: Medicaid and the ACA. I build on these models to offer solutions that create balanced roles involving the federal government, states, *and* private entities, in that order. First, with data collection and network regulation, states can be given the right of first refusal to act as federal contractors, as with the ACA.[35] Such engagement preserves the role of states ex ante. Second, absent such an approach, private actors must act within governance frameworks that balance power among states, firms, and the federal government, such that all actors have a say. Third, where private firms administer programs, states should have the ability to monitor and ensure compliance by firms ex post, as they already do with respect to compliance with federal privacy standards. In offering these three solutions, I draw from the structures states themselves have put into place to ensure uniformity and impartiality.

Studying health data federalism is thus not just important in its own right. Because it is one of the newest kinds of healthcare resources to be regulated, it also provides insights into novel forms of federalism yet to be explored by the healthcare literature. Healthcare federalism may tend towards privatization unless this model of devolving state power to firms is stopped. Finally, it allows us to apply familiar forms of healthcare federalism to explore potential solutions that may be portable into other areas of regulation as the reach of privatization expands.

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[33] *See infra* notes 357-363 and accompanying text (discussing data profiteering by private firms).

[34] *See supra* note 5.

[35] 42 U.S.C. §§ 18031(b)(1), 18041(c)(1).

I. HEALTHCARE RESOURCES AND FEDERALISM

The healthcare ecosystem requires a range of resources: medical equipment and drugs to provide treatment, medical personnel to administer the treatment, and money to pay for it all. This Part describes the traditional frameworks that health federalism scholarship has applied in understanding who administers these resources. These frameworks take cognizance of two entities: federal and state governments. Yet, it explains, health *data* analyses have not been part of this federalism scholarship. Analyzing health data brings new players into traditional federalism models.

Scholars have long wrestled with federalism in the healthcare space with respect to traditional healthcare resources. In healthcare finance, especially after the ACA's passage, Abbe Gluck, Nicole Huberfeld, and Nicholas Bagley—among others—have produced a veritable cottage industry of writings.[36] When it comes to drugs and devices, Myrisha Lewis, Catherine Sharkey, and Patricia Zettler—again, among others—have produced important work.[37] In considering control over medical personnel such as licensing and malpractice, Lars Noah, Gabriel Scheffler, and Abigail Moncrieff, number among several who have written thoughtful articles.[38] The courts have provided plenty of grist for the scholarly mill, with the Supreme Court itself hearing numerous cases raising federalism issues in the context of healthcare financing,[39] drug and device regulation,[40] and medical licensing and practice.[41]

These resources are governed by a range of federal and state regulation. At base, the nuanced models of healthcare federalism that the scholarship has analyzed so far come in three flavors: separate spheres federalism, cooperative federalism, and interstitial federalism.[42]

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[36] *See* sources cited *supra* note 6.

[37] *See* sources cited *supra* notes 7, 8.

[38] *See* sources cited *supra* note 8.

[39] *E.g.*, Nat'l Fed'n of Indep. Bus. v. Sebelius, 567 U.S. 519, 576-80 (2012) (discussing federalism in context of ACA); King v. Burwell, 576 U.S. 473, 492-96 (2015) (interpreting ACA's respective treatment of federal and state exchanges for purposes of insurance subsidies).

[40] *E.g.*, Cipollone v. Liggett Grp., Inc., 505 U.S. 504, 508 (1992) (liability of cigarette manufacturers); Wyeth v. Levine, 555 U.S. 555, 573-81 (2009) (whether state failure-to-warn law survived FDA regulations); Medtronic, Inc. v. Lohr, 518 U.S. 470, 492-97 (1996) (preemption of state medical device law by FDA regulation).

[41] *E.g.*, N.C. State Bd. of Dental Exam'rs v. FTC, 574 U.S. 494, 515-16 (2015) (whether state licensing board satisfied federal antitrust requirements); Wos v. E.M.A., 568 U.S. 627, 636 (2013) (Medicaid preemption of state medical malpractice tort recovery).

[42] In this description, I am ruthlessly reductive of rich scholarship and analysis. *See, e.g.*, Elizabeth Y. McCuskey, *Body of Preemption: Health Law Traditions and the Presumption Against Preemption*, 89 TEMP. L. REV. 95, 112-44 (2016); Gluck, *supra* note 6, at 584-89.

First, Congress might choose to assign federal and state governments separate policy fiefs—what Gluck calls the "separate spheres" approach.[43] States maintain primacy in some areas, while the federal government retains authority in others. For example, states have historically regulated the "practice of medicine" and medical personnel through licensing and malpractice laws, while the federal government retains a monopoly on Medicare and in regulating drug safety.[44] In theory, such regulation could impinge upon regulating medical practice. But the separate spheres have been maintained. Congress has affirmed such autonomous approaches time and again, stating in several important pieces of federal legislation that any grants to agencies should not be construed to affect state autonomy in the practice of medicine.[45] Courts have similarly reaffirmed state authority to regulate medical practice,[46] and agencies like the Food and Drug Administration have always claimed a lack of power to regulate the practice of medicine.[47]

At the other end of the spectrum are the so-called "cooperative federalism" models.[48] In such situations, the federal government devolves authority to states to help administer programs. As historian Jamila Michener reports, this trend is the result of compromise dynamics since the 1920s. When some policy makers wanted universal healthcare and others wanted no change, the compromise was to delegate to states.[49] Thus, the Sheppard-Towner Act of 1921 provided federal

[43] Gluck, *supra* note 6, at 582. I avoid the term "dual sovereignty" because that has constitutional overtones, whereas here, I am discussing congressional choice. *See* Edward S. Corwin, *The Passing of Dual Federalism*, 36 VA. L. REV. 1, 16-17 (1950); Ernest A. Young, *Dual Federalism, Concurrent Jurisdiction, and the Foreign Affairs Exception*, 69 GEO. WASH. L. REV. 139, 142-67 (2001). Rather, my claims are based on the policy approaches that healthcare law takes. Gluck also uses the term "separate spheres," possibly for the same reason. *See* Gluck, *supra* note 6, at 553.

[44] Lewis, *supra* note 7, at 391-401; McCuskey, *supra* note 42, at 124 ("Deriving authority from their police power, states have regulated medical provider licensing, training, and professional discipline for nearly 150 years. They have done so with minimal, if any, federal intrusion." (footnote omitted)); Gluck, *supra* note 6, at 582.

[45] *See, e.g.*, Health Insurance for the Aged (Medicare) Act, Pub. L. No. 89-97, § 102(a), 79 Stat. 286, 290, 291-332 (1965) (codified as amended at 42 U.S.C. §§ 1395-1395ll); Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, § 214, 111 Stat. 2296, 2348 (codified at 21 U.S.C. § 396).

[46] *See* Linder v. United States, 268 U.S. 5, 18 (1925) ("Obviously, direct control of medical practice in the States is beyond the power of the Federal Government.").

[47] Carol R. Berry, The Dividing Line Between the Role of the FDA and the Practice of Medicine: A Historical Review and Current Analysis 2 (1997) (third-year paper, Harvard Law School) (on file with Harvard Library).

[48] *See* Gluck, *supra* note 6, at 584-85.

[49] JAMILA MICHENER, FRAGMENTED DEMOCRACY: MEDICAID, FEDERALISM, AND UNEQUAL POLITICS 39 (2018) ("[The conflicts] served to orient health care policy toward a model of federalist fragmentation. For opponents of a federally subsidized universal health care system, one key to keeping victory out of the hands of their adversaries was to offer viable but more limited alternatives." (citation omitted)). The initiatives "shared a common denominator: they afforded states and localities tremendous power and resources." *Id.* at 40.

funds for state programs to support maternal and infant health,[50] the Hill Burton Hospital Survey and Construction Act of 1946 distributed funds to local entities to build hospitals,[51] and other similar programs culminated in Medicaid, which delegated significant powers to states to run health programs for the poor, with federal funding, baselines, and oversight.[52]

The ACA—the focus of healthcare federalism in the last decade—adopts this kind of approach. A key feature of the ACA is that it provides for insurance exchanges: virtual insurance marketplaces where consumers who may otherwise lack sufficient coverage can buy insurance products that conform to certain guidelines and come with certain protections.[53] This story tracks the other stories in the health world. The solidly Democrat-controlled House's version of the ACA contemplated only federal exchanges. But this met opposition in the Senate—where the Democrats had recently lost their sixtieth vote—by Senators who did not or could not support the full-throated nationalized version of the ACA and demanded that states have the option of first refusal as the price of their support.[54] Once more, those who were less supportive of, or opposed to, a federal health program demanded state federalization as a condition of its passage.

Third, the federal government may not always coordinate with state entities. What I call interstitial federalism imagines contexts in which federal and state governments legislate jointly in a specific field. Unlike cooperative federalism, there is no formal arrangement between the two governments. *If* they choose to, states can legislate in the interstices that the federal government has not occupied, but federal statute is indifferent as to whether they do so (unlike cooperative federalism arrangements where states are assigned particular tasks). Thus, as some courts hold, as long as the federal government is acting pursuant to appropriate legal authority, it can incidentally infringe on the practice of medicine.[55] Similarly, as I describe below, the federal government has legislated to maintain the privacy of medical records; at the same time, it explicitly leaves room for more stringent state privacy regulation.[56]

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[50] *Id.*

[51] *Id.*

[52] *See id.* at 40-48 (naming Social Security Act Amendments of 1950, which authorized federal grants to states for aid to dependent children and maternal and child welfare, as another example of statute leading to Medicaid); *see also* Social Security Amendments of 1965 (Medicaid), Pub. L. No. 89-97, § 121, 79 Stat. 286, 343-352 (codified as amended at 42 U.S.C. §§ 1396-1 to 1396d); Nicole Huberfeld, Elizabeth Weeks Leonard & Kevin Outterson, *Plunging into Endless Difficulties: Medicaid and Coercion in* National Federation of Independent Business v. Sebelius, 93 B.U. L. REV. 1, 15 (2013).

[53] 42 U.S.C. § 18001.

[54] Gluck, *supra* note 6, at 575, 578 & n.118.

[55] *See, e.g.*, Pharm. Mfrs. Ass'n v. FDA, 484 F. Supp. 1179, 1187-88 (D. Del.), *aff'd*, 634 F.2d 106 (3d Cir. 1980).

[56] *See infra* Section III.B.

These traditional models of federalism can morph into each other over time. While some courts and commentators jealously police the boundaries of regulation,[57] others are open to an overlapping approach. This, some scholars argue, is in fact the case with the practice of medicine. While Congress, courts, and scholarship may pay lip service to state autonomy over the practice of medicine, in fact there is overlapping jurisdiction on this front.[58] Some scholars argue for hybrid models in context, such as life sciences innovations and licensing.[59] And collaboration, conflict, and litigation may transform one federalism model into another.[60]

The models of federalism I offer are ideal types—but they roughly capture how the existing scholarship conceptualizes the regulation of existing healthcare resources. The separate spheres narrative permeates medical professional regulation (which falls within state prerogatives) through malpractice and licensing laws.[61] On the flipside, drugs and devices are regulated by the federal government.[62] Cooperative federalism describes healthcare financing—the federal government runs point but delegates significant functions to the states.[63] What is key is that in each of these models there are two entities involved—states and the federal government.

But these traditional federalism models of healthcare regulation do not tell the full story because they do not consider all the resources upon which healthcare relies. When it comes to health data, there is little to no federalism scholarship, apart from articles on privacy law—generally all pertaining to a single set of federal privacy rules.[64] Even when some scholars purport to consider federalism and health data technology, they do so in the context of professional regulation

[57] *See* Cal. State Bd. of Optometry v. FTC, 910 F.2d 976, 982 (D.C. Cir. 1990) (noting federal agencies "may not exercise authority over States as sovereigns unless that authority has been unambiguously granted to it" while finding FTC exceeded power in promulgating rule regarding optometry); FTC v. Simeon Mgmt. Corp., 391 F. Supp. 697, 705 (N.D. Cal. 1975), *aff'd*, 532 F.2d 708 (9th Cir. 1976) (denying FTC's preliminary injunction against operators of weight reduction clinics while noting the fact that FDA had not yet approved program did not mean program lacked acceptance within medical community).

[58] Noah, *supra* note 8, at 150 ("Recent federal initiatives, however, represent a potentially serious assault on that tradition of deference to state control over [medical practice].").

[59] Lewis, *supra* note 7, at 402 (arguing that hybrid model for life sciences like gene therapy would better regulate innovations); Scheffler, *supra* note 8, at 293 (suggesting that hybrid model for healthcare licensing would incentivize state experimentation with reforms).

[60] *See, e.g.*, FDA, *Federal and State Cooperation*, *in* INVESTIGATIONS OPERATIONS MANUAL 3-1, 3-2 (2021), https://www.fda.gov/media/75233/download [https://perma.cc/VD66-372S] (noting agreements between FDA and states arguably transform separate spheres into cooperative federalism); Gluck & Huberfeld, *supra* note 6, at 1695.

[61] *See supra* note 44 and accompanying text.

[62] *See supra* note 44 and accompanying text.

[63] *See supra* note 6 and accompanying text.

[64] That is, the Privacy Rule under HIPAA. *See supra* note 10 and accompanying text.

or payment reform.[65] Turning to health federalism analyses suggests that new models of federalism with a third entity—private entities—must be developed.

II. FEDERALISM AND STATE REGULATION OF HEALTH DATA COLLECTION

States report certain streams of health data to the federal government. This includes diseases and conditions reportable to the Centers for Disease Control[66] and specific programs such as Medicaid.[67] Further, the U.S. Constitution has limited certain kinds of data-sharing mandates under the First Amendment.[68] States have sometimes resisted such measures, most recently, in the context of sharing COVID-19 vaccine information.[69]

But these reporting mandates are piecemeal—they pertain only to reporting certain conditions to certain programs, and therefore apply to only certain individuals. The focus of this Article, however, is on *all* the data in the healthcare system—that is, on *all* the health records that contain *all* the health data of *all* individuals, no matter their condition or payment system.[70]

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[65] Kevin Outterson, *Health Care, Technology and Federalism*, 103 W. VA. L. REV. 503, 527-28 (2001) (discussing licensing issues that arise when providers treat patients remotely using technology).

[66] *See* Deborah A. Adams, Kimberly R. Thomas, Ruth Ann Jajosky, Loretta Foster, Pearl Sharp, Diana H. Onweh, Alan W. Schley & Willie J. Anderson, *Summary of Notifiable Infectious Diseases and Conditions—United States, 2014*, MORBIDITY & MORTALITY WKLY. REP., Oct. 14, 2016, at 2 (2016), https://www.cdc.gov/mmwr/volumes/63/wr/pdfs/mm6354.pdf [https://perma.cc/84CT-8NW8]. Such reporting is voluntary. *Id.* ("Although infectious disease and condition reporting is mandated at the state, territory, and local levels by legislation or regulation, state and territory notification to CDC is voluntary.").

[67] Ctrs. for Medicare & Medicaid Servs., *Submitting Accurate and Complete Encounter Data (Managed Care)*, MEDICAID.GOV, https://www.medicaid.gov/medicaid/data-and-systems/macbis/tmsis/tmsis-blog/entry/47579 [https://perma.cc/R2S4-SVK6] (last visited Dec. 5, 2021). Such reporting only applies to states that voluntarily choose to participate in Medicaid, so, in theory, it is also voluntary.

[68] Sorrell v. IMS Health Inc., 564 U.S. 552, 580 (2011) (using heightened judicial scrutiny to strike down state statute restricting disclosure of medical records).

[69] Kat Jercich, *States Push Back on Trump Admin's Request for COVID-19 Vaccine Patient Data*, HEALTHCARE IT NEWS (Dec. 10, 2020, 3:26 PM), https://www.healthcareitnews.com/news/states-push-back-trump-admins-request-covid-19-vaccine-patient-data [https://perma.cc/6DBV-EEQ5].

[70] Today, health data comes from various sources, including consumer contexts such as genetic testing, grocery purchases, or internet searches, as well as from criminal databases, and can be used for many purposes, including marketing, law enforcement, and the like. *See* W. Nicholson Price II, Margot E. Kaminski, Timo Minssen & Kayte Spector-Bagdady, *Shadow Health Records Meet New Data Privacy Laws*, 363 SCIENCE 448, 448-49 (2018). This Article focuses on data collection from medical entities like providers and payers. Data in this context includes EHR data, which comprises information on symptoms, biometrics, and demographics, such as family circumstances. It also includes billing data, which contains diagnosis codes and procedure codes, that is, information regarding the modalities used to treat the patient. Konnoth, *Health Information*, *supra* note 13, at 1324.

When it comes to this broad expanse of health records, states have generally had great autonomy. Until the early 2000s, states created and regulated the data collection infrastructure almost exclusively. Starting in the 1980s, states *collected* health data themselves for population-level health analyses.[71] In the 1990s, they created *networks* so that private entities could transmit data to each other for individual clinical care.[72] During this period, they also promulgated the first *privacy* laws.[73] While the federal government also began participating in this area starting in the 2000s, until the last few years, federal efforts largely complemented and supported state policies.[74]

This Part first explains the importance of health data regulation, and then shows how states have largely acted autonomously in this field. While there has been more hybrid regulation, especially on the privacy front, with joint federal and state regulation,[75] state primacy overall has remained.

A. *The Importance of Health Data*

Why does it matter who regulates health data? Health data is important to promote the health of individuals and the community. And corporations and other specific interests also find data attractive for their own specific goals—from making money through data sales, to discriminating against those who might cause the corporation to lose money, such as sick employees. I consider each of these purposes in turn.

The healthcare system requires medical personnel, drugs and devices, and financial support. But each of these resources is undergirded by health data. For a physician to diagnose a patient, she must receive data from laboratories, imaging equipment, and the patient herself. Often, diagnoses depend on a patient's history, which requires data to be stored and retrieved. In some cases, the data must be transmitted to specialists.[76] Upon diagnosis, a provider must transmit information to pharmacies,[77] downstream care providers like physical

[71] *See infra* Section II.B.1.

[72] *See infra* Section II.C.1.

[73] *See infra* Section II.C.1.

[74] *See infra* Section II.C.2.

[75] *See, e.g.*, Satz, *supra* note 10, at 1561 (addressing "challenges of federalism in protecting medical privacy in workers' compensation after the promulgation of the [HIPAA Privacy Rule]").

[76] Off. of the Nat'l Coordinator for Health Info. Tech., *What Is HIE?*, HEALTHIT.GOV, https://www.healthit.gov/topic/health-it-and-health-information-exchange-basics/what-hie [https://perma.cc/SJJ2-XFYL] (last reviewed July 24, 2020) ("A primary care provider can directly send electronic care summaries that include medications, problems, and lab results to a specialist when referring their patients.").

[77] *See id.*

or occupational therapists,[78] and appropriate institutional or family caretakers.[79] Providers must also transmit health information to insurance companies to obtain payment or to other providers if the patient changes providers.[80] In reality, the data exchanges go beyond these clear lines and often involve iterative interactions between these various entities—multiple providers, insurers, and auxiliaries—in order to provide healthcare.

And that is just at the level of the individual. Data is essential for public health efforts—as debates over COVID-19 surveillance and analysis showed.[81] Medical data derived from healthcare institutions has long been used to allocate resources, develop institutional policies within healthcare entities, and carry out public health interventions at the institutional level.[82] In the long run, individual and population level interventions will merge. The vision of the "learning health system" promises a world in which yottabytes of real-time health data will be analyzed to determine how precisely to treat patients with specific traits.[83] The system will hold data regarding the treatment outcomes for each patient, and with each new data point, the system will more finely calibrate its approach.[84] The system might advise minute variations in amounts and times of dosage, in treatment approaches, or even in probable diagnoses, among other possibilities, to optimize treatment for a specific patient.[85] In this ultimate form, data from each patient encounter will be fed back into the system and will calibrate treatment guidelines for the next patient in real time, in a "continuous feedback loop."[86]

Collecting, transmitting, and analyzing data within the health ecosystem clearly has its uses. However, there is demand for this data outside the system as well. Firms see health data as a boon for targeted marketing: mattress

[78] *See id.*

[79] U.S. Dep't of Health & Hum. Servs., *Does the HIPAA Privacy Rule Permit a Doctor to Discuss a Patient's Health Status, Treatment, or Payment Arrangements with the Patient's Family and Friends?*, HHS.GOV, https://www.hhs.gov/hipaa/for-professionals/faq/488/does-hipaa-permit-a-doctor-to-discuss-a-patients-health-status-with-the-patients-family-and-friends/index.html [https://perma.cc/FA3H-6U4K] (last reviewed July 26, 2013) (concluding Privacy Rule allows doctors to disclose patient information to family or friends).

[80] 45 C.F.R. § 164.506 (2021).

[81] *See, e.g.*, Leslie Lenert & Brooke Yeager McSwain, *Balancing Health Privacy, Health Information Exchange, and Research in the Context of the COVID-19 Pandemic*, 27 J. AM. MED. INFORMATICS ASS'N 963, 963 (2020).

[82] INST. OF MED., HEALTH DATA IN THE INFORMATION AGE: USE, DISCLOSURE, AND PRIVACY 41 (Molla S. Donaldson & Kathleen N. Lohr eds., 1994).

[83] *See* Konnoth, *Health Information*, *supra* note 13, at 1319, 1372 n.262; INST. OF MED., *supra* note 82, at 5.

[84] INST. OF MED., *supra* note 82, at 14.

[85] *See* Konnoth, *Health Information*, *supra* note 13, at 1319.

[86] *Id.*

companies want to know who has sleeping dysfunctions,[87] department stores seek data about who is pregnant,[88] and gyms and grocery stores market to those with eating disorders.[89] Employers use the data for a range of purposes from determining worker productivity to health; employees with health conditions regularly experience hard-to-detect discrimination.[90] Law enforcement uses biometric and genetic data for a range of law enforcement purposes.[91] Insurance companies can use health data to discriminate in various ways, though their discrimination is limited both by the ACA and state laws.[92] Thus, there is pressure to have healthcare data leave the healthcare ecosystem in ways that would increase the profit of various actors. Massive data brokers—which others have described in detail—trade in health data that comes from medical and other sources to cater to this appetite, which has raised significant privacy concerns.[93]

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Thus, whether simply seeking to transmit individual health data for treatment or to agglomerate population level data for a learning health system, there is a range of regulation. States historically took the primary role in regulating the vast expanse of health data in three ways. They have sought to enable data *collection* in part for the research purposes I describe above. They regulate data *transmission* to enable the treatment of particular patients as well as for research purposes. And third, they took the lead on *privacy* regulation to limit the spillover of data outside the healthcare ecosystem.

[87] DAN GOLDMAN, MCKINSEY & CO., INVESTING IN THE GROWING SLEEP-HEALTH ECONOMY 2 (2017), https://www.mckinsey.com/~/media/mckinsey/industries/private%20equity%20and%20principal%20investors/our%20insights/investing%20in%20the%20growing%20sleep%20health%20economy/investing-in-the-growing-sleep-health-economy.ashx [https://perma.cc/D2HV-Q5R8].

[88] Kashmir Hill, *How Target Figured Out a Teen Girl Was Pregnant Before Her Father Did*, FORBES (Feb. 16, 2012, 11:02 AM), https://www.forbes.com/sites/kashmirhill/2012/02/16/how-target-figured-out-a-teen-girl-was-pregnant-before-her-father-did/#3a0620a16668.

[89] Maria LaMagna, *The Unexpected Costs of Eating Disorders*, MARKETWATCH (Mar. 3, 2018, 1:34 PM), https://www.marketwatch.com/story/the-unexpected-costs-of-eating-disorders-2018-03-01 [https://perma.cc/8YUR-GQ5N].

[90] Ifeoma Ajunwa, Kate Crawford & Jason Schultz, *Limitless Worker Surveillance*, 105 CALIF. L. REV. 735, 739, 763 (2017).

[91] Natalie Ram, *Genetic Privacy After* Carpenter, 105 VA. L. REV. 1357, 1359 (2019) (explaining how online third-party DNA database helped lead to arrest of the Golden State Killer).

[92] Craig Konnoth, *Medicalization and the New Civil Rights*, 72 STAN. L. REV. 1165, 1229 (2020).

[93] Adam Tanner, *For Sale: Your Medical Records*, SCI. AM., Feb. 2016, at 26, 26-27.

B. *Data Collection*

Modern state data collection efforts have roots in the 1980s cost crisis and the electronization of medical data. They involved public-private participation—but governments had the final say.[94] Those efforts grew into modern all-payer claims databases ("APCDs"), which mandate all payers, including private payers, to submit billing data for all insured residents in the state to a central state entity.[95] While several states have such APCDs, the federal government does not.

1. Early Collection Efforts

State public health data collection laws date back at least a century; the Gilded Age saw a push in requirements to report contagious diseases.[96] In the middle of the twentieth century, there was an additional push to link health data to vital statistics.[97] In the 1970s, the federal government encouraged states to collect data as part of a larger federal-state program involving health delivery reform.[98] But the notion of comprehensive health data collection appears to have taken root only in the 1980s, as data became electronic; states sought to collect data from all providers—including private ones.[99] The federal government, by contrast, to this day comprehensively collects only Medicare and Medicaid data, which, of course, concerns the claims of only public beneficiaries.[100]

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[94] *See, e.g.*, Act of Sept. 23, 1984, ch. 1326, 1984 Cal. Stat. 4568 (creating advisory commission which would send data to Office of Statewide Health Planning and Development).

[95] *See* Konnoth, *Health Information*, *supra* note 13, at 1330-31 (stating nearly twenty states have APCDs, which have become "the largest source of private claims data for research").

[96] *See, e.g.*, Philip M. Teigen, *Legislating Fear and the Public Health in Gilded Age Massachusetts*, 62 J. HIST. MED. & ALLIED SCI. 141, 143-44 (2006) (explaining how rabies outbreak of 1876-1881 created new requirements and regulations in Massachusetts).

[97] *See, e.g.*, Nat'l Ctr. For Health Stat., *The U.S. Vital Statistics System: A National Perspective*, *in* NAT'L RSCH. COUNCIL, VITAL STATISTICS: SUMMARY OF A WORKSHOP 87, 88 (Michael J. Siri & Daniel L. Cork eds., 2009).

[98] Under the National Health Planning and Resources Development Act of 1974, Pub. L. No. 93-641, sec. 3, § 1513, 88 Stat. 2225, 2236 (1975) (repealed 1986), entities were asked to "assemble and analyze data concerning," inter alia, healthcare delivery; "the number, type, and location of the area's health resources, including health services, manpower, and facilities"; and "patterns of utilization." *See also* Health Services Research, Health Statistics, and Medical Libraries Act of 1974, Pub. L. No. 93-353, sec. 105, § 306, 88 Stat. 362, 365-66 (codified as amended at 42 U.S.C. § 242k) (charged with helping in "the design and implementation of a cooperative system for producing comparable and uniform health information and statistics at the Federal, State, and local levels").

[99] *See infra* notes 104-122 and accompanying text.

[100] *See* Konnoth, *Health Information*, *supra* note 13, at 1325-26 (noting that Centers for Medicare and Medicaid Services ("CMS") "now mandate[] the use of electronic health records").

In the 1980s, American healthcare faced a cost crisis.[101] The inflation and oil shocks of the 1970s, the lack of a single-payer system and otherwise limited social safety net, and the explosion of novel medical technology all contributed to rising spending on healthcare.[102] The healthcare system responded with a variety of innovations: most famously, the explosion of health maintenance organizations ("HMOs"), a payment model which involved shifting risk to patients and providers through limited networks, co-payments, and payment caps.[103]

Another innovation was the development of state health data collection efforts. Iowa was one of the first movers in this space. In 1983, citing the need to control exploding health costs, the state legislature created the "health data commission," which could mandate data collection from healthcare providers, third-party payers, and the state Medicaid program.[104] The commission's existence was reenacted in subsequent years, each time subject to a sunset provision until it was made permanent in 1989.[105] Data was collected in various formats, including magnetic tapes.[106] Many states followed the Iowa model, including Oregon and Colorado in 1985.[107] In the next decade, numerous other states followed suit, including Indiana,[108] Arkansas (which declared the lack of

[101] *See* Brief for Petitioner at 4-9, Gobeille v. Liberty Mut. Ins. Co., 136 S. Ct. 936 (2016) (No. 14-181) (noting states collected public health data and federal government provided support, but these efforts were "limited" relying primarily on "hospital discharge data" rather than multiple sources); *see also* Brief for Amici Curiae National Governors Ass'n et al. in Support of Petitioner at 5-7, *Gobeille*, 136 S. Ct. 936 (No. 14-181) [hereinafter Nat'l Governors Ass'n Brief] (explaining how hospital discharge data ignores data from non-hospital contexts that comprise majority of healthcare).

[102] Austin Frakt, *Medical Mystery: Something Happened to U.S. Health Spending After 1980*, N.Y. TIMES (May 14, 2018), https://www.nytimes.com/2018/05/14/upshot/medical-mystery-health-spending-1980.html.

[103] Lynn R. Gruber, Maureen Shadle & Cynthia L. Polich, *From Movement to Industry: The Growth of HMOs*, HEALTH AFFS., Summer 1988, at 197, 197.

[104] Act of Apr. 26, 1983, ch. 27, 1983 Iowa Acts 40.

[105] Act of Mar. 30, 1989, ch. 23, 1989 Iowa Acts 27.

[106] Act of June 3, 1992, ch. 1237, § 4.1(e), 1992 Iowa Acts 596, 598.

[107] Act of July 1, 1985, ch. 747, § 14, 1985 Or. Laws 1718, 1723-24; Act of June 6, 1985, ch. 224, 1985 Colo. Sess. Laws 929. The following year, the Colorado legislature specified elements that had to be collected, including diagnosis and findings or information related to discharge. Act of May 28, 1986, ch. 196, § 2, 1986 Colo. Sess. Laws 982, 983.

[108] Act of Feb. 25, 1988, P.L. 36-1988, § 2, 1988 Ind. Acts 945, 946-47.

health data availability an "emergency"),[109] New Mexico,[110] Virginia,[111] Utah,[112] Oklahoma,[113] South Carolina,[114] and Texas,[115] among others. This is likely an incomplete list as some agencies may have engaged in collection efforts without legislation—indeed, as discussed below, some collection efforts were authorized in large part through executive orders.

These data collecting entities were largely state government bodies. Some of these entities were set up as agencies within the appropriate health department, with various powers.[116] Others were set up as advisory committees or councils to government bodies.[117] In such cases, most states mandated that the entity's members be appointed by the governor with the advice and consent of the state senate.[118] Many states designated specific government officials such as the commissioner of insurance or the chief health officer as members of the body; some states included legislators as well.[119]

Some states required private-public collaboration in innovative ways. For example, the Connecticut entity was run by an executive director appointed by the state agency based out of the University of Connecticut.[120] In addition to the agency, however, the legislation mandated an advisory board comprised of representatives from private groups.[121] The government entity had the final say unless a *majority* of the private board objected, in which case the issue would be

[109] Act of Feb. 20, 1989, No. 107, § 7, 1989 Ark. Acts 175, 178.

[110] Health Information System Act, ch. 29, §§ 3, 4, 1989 N.M. Laws 209, 210-12 (creating system for "collection . . . of health information from a variety of public and private sector sources"; mandating that "[a]ll hospitals, long-term care facilities, third party payers and public sector and private sector data sources shall participate in the health information system"; imposing penalties for noncompliance; and seeking information about health behavior, health system costs, utilization, environmental factors, and socio-economic health related conditions).

[111] Act of Mar. 26, 1989, ch. 633, sec 1, §§ 32.1-122.01 to .08, 1989 Va. Acts 1005, 1012-15.

[112] Act of Mar. 13, 1990, ch. 305, 1990 Utah Laws 1437.

[113] Oklahoma Health Care Information System Act, ch. 347, 1992 Okla. Sess. Laws 1684.

[114] Act of June 14, 1993, No. 130, § 3, 1993 S.C. Acts 351, 355.

[115] Act of June 14, 1995, ch. 575, 1995 Tex. Gen. Laws 3370.

[116] *See, e.g.*, Health Information System Act, ch. 29, § 3, 1989 N.M. Laws 209, 210-12.

[117] *See* Act of Sept. 23, 1984, ch. 1326, § 7, 1984 Cal. Stat. 4566, 4568; Act of June 6, 1985, ch. 224, § 1, 1985 Colo. Sess. Laws 929, 930-31.

[118] Act of June 6, 1985, § 2, 1985 Colo. Sess. Laws at 930 (requiring seven-member commission be appointed by governor with consent of senate, among other requirements); Act of Mar. 13, 1990, ch. 305, § 4, 1990 Utah Laws 1437, 1438 (requiring eleven-member commission appointed by governor with consent of senate). *But see* Act of Sept. 23, 1984, § 7, 1984 Cal. Stat. at 4568 (chairperson of advisory council appointed by governor without senate involvement).

[119] Act of Apr. 26, 1983, ch. 27, § 2, 1983 Iowa Acts 40, 41.

[120] Act of July 1, 1994, Pub. Act No. 94-3, §§ 9, 12, 1994 Conn. Acts 1343, 1347, 1349-50 (Spec. Sess.).

[121] *Id.* § 12, 1994 Conn. Acts at 1350.

decided by senior officials in the state health agency.[122] The bottom line, however, was that the state had the final say over the information collection system.

2. All-Payer Claims Databases

These early efforts set the stage for the modern collection systems that states have put into place. Today, APCDs comprise the primary form of comprehensive health data collection in most states.[123] These databases do not contain all health data that providers may collect, including clinical notes. Rather, they consist of the data that hospitals, providers (such as mental health providers), and pharmacists send to insurance companies for reimbursement.[124] This includes diagnoses, types of procedures carried out or drugs sold, and other information, including data about member demographics, necessary to allow the payer to adjudicate and provide payment.[125]

APCDs require all insurance payers for healthcare services in the state—public and private—to submit claims data to a centralized state agency.[126] As of 2016, between twenty to thirty states had implemented, or had made moves towards implementing, APCDs.[127] These databases do not just provide information about cost and price transparency for consumers but also allow states to assess healthcare access and quality of care across each state, especially for low-income groups, and allow states to cross-check clinical and electronic health records data received from other entities for accuracy.[128]

As states and others explain, such databases are useful for a range of purposes. They allow states to determine the capacity of the state's healthcare resource and health needs.[129] This is essential to determining how to handle crises like

[122] *Id.*

[123] States do require hospitals to provide data. *See* Brief for Petitioner, *supra* note 101, at 4-9. However, hospital discharge data is hardly comprehensive. *Id.*

[124] *See, e.g.*, Act of Nov. 1, 1995, ch. 310, § 56, 1995 N.H. Laws 1, 35. Colorado is an interesting exception. The agency was prohibited from collecting data from third-party payers in 1991, though that authority was later restored. *See* Act of May 1, 1991, ch. 183, § 2, 1991 Colo. Sess. Laws 1002, 1003.

[125] *See, e.g.*, 21-040-021 VT. CODE R. §§ 3-4 (2021); Liberty Mut. Ins. Co. v. Donegan, 746 F.3d 497, 509-10 (2d Cir. 2014) (analyzing Vermont statute and regulation briefly).

[126] *See* JENNIFER RICARDS & LYNN BLEWETT, STATE HEALTH ACCESS DATA ASSISTANCE CTR., MAKING USE OF ALL-PAYER CLAIMS DATABASES FOR HEALTH CARE REFORM EVALUATION 2-4 (2014), https://www.shadac.org/sites/default/files/Old_files/shadac/publications/ACADataAnalytics_Paper%20%231%20Making%20Use%20of%20APCDs%20for%20web_0.pdf [https://perma.cc/TYE6-9SSC].

[127] Gobeille v. Liberty Mut. Ins. Co., 136 S. Ct. 936, 940-41 (2016); *Interactive State Report Map*, APCD COUNCIL, https://www.apcdcouncil.org/state/map [https://perma.cc/GL7X-5JJK] (last visited Dec. 5, 2021) (providing status of APCDs in each state).

[128] RICARDS & BLEWETT, *supra* note 126, at 2; Konnoth, *Health Information*, *supra* note 13, at 1320.

[129] VT. STAT. ANN. tit. 18, § 9410(a)(1) (2021).

COVID-19, addressing health disparities that minorities face, and reducing health costs.[130] They help states determine how best to reimburse providers for state health programs based on how much value they provide—that is, based not just on the number of patients they see but on how sick the patients are and how much the treatment they receive improves their health.[131] They also allow states to assess the effects of certain health intervention programs and to compare different treatment approaches.[132] This has allowed states to study issues involving opioid and tobacco use and cancer trends to name a few.[133] Finally, these databases allow states to increase transparency by providing information to consumers and others who purchase healthcare.[134]

[130] *See* Statement, Richard Gottfried, Assembly Health Comm. Chair, New York State Assembly, State Budget Includes Major Health Reforms (Mar. 31, 2011), https://www.assembly.state.ny.us/mem/Richard-N-Gottfried/story/41695 [https://perma.cc/RLQ8-9D3H] (stating APCD would "go a long way to improving the quality of care and controlling costs"); LINDA GREEN, AMY LISCHKO & TANYA BERNSTEIN, FREEDMAN HEALTHCARE, LLC, REALIZING THE POTENTIAL OF ALL-PAYER CLAIMS DATABASES 3 (2014) (discussing how APCD data can improve quality of care); *see also* Brief for the States of New York, Maryland, Massachusetts, New Hampshire, Oregon, and Utah as Amici Curiae in Support of Petitioner at 5, *Gobeille*, 136 S. Ct. 936 (No. 14-181) [hereinafter N.Y. Amicus Brief I] (noting New York's statute allows its Commissioner of Health to use APCD data to assess reform efforts, analyze healthcare disparities, and identify communities that provide cost-effective care "in ways that could be applied elsewhere").

[131] Brief of Amici Curiae American Hospital Ass'n & Ass'n of American Medical Colleges in Support of Petitioner at 4, 15, *Gobeille*, 136 S. Ct. 936 (No. 14-181) [hereinafter Hosp. Ass'n Brief]. For a discussion of value-based payment, see generally Sylvia M. Burwell, *Setting Value-Based Payment Goals—HHS Efforts to Improve U.S. Health Care*, 372 NEW ENG. J. MED. 897 (2015).

[132] *See* VT. STAT. ANN. tit. 18, § 9410(a)(1); Act of June 19, 2013, Pub. Act No. 13-247, § 144, 2013 Conn. Acts 1399, 1527 (Reg. Sess.) ("The [APCD] Group shall develop a plan . . . to increase efficiency, enhance outcomes and improve the understanding of health care expenditures in the public and private sectors."); *Identify Opportunities to Reduce Use of Potentially Harmful Medications During and Post Surgery*, APCD SHOWCASE (Mar. 2015), https://www.apcdshowcase.org/content/identify-opportunities-reduce-use-potentially-harmful-medications-during-and-post-surgery [https://perma.cc/CCA2-9ESU] (studying opioid prescriptions after surgery); Christine Vestal, *Debating the Value of an All-Payer Claims Database*, MEDCITY NEWS (June 19, 2014, 11:01 AM), https://medcitynews.com/2014/06/debating-value-payer-claims-databases/ [https://perma.cc/YL4A-SJY2] (tracking whether doctors have followed nationally recommended medical protocols).

[133] Brief for the States of New York, Colorado, Connecticut, Hawai'i, Illinois, Kansas, Maine, Maryland, Massachusetts, Minnesota, Nebraska, Oregon, Rhode Island, Tennessee, Texas, Utah, and Washington, and the District of Columbia, as Amici Curiae in Support of Petitioner at 10-17, *Gobeille*, 136 S. Ct. 936 (No. 14-181) [hereinafter N.Y. Amicus Brief II].

[134] VT. STAT. ANN. tit. 18, § 9410(a)(1); Hosp. Ass'n Brief, *supra* note 131, at 14.

The federal government has begun to support these efforts; for example, Connecticut received a $6.5 million grant to implement its database.[135] Similarly, the ACA instructed federal research entities to test models of payment reform by, inter alia, "[a]llowing States to test and evaluate systems of all-payer payment reform for the medical care of residents of the State."[136] At the same time, "[v]arious business interests, including those of payers and employers, are represented and often specifically identified by state law" in running the APCD.[137]

These efforts remain state led: as the United States acknowledged before the Supreme Court in 2015, "no federal agency has created an all-payer database that encompasses" all employee plans, and "[s]tates are uniquely positioned to improve quality of care and to control costs through the collection and publication of claims data."[138]

C. *Data Networks and Exchange*

If the mid-1980s saw the advent of state data *collection*, the mid-1990s saw the vanguard of state data networks for data *transmission*. Unlike with data collection, which promotes research, the goal of this early network creation was to promote clinical care.[139] With an efficient network, data followed patients if they moved from one provider to another, allowing for efficient transmission to payers and others who paid for claims.[140]

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[135] N.Y. Amicus Brief I, *supra* note 130, at 3; *see also* ACCESS HEALTH CT, CONNECTICUT ALL PAYERS CLAIMS DATABASE: DATA SUBMISSION GUIDE 5 (2013), https://agency.accesshealthct.com/wp-content/uploads/2016/11/Data_Submission_Guide_-_All-Payer_Claims_Database_20131205.pdf [https://perma.cc/VM5D-6X6Z]; *State Innovation Models Initiative: Model Test Awards Round Two*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://innovation.cms.gov/innovation-models/state-innovations-model-testing-round-two [https://perma.cc/H5DA-SYLH] (last updated Oct. 8, 2021) (displaying CMS funding for APCDs); Brief for the United States as Amicus Curiae at 21, *Gobeille*, 136 S. Ct. 936 (No. 14-181) [hereinafter U.S. Merits Stage Brief] (describing how "federal Center for Medicare and Medicaid Innovation . . . funds a variety of state-conducted models").

[136] 42 U.S.C. § 1315a(b)(2)(B)(xi).

[137] Brief of Amici Curiae the National Ass'n of Health Data Organizations (NAHDO), et al. in Support of Petitioner at 14, 15, *Gobeille*, 136 S. Ct. 936 (No. 14-181) [hereinafter NAHDO Brief] (noting payer representation on Vermont board); *see also* VT. STAT. ANN. tit. 18, § 9374(e)(1) ("The Board shall establish a consumer, patient, business, and health care professional advisory group to provide input and recommendations to the Board."); ME. REV. STAT. ANN. tit. 22, §§ 8702, 8703 (2020) (requiring that board include two representatives of third-party payors); MASS. GEN. LAWS ch. 12C, § 5 (2020) (establishing consultation requirement with payers to ensure requirements are not too broad); ARK. CODE ANN. § 23-61-905 (2021) (stating duties of Arkansas Healthcare Transparency Initiative Board).

[138] U.S. Merits Stage Brief, *supra* note 135, at 22.

[139] *Interoperability in Healthcare*, HEALTHCARE INFO. & MGMT. SYS. SOC'Y, https://www.himss.org/resources/interoperability-healthcare#Part2 [https://perma.cc/9ASD-UHPH] (last visited Dec. 5, 2021).

[140] *Id.*

Promoting data exchange through networks consisted of two efforts. First, it required creating the electronic *network* infrastructure for the actual network exchange—what experts refer to as "structural interoperability."[141] But even before electronic networks were technologically possible, states recognized that exchange required consistent data *formats* so that one system could understand the data format used by another system—that is, "semantic interoperability."[142] For example, hospitals and insurance companies would store information in different formats—meaning that before sending the data, hospitals would have to manipulate the formats and fields of the data they sent to each insurance company so that the latter's systems could read their claims.[143] Such conditions harmed data exchange—uniform formats were needed.

These two components—*data formats* and *electronic networks*—chart the process of developing data networks and exchange. In this Section, I describe how states promoted data exchange on networks in the 1990s. I then show how the federal government began to intervene in the 2000s. States, however, retained great control.

1. State Network Development in the 1980s and 1990s

Transmission required the state to create uniform data *formats* and then build *networks.* States implemented these processes along two tracks. First, there was government reporting: entities had to transfer data to the state, including to the APCDs and their precursors.[144] In its next phase, *government* collection, these programs sought to promote data sharing among private healthcare entities.[145]

At first, government reporting involved large payers conveying billing data to the precursors of state APCDs and other programs like Medicaid.[146] When it came to the APCD precursors in the 1980s, the focus was on semantic interoperability; for example, Iowa's original 1983 law required the use of a

[141] As the leading health data industry organization, Healthcare Information and Management Systems Society, Inc. ("HIMSS") explains, foundational interoperability "allows data exchange from one information technology system to be received by another and does not require the ability for the receiving information technology system to interpret the data," structural interoperability ensures "that the clinical or operational purpose and meaning of the data is preserved," and semantic interoperability allows the "receiving . . . systems [to] interpret the data." HEALTHCARE INFO. & MGMT. SYS. SOC'Y, INC., HIMSS DICTIONARY OF HEALTH INFORMATION TECHNOLOGY TERMS, ACRONYMS, AND ORGANIZATIONS 117 (4th ed. 2017); *Interoperability in Healthcare*, *supra* note 139.

[142] HEALTHCARE INFO. & MGMT. SYS. SOC'Y, INC., *supra* note 141, at 117.

[143] Epstein, *supra* note 10, at 750.

[144] *See supra* Section II.B.

[145] *See, e.g.*, *About DHIN*, DEL. HEALTH INFO. NETWORK, https://dhin.org/about/ [https://perma.cc/5ZQY-RLLB] (last visited Dec. 5, 2021) ("Delaware Health Information Network's roots reach back to 1997 when the Delaware General Assembly enacted the organization as a public/private partnership.").

[146] *See supra* note 98 and accompanying text.

uniform billing form and the use of uniform definitions.[147] By the end of the decade, other states recognized that, given the proliferation of technology (at the time, in the form of magnetic tape in addition to electronic transmission), electronic interoperability was necessary.[148] Those specifications have remained in place as APCDs have developed, with large insurers (such as Aetna, Cigna, Humana, and Kaiser Permanente) collaborating with states and each other.[149]

As only payment data was involved, proto-APCD submissions of the 1980s generally involved a few large insurance companies—formats had to be standard, but there was no need for electronic network infrastructure.[150] That changed, however, when state Medicaid programs began to collect data from *providers*. Providers far outnumbered payers, and the network involved would be larger: each individual doctor's office potentially would be submitting data to the state.[151] The state thus needed not just to create standard *formats* but also a *network* these providers could use to submit to Medicaid.

Thus, in the 1990s, as electronic transmission became a possibility, the focus expanded from semantic interoperability (formats) to include structural interoperability (networks).[152] Again, this was primarily in the context of submission to the government, namely for state benefit programs such as Medicaid. States mandated electronic submission of claims.[153] Thus, in 1994, Ohio created the first compulsory electronic submission system, which mandated that the state's "health data advisory committee, shall establish a statewide, uniform electronic system that will simultaneously transact claims under public health care programs and submit data to the Ohio health care data center."[154] It further provided that "[no] person . . . transacting claims under a public health care program shall fail to use the electronic system."[155]

The uniform formats and networks I have described so far supported submission of data by payers and providers to *the government*. But various

[147] Act of Apr. 26, 1983, ch. 27, § 3, 1983 Iowa Acts 40, 42.

[148] *See, e.g.*, Act of Apr. 15, 1994, ch. 512, § 8, 1994 Ky. Acts 1871, 1879 (requiring uniformity of data elements "which may be in the form of magnetic computer tape, computer diskettes, or other electronic media, or through an electronic network, or in the form of hard copy"); Act of Mar. 13, 1990, ch. 305, 1990 Utah Laws 1437 (setting up coding mechanisms and uniform identification systems).

[149] Nat'l Governors Ass'n Brief, *supra* note 101, at 15.

[150] *Id.*

[151] *See* Louis Enriquez-Sarano, Note, *Data-Rich and Knowledge-Poor: How Privacy Law Privatized Medical Data and What to Do About It*, 120 COLUM. L. REV. 2319, 2335 (2020).

[152] *See* HEALTHCARE INFO. & MGMT. SYS. SOC'Y, INC., *supra* note 141, at 117.

[153] *See, e.g.*, Act of Apr. 28, 1993, ch. 62, 1993 Iowa Acts 95; Act of Aug. 8, 1993, Pub. Act No. 88-308, 1993 Ill. Laws 2601 (encouraging providers to transmit claims electronically to the state); Act of July 1, 1994, Pub. Act No. 94-3, §§ 12, 16, 1994 Conn. Acts 1343, 1349-50, 1352 (Spec. Sess.) (encouraging electronic submission and mandating standardized formats); Act of Aug. 10, 1994, Sub. H.B. No. 499, § 1, 1994 Ohio Laws 6243, 6244.

[154] Act of Aug. 10, 1994, § 1, 1994 Ohio Laws at 6243, 6244.

[155] *Id.*

jurisdictions simultaneously also began to see the potential of health data programs where data were exchanged between *private* entities, rather than being submitted to the state.[156] While (the scant) existing scholarship on state networks gives credit to North Carolina for creating the infrastructure for the first network in 1994,[157] Puerto Rico was the first to offer the legislative vision for such a network in 1988.[158] But true growth of data networks only came when *electronic* transmission and interoperability became possible in the mid-1990s and could build on the Medicaid submission systems. The period thus saw a flurry of state legislation. After a 1995 study, New Jersey provided "annual funding to the Department of Health and Senior Services (DHSS) for strategic investments in the information technology (IT) infrastructure of the health care system" and passed "the [Healthcare Information Networks and Technologies] law, which created a regulatory framework to standardize administrative transactions related to health insurance."[159] That same year, Ohio followed suit.[160] The bug struck even some rural states: in 1995, West Virginia created an advisory committee to determine methods for the "development of health information systems that will allow for the electronic transmittal of data" within the state.[161] Several modern state networks trace their histories back to these efforts of the mid-1990s.[162]

[156] *See, e.g.*, Act of Apr. 22, 1994, Sub. H.B. No. 715, sec. 129, § 48.01, 1994 Ohio Laws 7047, 7555.

[157] Epstein, *supra* note 10, at 752.

[158] As the Puerto Rico legislature explained: "information is not organized, nor does it have the uniformity needed to facilitate its analysis . . . and use." Act of July 21, 1988, No. 120, pmbl, 1988 P.R. Laws 508, 508. It therefore set up a "Coordinating Committee" to create a "master plan" that spanned health entities across the state. *Id.* § 1, 1988 P.R. Laws at 509-10.

[159] CLIFTON R. LACY, REPORT ON HEALTHCARE INFORMATION NETWORKS & TECHNOLOGIES (HINT) INITIATIVES IN NEW JERSEY 3 (2003) (explaining 1995 study on "Health Information Networks and Technologies" that anticipated savings and efficiency by using technology).

[160] Sub. H.B. No. 715, sec. 129, § 48.01, 1994 Ohio Laws at 7555 (stating that "$750,000 in fiscal year 1995 shall be distributed to the Ohio Corporation for Health Information to design and implement an inter-connected health information infrastructure").

[161] Act of Mar. 11, 1995, ch. 126, 1995 W. Va. Acts 872, 880. Other examples abound. Washington appears to have set up a "state-wide health care data system" with a "technical advisory committee," in 1993, but details are scant. Act of July 1, 1993, ch. 492, § 259, 1993 Wash. Sess. Laws 2070, 2109; *see also* Act of Mar. 4, 1994, ch. 59, § 6, 1994 N.M. Laws 570, 578 (establishing health information reporting requirements); *id.* § 16, 1994 N.M. Laws at 587 (requiring that health information issues be presented to "the New Mexico health policy commission and the legislative health care task force").

[162] *About GaHIN*, GA. HEALTH INFO. NETWORK, https://www.gahin.org/about-gahin [https://perma.cc/7LC9-SJG9] (last visited Dec. 5, 2021) (outlining history of Georgia's Health Information Network and mission of organization); *About DHIN*, *supra* note 145.

2. Federal Involvement

While states initially took the lead on creating state networks, the federal government slowly became involved. First, the federal government acted as referee on semantic interoperability, reconciling the format standardization of both states and national professional organizations; however, states retained a major role.[163] Second, the federal government supported state networks and exchange efforts financially.[164]

First, at the level of *semantic* interoperability, the federal government stepped in as referee. Apart from states, private entities and professional organizations had also developed standard formats at the national level; the earliest developments were in the 1960s in the fields of pathology, testing, and veterinary medicine.[165] By the mid-1990s, numerous other organizations had entered the fray, including the still-foundational Health Level Seven message format standards for patient registration, orders, and observations reporting, published in October 1987.[166] Standards were developed for health claims and other financial and administrative data.[167] However, coordination across the industry was limited: as the National Committee on Vital and Health Statistics ("NCVHS") explained in 2000, unlike in banking or computer software (at the time) "there [were] no truly dominant vendors in the [healthcare] industry, nor [were] there industry action groups powerful enough to achieve voluntary convergence."[168]

Thus, by the 2000s, the United States was awash with attempts at data standardization mandates—some from states, and others from professional organizations—and the federal government had to play referee. The federal government made an early foray towards achieving semantic interoperability in 1974 when the Department of Health and Human Services ("HHS"), in coordination with NCVHS, set out the first Uniform Hospital Discharge Data

[163] *See, e.g.*, H.R. REP. NO. 104-736, at 91-92 (1996) (Conf. Rep.) (outlining standards for information transactions and data elements).

[164] *See infra* notes 180-195 and accompanying text.

[165] In the 1960s, the American Society for Testing and Materials began to set standards for "laboratory message exchange, properties for [EHR] systems, . . . and health information system security . . . ." NAT'L COMM. ON VITAL & HEALTH STATS., REPORT TO THE SECRETARY OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES ON UNIFORM DATA STANDARDS FOR PATIENT MEDICAL RECORD INFORMATION 20 (2000) [hereinafter NCVHS Report]. Simultaneously, the College of American Pathologists started developing what would become the international Systematized Nomenclature of Human and Veterinary Medicine in 1965. *Id.*

[166] *Id. See generally* W. Ed Hammond, *Health Level 7: An Application Standard for Electronic Medical Data Exchange*, 11 TOPICS HEALTH REC. MGMT. 59 (1991) (detailing Health Level Seven's formation as a group and development of data interchange standard).

[167] *FAQ*, DATA INTERCHANGE STANDARDS ASS'N, https://disa.org/technotes/technote2002_01.html [https://perma.cc/VMF3-992L] (last visited Dec. 5, 2021).

[168] NCVHS Report, *supra* note 165, at 21.

Set.[169] In 1996, Congress passed the Health Insurance Portability and Accountability Act ("HIPAA").[170] Sections 261-264 of HIPAA sought to reduce "administrative costs through [federal] adoption of certain standards for information transactions (including enrollment, disenrollment, claims attachments, and coordination of benefits)."[171] The HHS Secretary was given the task of promulgating these standards: he could either borrow from a private standards setting organization, or adopt more efficient standards of his own through rulemaking.[172]

While it seemed like the federal government was displacing the states' role in developing standard formats, that was not the case. The federal government set out some relatively broad standards but left the task of implementation to states and private entities.[173] As a result, HIPAA actually encouraged *states* to take the lead on implementation.

Thus, prominent state-run data "collaboratives," sprung up to implement the semantic interoperability mandates of HIPAA.[174] As Wendy Epstein concluded based on many interviews, these collaboratives provided "implementation procedures and 'best practices' so that the vision of Congress and HHS c[ould] actually be realized."[175] They sought "to offset the financial burden of HIPAA implementation through a collaborative process,"[176] and thus provided the standardization for many state health data collection efforts.[177] One prominent example is North Carolina's collaborative, which became completely fee

[169] Fernando M. Trevino, *Uniform Minimum Data Sets: In Search of Demographic Comparability*, 78 AM. J. PUB. HEALTH 126, 127 (1988).

[170] Health Insurance Portability & Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936.

[171] Cong. Rsch. Serv., *Summary: H.R.3063—104th Congress (1995-1996)*, CONGRESS.GOV, https://www.congress.gov/bill/104th-congress/house-bill/3063 (last visited Dec. 5, 2021); *see also* Health Insurance Portability & Accountability Act of 1996, §§ 261-264, 110 Stat. at 2021-34 (codified as amended at 42 U.S.C. §§ 242k, 1320d to 1320d-8).

[172] H.R. REP. NO. 104-736, at 264 (1996). For detailed guidelines, see generally HIPAA Administrative Simplification: Standards for Electronic Health Care Claims Attachments, 70 Fed. Reg. 55,990 (proposed Sept. 23, 2005) (to be codified at 45 C.F.R. pt. 162); and Health Insurance Reform: Standards for Electronic Transactions, 65 Fed. Reg. 50,312 (Aug. 17, 2000) (to be codified at 45 C.F.R. pts. 160, 162).

[173] *See supra* notes 169-171.

[174] Epstein, *supra* note 10, at 750-51.

[175] *Id.* at 761.

[176] *Id.* at 751 n.61.

[177] *See* NAHDO Brief, *supra* note 137, at 6-11 (describing how providers must standardize submissions, and payers must standardize payments/interactions with third-party administrators).

based.[178] Other states with collaboratives include "Utah, Minnesota, Maryland, . . . Wisconsin, Hawaii, and New Mexico."[179]

Next, on the *structural* interoperability front, the federal government stepped in as funder. As states developed their programs, they began to face funding shortfalls. In 1993, for example, South Dakota set up a "healthcare data advisory committee" to report on "national standards for clinical and administrative data and national electronic data interchange standards for the transfer of information."[180] But concrete steps were "contingent upon the receipt of federal or other funds."[181] Similarly, Minnesota envisaged that its highly sophisticated (for the time) scheme would receive funds from private sources and become "self-supporting by the end of the second year."[182]

To address this concern, among others, Congress passed the Health Information Technology for Economic and Clinical Health Act ("HITECH Act") in 2009, which infused money into the process through four funding streams; states, however, continued to run point.[183] The first funding stream provided *direct* grants to states for health information exchange ("HIE") development.[184] Of the HITECH Act's initial $2 billion in grant funding, states received over a quarter ($564 million) through this stream.[185] Participating states would collaborate with the Office of the National Coordinator for Health Information Technology ("ONC") on the planning and implementation of their individual state HIE.[186]

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[178] Epstein, *supra* note 10, at 753.

[179] *Id.* at 750-51 (footnotes omitted); *About Us*, HIPAA COW, https://hipaacow.org/about-us/ [https://perma.cc/SBS8-YTHK] (last visited Dec. 5, 2021) (describing Wisconsin's HIPAA collaborative).

[180] Act of Mar. 4, 1994, ch. 24, § 3, 1994 S.D. Sess. Laws 45, 46.

[181] *Id.* § 6, 1994 S.D. Sess. Laws at 46.

[182] Act of May 10, 1994, ch. 625, art. 9, § 8, 1994 Minn. Laws 1507, 1638.

[183] For details on the incentive programs, see Konnoth, *Health Information*, *supra* note 13, at 1325-29.

[184] Health Information Technology for Economic and Clinical Health Act, Pub. L. No. 111-5, sec. 13301, §§ 3013, 3014, 123 Stat. 226, 250-53 (2009) (codified at 42 U.S.C. §§ 300jj-33 to -34). The federal government did, however, continue HIPAA's efforts to standardize data standardization. *Id.* sec. 13101, §§ 3003-3006, 123 Stat. at 238-41 (codified as amended at 42 U.S.C. §§ 300jj-14 to -16).

[185] Off. of the Nat'l Coordinator for Health Info. Tech., *ONC Health Information Technology for Economic and Clinical Health Act Grantee List*, HEALTHIT.GOV, https://dashboard.healthit.gov/datadashboard/hitech-grantee-list.php [https://perma.cc/AQ2S-BZGQ] (last visited Dec. 5, 2021).

[186] *See generally* PRASHILA DULLABH, LAUREN HOVEY & PETRY UBRI, U.S. DEP'T OF HEALTH & HUMAN SERVS., EVALUATION OF THE STATE HEALTH INFORMATION EXCHANGE COOPERATIVE AGREEMENT PROGRAM: CASE STUDY SYNTHESIS: EXPERIENCES FROM FIVE STATES IN ENABLING HIE 6 (2013), https://www.healthit.gov/sites/default/files/casestudysynthesisdocument_2-8-13.pdf [https://perma.cc/X3JD-EV6X] (discussing focus on "developing statewide policy, governance, technical infrastructure and business practices needed to support the delivery of HIE services").

The second funding stream came from the remainder of the $2 billion, and provided significant *indirect* HIE development funds to states.[187] The stream offered funds to providers, medical schools, and other entities, prioritizing public or nonprofit hospitals and providers serving underserved populations, many of which are state run.[188] Most of the remaining money went to informatics and medical school curriculum development, a significant amount of which occurred at state-run institutions.[189]

However, perhaps the biggest transfers to states occurred through the third and fourth funding streams respectively—Medicaid transfers. Recall that the federal government pays providers directly for treating patients enrolled in Medicare, who tend to be elderly individuals. However, when it comes to Medicaid, the program for indigent individuals, *states* pay the providers and, in turn, get significant reimbursement from the federal government.[190] Under the HITECH Act, state Medicaid programs benefited from HITECH's Meaningful Use incentive program; as one industry headline recently put it, "States Cash Out in Meaningful Use Fund Matching Program."[191] Under this program, providers would receive bonuses for implementing EHR systems and transmitting data.[192] Medicare providers received direct payment from the federal government;[193] when it came to Medicaid, however, the federal government paid states, which then disbursed funds. Thus *states* received this

[187] Health Information Technology for Economic and Clinical Health Act, sec. 13301, § 3012(c)(4), 123 Stat. at 248 (codified at 42 U.S.C. § 300jj-32).

[188] *Id.*

[189] *Id.* sec. 13101, 13301, §§ 3003, 3015, 3016, 123 Stat. at 238, 256-57 (codified as amended at 42 U.S.C. § 300jj-35 to -36). For a full list of grantees, see Off. of the Nat'l Coordinator for Health Info. Tech., *supra* note 185.

[190] Tanya Feke, *How the Federal Government Funds Medicaid*, VERYWELL HEALTH (Mar. 7, 2020), https://www.verywellhealth.com/how-the-federal-government-funds-medicaid-4129352 [https://perma.cc/9SXA-2UT3].

[191] Sara Heath, *States Cash Out in Meaningful Use Fund Matching Program*, EHR INTEL. (Mar. 4, 2016), https://ehrintelligence.com/news/states-cash-out-in-meaningful-use-fund-matching-program [https://perma.cc/DE9Y-MPSQ].

[192] *Id.* ("CMS is offering 90% fund matching for meaningful use providers who practice interoperability.").

[193] *See* Konnoth, *Health Information*, *supra* note 13, at 1362-63. The effects of these programs are unclear. *See* Off. of the Nat'l Coordinator for Health Info. Tech., *Non-Federal Acute Care Hospital Electronic Health Record Adoption*, HEALTHIT.GOV, https://dashboard.healthit.gov/quickstats/pages/FIG-Hospital-EHR-Adoption.php [https://perma.cc/C4ZX-LHN5] (last reviewed July 22, 2021) (tracking use of EHR by non-federal acute care hospitals since 2008); Off. of the Nat'l Coordinator for Health Info. Tech., *Office-Based Physician Electronic Health Record Adoption*, HEALTHIT.GOV, https://dashboard.healthit.gov/quickstats/pages/physician-ehr-adoption-trends.php [https://perma.cc/2DNN-YBMZ] (last reviewed Aug. 6, 2021) (showing increased EHR use among hospitals but not necessarily among private providers).

money, and each state created its own EHR incentive program for Medicaid providers, each with their own deadlines and requirements.[194]

Second, and more importantly, in 2016, the federal government expanded the range of activities for which matching Medicaid funds were available—states could claim 90% federal reimbursement for developing HIE infrastructure for Medicaid providers.[195]

The key takeaway here is that even as the federal government intervened in health data regulation, it did so in ways that encouraged state collaboration. States were on the frontlines of implementing federal mandates. Further, states were assisted in their efforts through federal funding.

D. *Privacy Regulation*

If health data networks encourage the exchange of information, privacy law helps regulate it. States were the pioneers in putting together privacy legislation right from the outset.[196] Before the HIPAA Privacy Rule became active in 2003, numerous states created a panoply of privacy protections.[197] Many of these laws granted patients various levels of access to their health records; limited disclosure by various entities; ensured various levels of privilege in judicial and

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[194] *See Medicaid States Program Links*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentive Programs/Downloads/Medicaid_StatesProgramLinks.pdf [https://perma.cc/VB2A-E5DK] (last updated Jan. 2017) (providing list of state incentive programs).

[195] Letter from Vikki Wachino, Dir., Ctrs. for Medicare & Medicaid Servs., to State Medicaid Dir. 1 (Feb. 29, 2016), https://www.medicaid.gov/federal-policy-guidance/downloads/smd16003.pdf [https://perma.cc/8BKL-4NWS] (updating guidance "about the availability of federal funding at the 90 percent matching rate for state expenditures on activities to promote health information exchange (HIE) and encourage the adoption of certified Electronic Health Record (EHR) technology by certain Medicaid providers"). These costs therefore add significantly to the official numbers on spending on meaningful reimbursements to Medicaid providers. *See* CTRS. FOR MEDICARE & MEDICAID SERVS., COMBINED MEDICARE AND MEDICAID PAYMENTS BY STATE, https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms /Downloads/September2018_PaymentsbyStatebyProgram.pdf [https://perma.cc/6KC4-PWWN] (last visited Dec. 5, 2021).

[196] Standards for Privacy of Individually Identifiable Health Information, 64 Fed. Reg. 59,918, 59,919-20 (proposed Nov. 3, 1999) (to be codified at 45 C.F.R. pts. 160-164) ("Efforts to provide legal protection against the inappropriate use of individually identifiable health information have been, to date, undertaken primarily by the States.").

[197] *See id.* Other authors have discussed these provisions in detail, so I only touch on them here. *See, e.g.*, Jean O'Connor & Gene Matthews, *Informational Privacy, Public Health, and State Laws*, 101 AM. J. PUB. HEALTH 1845, 1846 (2011); Rebecca H. Bishop, Note, *The Final Patient Privacy Regulations Under the Health Insurance Portability and Accountability Act—Promoting Patient Privacy or Public Confusion?*, 37 GA. L. REV. 723, 740-41 (2003). *See generally* JOY PRITTS, ANGELA CHOY, LEIGH EMMART & JOANNE HUSTEAD, GEORGETOWN UNIV. INST. FOR HEALTH CARE RSCH. & POL'Y, THE STATE OF HEALTH PRIVACY: A SURVEY OF STATE HEALTH PRIVACY STATUTES (2d ed. 2002). These surveys do not include regulations, common law, and general privacy statutes that go beyond the medical contexts. *Id.* at iv.

other proceedings; and put in place various condition-specific protections for cancer, HIV, mental health issues, and others.[198]

States also deployed their health IT programs with an eye towards protecting privacy.[199] From the outset, Iowa sought to maintain the privacy rights of individuals in its network by prohibiting the release of individual patient level data.[200] Minnesota similarly prohibited participants from accessing patient level data submitted by another participant; they could only access data that they themselves submitted.[201] Most states allowed disclosure—including patient-level disclosure—for research; though over time, more protections were added.[202]

The federal government entered this space as well but, again, respected state prerogatives. Apart from seeking to promote data standardization, HIPAA also delegated to HHS the power to develop rules for data privacy and security.[203] HIPAA's Privacy and Security Rules, which went into effect in 2003, prevented so-called "covered entities," namely, providers, payers, and data clearinghouses, from engaging in disclosure of individually identifiable health data.[204]

However, HIPAA does not preempt state laws that are "more stringent" than HIPAA.[205] Most states accordingly added to their privacy protections. For example, the recent California Consumer Privacy Act allows consumers to request information about themselves for free (whereas HIPAA allows for a "reasonable fee"); it also allows consumers to request that their information be deleted.[206] These extend beyond HIPAA mandates, and therefore survive HIPAA preemption. I discuss such laws below.

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In each of the three areas I describe above, states retained great authority. States retained authority over the data collection programs they had initiated that collected data from *private* health transactions with federal support, funding, and acknowledgement. They retained primacy in promoting health networks and data exchange, helping implement federal mandates, and promoting the network infrastructure and linkages with federal help. Finally, states continued to enact privacy legislation even after HIPAA's passage. Such laws assured continued federal-state dialogue and collaboration in health data regulation schemes.

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[198] *See generally* PRITTS ET AL., *supra* note 197.

[199] O'Connor & Matthews, *supra* note 197, at 1846, 1847 tbl.1.

[200] Act of Apr. 26, 1983, ch. 27, § 3, 1983 Iowa Acts 40, 41-42.

[201] Act of May 25, 1995, ch. 234, art. 5, § 16, 1995 Minn. Laws 2120, 2187.

[202] *Id.* § 16, 1995 Minn. Laws at 2185, 2186; Act of Apr. 11, 1996, ch. 440, art. 1, §§ 33-36, 1996 Minn. Laws 1146, 1163-65; Act of Mar. 13, 1990, ch. 305, §§ 7, 9, 1990 Utah Laws 1437, 1440.

[203] 42 U.S.C. § 1320d.

[204] 45 C.F.R. § 164.502(a) (2021).

[205] *See* sources cited *supra* note 10.

[206] California Consumer Privacy Act, CAL. CIV. CODE § 1798.100 (West 2021).

III. PRIVATIZATION AND DISPLACEMENT OF STATE HEALTH DATA REGULATION

As Part I described, healthcare federalism scholarship generally offered three archetypes: separate spheres regulation, as with medical licensing; cooperative federalism, as with Medicaid and the ACA; and interstitial regulation, as in the context of privacy law. The current trend in health data federalism follows none of these paths.

Federal action with respect to *state* health data regulation should be situated within a broader ecosystem. In the last two decades, privatization—that is, government support and subsidization of private industry to advance its policy objectives—has been rampant.[207] Among providers, the conversion from public hospitals and providers to private providers has continued apace.[208] In the payment context, the Bush Administration created and offered preferential treatment for privatized Medicare plans (so-called Medicare Advantage plans).[209] It also created a prescription plan under Medicare (Medicare Part D) that was completely privatized.[210] The ACA similarly created health exchanges where the work of providing coverage was contracted out—with the help of government subsidies.[211] Thus, as the administrator for the Centers of Medicare & Medicaid Services under George Bush noted, the ACA is "not a government takeover of medicine . . . . It's the privatization of health care."[212] And, to promote Medicaid expansion in unwilling states, the Obama Administration

[207] *See* Mark Duggan, Jonathan Gruber & Boris Vabson, *The Consequences of Health Care Privatization: Evidence from Medicare Advantage Exits*, 10 AM. ECON. J. 153, 154 (2018) (explaining increased privatization of Medicare and analyzing its consequences).

[208] *See* Zo Ramamonjiarivelo, Josué Patien Epané, Larry Hearld, Luceta McRoy & Robert Weech-Maldonado, *The Impact of Privatization on Efficiency and Productivity: The Case of US Public Hospitals*, 43 J. HEALTH CARE FIN. (SPECIAL ISSUE) 105, 106 (2016).

[209] David A. Lipschutz, *Commentary: Don't Further Privatize Medicare,* 56 INQUIRY 1, 1-3 (2019); Robert A. Berenson & Melissa M. Goldstein, *Will Medicare Wither on the Vine? How Congress Has Advantaged Medicare Advantage—and What's a Level Playing Field Anyway?*, 1 ST. LOUIS U. J. HEALTH L. & POL'Y 5, 8-9 (2007); Nicholas Bagley, *Bedside Bureaucrats: Why Medicare Reform Hasn't Worked*, 101 GEO. L.J. 519, 546-49 (2013). These plans were not the first privatized Medicare plans that existed, but no program of this scale had existed before. Duggan et al., *supra* note 207, at 155-56.

[210] Daniel Katz & Monica Deshpande, *An Rx for the Modification of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Toward a Reform with Results*, 14 ANNALS HEALTH L. 183, 185 (2005).

[211] *See* 42 U.S.C. § 18031 (establishing creation of and funding for state health exchanges).

[212] Adam Davidson, *Who Is Betting On Obamacare?*, N.Y. TIMES MAG., Nov. 3, 2013, at 37, 38; *see also* Sean Petty, *The Neoliberal Restructuring of Healthcare in the US*, INT'L SOCIALIST REV., Fall 2014, at 63, 70 (2014) ("[H]undreds of billions of federal taxpayer dollars will be used to subsidize companies that continue to have economic interests diametrically opposed to the healthcare needs of their customers, sometimes known as patients.").

permitted Medicaid privatization—a trend that the Trump Administration continued.[213]

The health data space has been no exception. As others have explained, on the one hand, the federal government has promoted policies that have subsidized EHR use among private entities.[214] The data this has generated have produced vast profits for those entities.[215] On the other hand, these entities have avoided sharing data for the general public good and are subject to fewer ethical and legal limitations on how they use this data than are academic or nonprofit entities.[216]

When it comes to federalism, the federal government has similarly promoted the interests of private entities in the healthcare space—this time at the expense of states. Unlike health-finance programs, such as Medicaid, where moves towards privatization had to be reconciled with existing delegations to states, in the health-*data* space, there is no established, long-lasting commitment to state administration.[217] Thus, in the last few years, the federal government has taken action that displaced state law and programs in favor of private policies. But what has occurred has not been preemption in the classical sense where the federal government passed regulations that displaced state law; rather, the federal government has given over power in the area to private entities.[218]

First, state *data collection*. In 2016, the Supreme Court held in *Gobeille v. Liberty Mutual Insurance Co.*[219] that a federal statute preempted state APCD data collection.[220] But notably, this did not mean that state law gave way to federal law.[221] Rather, state law gave way to private regulation—the rules of the

[213] Brendan Williams, *The Inexorable Expansion of Medicaid Expansion*, 39 N. ILL. U. L. REV. 240, 250-58 (2019).

[214] *See* Enriquez-Sarano, *supra* note 151, at 2335 ("HITECH increased EHR penetration rates from approximately ten percent to ninety percent—thereby increasing the sheer number of analyzable medical records. EHRs also increase the scope of available data by capturing more data points covering more measurements in each patient-doctor interaction . . . ." (footnote omitted)).

[215] *Id.* at 2335-36 ("The increased scope and scale of data capture were crucial to the formation of a robust data market. Clinical investigators have studied medical records for hundreds of years. But the promise of big data for EHR-based research lies in leveraging millions, not hundreds or thousands, of records." (footnote omitted)).

[216] *Id.* at 2344-47 (explaining absence of ethical supervision).

[217] *See* Nat'l Governors Ass'n Brief, *supra* note 101, at 5 ("Historically, state health care data collection has been limited.").

[218] *See* Gobeille v. Liberty Mut. Ins. Co., 136 S. Ct. 936, 947 (2016) (holding that Vermont could not compel Blue Cross to comply with state's data collection law).

[219] 136 S. Ct. at 947.

[220] *Id.*

[221] *Cf. id.* at 958 (Ginsburg, J., dissenting) ("It is unsettling, however, to leave the States dependent on a federal agency's grace . . . .").

game were determined here by private contract rather than state regulation.[222] Second, state *network formation* is being displaced. Both states and private entities run health networks that providers choose to join; these networks compete with each other, but states often assist commercially nonviable providers who treat underserved populations.[223] Nonetheless, the federal government has shifted competitive advantages from states to private entities, thus harming the former. Third, state control over *privacy law* was nearly displaced, not through direct preemption by the federal government but by a grant of preemption power to private entities.[224]

Note how, in each of these federal actions, the extent of federal involvement decreases, while the power given to the private entity increases. In the data collection context, the federal government made the decision as to whether to enable such displacement. In the case of network formation, the displacement is the result of private action with federal catalyzation and assistance. When it came to privacy law, the federal government simply sought to provide a grant of authority; the private entity decides whether to displace the law.

A. *Data Collection and Contractual Preemption*

Recall that state data collection efforts have culminated in APCDs that collect all claims data from the state—efforts that have been supported both by ACA text and by federal funding.[225] In 2016, the Supreme Court "[blew] an enormous hole" in these state APCDs, allowing up to 60% of all employers to ignore state laws requiring them to submit information to these plans if they so choose.[226]

Importantly, while scholars treat this case as a straightforward example of preemption,[227] as the employer suggested in its briefing, state law is only

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[222] Nicholas Bagley, *The Supreme Court's Wrongheaded Decision in* Gobeille, INCIDENTAL ECONOMIST (Mar. 3, 2016), https://theincidentaleconomist.com/wordpress/the-supreme-courts-wrongheaded-decision-in-gobeille/ [https://perma.cc/J8VA-9VEG] ("[T]he states can try to work around *Gobeille* by requiring providers instead of payers to report the prices they charge.").

[223] *See generally* OFF. OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., *SPOTLIGHT ON: HEALTH INFORMATION EXCHANGE IN RURAL AMERICA* (2013) [hereinafter *SPOTLIGHT*], https://www.healthit.gov/sites/default/files/health_information_exchange_in_rural_america_issue-brief_final_082113.pdf [https://perma.cc/2U8F-3HF4] (describing state initiatives to increase HIE in rural areas).

[224] *See Gobeille*, 136 S. Ct. at 947.

[225] *See supra* notes 143-158 (providing examples of relevant state laws).

[226] Bagley, *supra* note 222 ("Because two-thirds of all employers self-insure, the databases will lose about two-thirds of the data that they hoped to collect."). Most commentators hold this view. A minority view suggests that the decision may not be so fatal. *See* David Newman, Eric Barrette, Amanda Frost & Katharine McGraves-Lloyd, *Losing the 'All' in All-Payer Claims Databases*, HEALTH AFFS. BLOG (July 18, 2016), http://healthaffairs.org/blog/2016/07/18/losing-the-all-in-all-payer-claims-databases/ ("While we understand that the potential loss of ERISA data is viewed with concern . . . , the Court's decision may not be fatal to policy-relevant research.").

[227] *See supra* note 226 and accompanying text.

displaced *if* employers enter contracts with insurance companies or beneficiaries that say they will not follow state law regarding data collection.[228] In other words, preemption of state law is not purely a federal decision: if the contract chooses to comply with state data collection, then state law remains in place; if the contract does not, then state law must give way to the contract. As a practical matter, this also means that the state's APCD would functionally be displaced by private insurer databases.

Let us return to the state data collection efforts, namely APCDs. States continued pouring resources into these efforts until recently. New York, for example, enacted authorizing legislation in 2011 and, as of 2014, had dedicated $10 million to the project.[229] State efforts—especially state transparency efforts—however, met resistance from insurers who purported to maintain their own databases to which they submit data.[230] While insurers would submit data to these private databases, insurers filed suit arguing that submitting data to *public* databases was burdensome and largely preempted by federal law.[231]

In 2015, the Supreme Court heard arguments in *Gobeille*, where insurers argued that the Employee Retirement Income Security Act of 1974 ("ERISA") preempted a large portion of Vermont's APCD efforts.[232] For the purposes of this case, ERISA preemption effectively applies only to companies that choose to self-insure—that is to say, instead of paying premiums to an insurance company which then pays medical claims for employees who get sick, a self-

[228] *See* Brief for Respondent at 44-46, *Gobeille*, 136 S. Ct. 936 (No. 14-181) [hereinafter Brief for Respondent] (arguing ERISA preempts Vermont's reporting requirements because they conflict with terms of Liberty Mutual's employee health plan); Konnoth, *Privatization*, *supra* note 21, at 1966 ("The ERISA context presents a similar scenario—but for a firm's decision to self-fund their insurance plan, a consumer's insurance benefits would be state law determined. The duties of the parties are determined by private contractual arrangements, rather than state prescription; the former displaces the latter.").

[229] N.Y. PUB. HEALTH LAW § 2816 (McKinney 2021); *see* N.Y. Amicus Brief I, *supra* note 130, at 3-6.

[230] Brief of Amici Curiae American Medical Ass'n & Vermont Medical Society in Support of Petitioner at 16-17, *Gobeille*, 136 S. Ct. 936 (No. 14-181) [hereinafter AMA Brief]; *see* OFF. OF THE ATT'Y GEN., STATE OF N.Y., HEALTH CARE REPORT: THE CONSUMER REIMBURSEMENT SYSTEM IS CODE BLUE 2 (2009), https://ag.ny.gov/sites/default/files/pdfs/bureaus/health_care/FINALHITIngenixReportJan.13,%202009.pdf [https://perma.cc/487C-C2D8]; Reply Brief for Petitioner at 19-20, *Gobeille*, 136 S. Ct. 936 (No. 14-181) (citing Press Release, Blue Cross Blue Shield Ass'n, Blue Cross Blue Shield Ass'n Announces Industry-Leading Healthcare Data Capability to Drive Improved Quality and Affordable Care (Sept. 24, 2015) [hereinafter BCBS Press Release], https://www.bcbs.com/news/press-releases/blue-cross-blue-shield-association-announces-industry-leading-healthcare-data [https://perma.cc/6ZUS-3DSR]).

[231] *Gobeille*, 136 S. Ct. at 945.

[232] *Id.* at 940-43.

insured company pays for any medical claims out of its own pocket.[233] In other words, a self-insured company bears the risk of employee sickness instead of outsourcing it to an insurance company.

With respect to such self-insured companies, ERISA preempts state laws that, inter alia, "govern[] . . . a central matter of plan administration" and "interfere[] with nationally uniform plan administration."[234] The Court held that the APCD reporting requirement failed the preemption test on both counts.[235] First, according to the Court, data reporting is a central matter of ERISA. The law requires significant "reporting, disclosure, and recordkeeping" to the Secretary of Labor,[236] who can "use the data . . . 'for statistical and research purposes'"[237] and can "requir[e] any . . . data from any [plan]."[238] By "compel[ling] plans to report detailed information about claims and plan members,"[239] "Vermont's reporting regime" directly regulates "a fundamental ERISA function."[240] Second, APCDs interfere with plan uniformity because multiple states have APCD regimes, so "[d]iffering, or even parallel, regulations from multiple jurisdictions could create wasteful administrative costs and threaten to subject plans to wide-ranging liability."[241] Vermont's APCD therefore also "interfer[ed] with nationally uniform plan administration."[242]

In some ways, the preemption story might seem standard: according to the Supreme Court, ERISA preempted state data collection, and the federal government chose not to regulate and to leave a regulatory void.[243] Federalism scholar Jonathan Nash refers to this federally mandated deregulation in other

[233] 29 U.S.C. §§ 1003, 1144. ERISA preemption is more complicated. First, it preempts all employee benefits plans but then excludes regulation of insurance from its preemptive ambit, which means that states can still regulate the business of insurance. *Id.* § 1003. That exception is subject to yet another deemer clause exception, which effectively prohibits regulation of self-insured plans as here. *Id.*

[234] *Gobeille*, 136 S. Ct. at 943 (first and second alterations in original) (quoting Egelhoff v. Egelhoff, 532 U.S. 141, 148 (2001)).

[235] *Id.* at 945.

[236] *Id.* at 944.

[237] *Id.* (quoting 29 U.S.C. § 1026(a)).

[238] *Id.* (first and third alterations in original) (quoting 29 U.S.C. § 1024(a)(2)(B)). The Court concluded from this that "reporting, disclosure, and recordkeeping are central to, and an essential part of, the uniform system of plan administration contemplated by ERISA." *Id.* at 945. Here, the Court appeared to resurrect an aspect of a test it had interred in *De Buono v. NYSA-ILA Medical & Clinical Services Fund*, 520 U.S. 806 (1997). In *De Buono*, the state "directly" taxed hospitals, including an employer-run hospital. *Id.* at 810. The Court held that "the supposed difference between direct and indirect impact . . . cannot withstand scrutiny." *Id.* at 816.

[239] *Gobeille*, 136 S. Ct. at 945.

[240] *Id.* at 946.

[241] *Id.* at 945.

[242] *Id.* (quoting Egelhoff v. Egelhoff, 532 U.S. 141, 148 (2001)).

[243] *Id.* at 947.

contexts—it is, as he puts it, "null preemption."[244] However, although the Court does not reach this issue, there is more to this narrative. As Liberty Mutual emphasized again and again, the problem was that state policy did not just fill a void but rather displaced existing private contracts.[245] On the one hand, it interfered with contracts with beneficiaries. On the other, it interfered with contracts with Liberty Mutual's subcontractor. Thus, while the Court does not address the issue, displacing state law does not give ERISA room for operation, as ERISA does not regulate data collection; rather, private arrangements determine how data will be shared.[246]

First, the plan documents form the contract with beneficiaries. As Liberty Mutual argued, the data reporting laws "interfere with the Plan's relationships with its members" because "[t]he documents governing the Plan obligate [Liberty Mutual] to keep many medical records strictly confidential."[247] Second, while Liberty Mutual would pay for the claims, its contractor, Blue Cross Blue Shield ("BCBS"), would actually administer them, and it was BCBS that ultimately submitted the data to Vermont.[248] Thus, the state laws "interfere with the Plan's relationships with its . . . [contractor]. The Plan's agreement with its [contractor] also requires that its members' medical information be used solely for the purpose of plan administration."[249] To put it differently, the state instructed BCBS to submit data regarding the claims it had administered; Liberty Mutual instructed BCBS not to do so.[250] As the American Hospital Association explained as an amicus, Liberty Mutual argued that the state statute's instructions to BCBS were trumped by Liberty Mutual's own instructions to BCBS in its contract.[251]

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[244] Jonathan Remy Nash, *Null Preemption*, 85 NOTRE DAME L. REV. 1015, 1017 (2010).

[245] Brief for Respondent, *supra* note 228, at 8, 44 ("Although the Vermont regime includes confidentiality protections, it nonetheless affects the documents governing Liberty Mutual's ERISA plan by 'impair[ing] or (at least) reassign[ing] the obligation in the Plan documents to keep medical records strictly confidential, as well as the undertaking by Blue Cross as [third-party administrator] to use information solely for Plan administration purposes and to prevent unauthorized disclosure.'" (alterations in original) (quoting Petition for a Writ of Certiorari at App. 27, *Gobeille*, 136 S. Ct. 936 (No. 14-181))); *see also* Brief in Opposition at 5, 29, *Gobeille*, 136 S. Ct. 936 (No. 14-181) (arguing Liberty Mutual must allow BCBS to turn over data in violation of its plan documents under Vermont law).

[246] Brief for Respondent, *supra* note 228, at 8, 44.

[247] *Id.* at 44.

[248] *Id.* at 8.

[249] *Id.* at 44.

[250] *See id.*

[251] Hosp. Ass'n Brief, *supra* note 131, at 21 (arguing that Liberty Mutual's motivation in the case was not to avoid a requirement "to assemble and produce the requested data," but to maintain its ability to "instruct [BCBS] . . . *not* to produce information that it already ha[d] on file"). Indeed, this would be the case in most situations involving self-insured firms, where a third party holds the data—few employers actually administer claims. *Id.* at 20 (citing Timothy Stoltzfus Jost & Mark A. Hall, *Self-Insurance for Small Employers Under the*

This, of course, is not how contract law works—government regulation trumps contract, absent some other limitation.[252] And indeed, both the United States and Vermont explained that to hold otherwise would mean that the opposite would be true—that private contracts would displace state regulation. As the United States explained in an amicus brief, a ruling against the state "supports the view that a state law . . . could be circumvented by a contrary term in a particular plan."[253] As the United States reminded the Court, litigants in a previous ERISA case had similarly argued that plan documents should trump state law.[254] As the Court explained in that case, allowing insurers to "displace any state regulation simply by inserting a contrary term in plan documents" would not be permissible.[255] Liberty Mutual, however, distinguished away that case—in other words, the company seemed to argue, plan documents could indeed "displace" state regulation.[256]

Liberty Mutual also seemed to argue that federal law demands such displacement of rules generated by the state with those generated by the parties in two ways. First, federal law *implicitly* allowed for contract to displace state law. Much of Liberty Mutual's brief focuses on the claim that ERISA preempted state law with respect to certain kinds of provisions which, in turn, allowed the employer to create contractual arrangements to set up the rules regarding data.[257] But it also argued that ERISA *explicitly* delegated to private entities the ability to craft rules that displace state law. As it argued, "Vermont's reporting requirements conflict with ERISA's commands that a plan 'shall' be administered 'in accordance with the documents and instruments governing the plan.'"[258] In other words, ERISA explicitly preferred these documents over state law.[259]

*Affordable Care Act: Federal and State Regulatory Option*s, 68 N.Y.U. ANN. SURV. AM. L. 539, 546 (2013)).

[252] *See* Unum Life Ins. Co. of Am. v. Ward, 526 U.S. 358, 375-76 (1999).

[253] Brief for the United States as Amicus Curiae Supporting Petitioner at 33-34, *Gobeille*, 136 S. Ct. 936 (No. 14-181) [hereinafter U.S. Cert. Stage Brief]; *see also* U.S. Merits Stage Brief, *supra* note 135, at 17 ("[T]his Court has never suggested that the mere fact that a state law could conflict with a plan term is sufficient for preemption, and such a rule would effectively allow plan sponsors to evade any state law merely by adding a contrary plan term.").

[254] U.S. Cert. Stage Brief, *supra* note 253, at 32-33.

[255] *Unum*, 526 U.S. at 376.

[256] Brief for Respondent, *supra* note 245, at 46-47.

[257] *See id.* at 24-43.

[258] *Id.* at 44 (quoting 29 U.S.C. § 1104(a)(1)(D)); *see also supra* note 245.

[259] While the Court in *Gobeille* refrained from holding that the federal government could explicitly allow private contracts to displace state law at the option of the private company, that is exactly what it held the following year. In *Coventry Health Care of Missouri, Inc. v. Nevils*, the Court upheld the reach of a federal statute which stated that a contract the federal government negotiated with a health insurance company could displace state law. 137 S. Ct.

The Supreme Court did not address this set of arguments, holding simply that ERISA preempted state law.[260] But ERISA itself does not dictate how data should be shared. Rather, in holding the way it did, the Supreme Court effectively allowed private firms to decide—through contractual and other arrangements—if and how they want to share their data with states.

By de facto letting this contractual web govern over state law, *Gobeille* prevented states from requiring self-insured companies to report, which harmed state programs.[261] As Justice Ginsburg's dissent noted, about a third of all insured individuals receive coverage through self-insured plans.[262] Further, as of 2018, 83% of employees in businesses with 1,000 or more employees receive insurance through self-funded plans, while only 14% of employees in businesses with fewer than 100 employees are similarly covered.[263] As amici noted, nearly 60% of Americans with private insurance are "[e]mployees covered by self-funded plans."[264] Thus, as a recent study explains, the scope of APCDs was limited in part because "a portion of the commercial market is not included in most APCDs due to [*Gobeille*]," and "[w]hile states have encouraged self-insured entities to submit their claims voluntarily, these efforts have proven an uphill battle."[265]

Not only do private contracts displace state law here, but private *databases* may also displace state databases. Indeed, BCBS at the time of the *Gobeille* litigation was touting its database, explaining how it "plan[ned] to do 'big things with big data,'" and how it sought to support "quality and cost improvement and further accelerat[e] the movement toward smart, data-driven healthcare," even as it argued that submitting the data to public databases was too burdensome.[266]

The fundamental takeaway is this: according to Liberty Mutual, federal law did not just demand that states refrain from regulating a certain area. Rather,

1190, 1194 (2017). The statute at issue in *Coventry Health*, 5 U.S.C. § 8902(m)(1), states that "[t]he terms of any contract . . . which relate to [federal employee health benefits] shall supersede and preempt any State or local law . . . which relates to health insurance or plans."

[260] *Gobeille*, 136 S. Ct. at 947.

[261] *See supra* note 226.

[262] *Gobeille*, 136 S. Ct. at 973 (Ginsburg, J., dissenting).

[263] PAUL FRONSTIN, EMP. BENEFIT RSCH. INST., EBRI ISSUE BRIEF NO. 488, SELF-INSURED HEALTH PLANS: RECENT TRENDS BY FIRM SIZE, 1996-2018, at 6 (2019), https://www.ebri.org/docs/default-source/ebri-issue-brief/ebri_ib_488_selfinsur-1aug19.pdf?sfvrsn=bd7e3c2f_6 [https://perma.cc/7TSJ-3HW7].

[264] *See* N.Y. Amicus Brief II, *supra* note 133, at 7 (citing Robert Pear, *Employers with Healthy Workers Could Opt Out of Insurance Market, Raising Others' Costs*, N.Y. TIMES, Feb. 18, 2013, at A9); *see also* Hosp. Ass'n Brief, *supra* note 131, at 19 ("Whereas only around 20% of employers in the construction industry and agriculture industry offer a self-insured plan, for example, over 55% of retail employers do.").

[265] Sarah H. Gordon, *Using All-Payer Data to Conduct Cross-State Comparisons of Health Insurance Enrollment*, HEALTH AFFS. BLOG (July 12, 2019), https://www.healthaffairs.org/do/10.1377/hblog20190708.605861/full/.

[266] Reply Brief for Petitioner, *supra* note 230, at 19-20, 19 n.10 (citing BCBS Press Release, *supra* note 230).

state law could control *unless* private entities contracted otherwise with their beneficiaries and contractors. In that case, state law was displaced by contract. This allowed private entities to effectively choose to displace state programs in favor of their own privately run programs.

B. *Data Networks and Incentivized State Law Displacement*

While the contractual preemption model requires the federal government to make a top-down decision that state law will give way to the arrangements that private entities put in place, incentivized displacement gives a greater role to private entities in the decision to displace state programs. The federal government here takes an action that offers incentives to private firms to expand programs in areas that states already serve. In its most direct form, such action can involve granting subsidies or monopolies to firms or taking them away from states—which, in turn, limits state primacy in an area. At a given time, a myriad federal actions determine a particular regulatory ecosystem that incentivize different behaviors. Taking the status quo as a baseline, a federal action (short of actual preemption) that departs from the status quo and shifts the balance away from states in favor of firms counts as incentivized displacement of state programs. This is what has happened specifically to the networks, or HIEs, that states established for health exchange—dominance in this area is being transferred to private entities.

First, some background on the developing HIE landscape. While states were the pioneers in the HIE space, they have been competing with private HIEs for a few years.[267] An HIE is only as robust as the number of clients, such as providers and labs, that connect to it—and states face competition from private networks in attracting clients.[268] The competition is stiffest with networks run by EHR developers.[269]

The federal government has taken steps that will worsen the positions of state programs while improving those of private entities. First, subsidies to states are ending. Recall that through four funding streams, state networks received both direct and indirect HIE development funds, as well as Medicaid funds, from the federal government.[270] However, both HIE development streams were a one-

[267] Off. of the Nat'l Coordinator for Health Info. Tech., *What Is the Role for the Private Sector in Advancing HIE?*, HEALTHIT.GOV [hereinafter *Private Sector Role*], https://www.healthit.gov/faq/what-role-private-sector-advancing-hie [https://perma.cc/9976-J99A] (last reviewed Jan. 15, 2013).

[268] Julia Adler-Milstein, Sunny C. Lin & Ashish K. Jha, *The Number of Health Information Exchange Efforts Is Declining, Leaving the Viability of Broad Clinical Data Exchange Uncertain*, 35 HEALTH AFFS. 1278, 1283 (2016) ("[C]ustomers are more difficult to secure.").

[269] *See id.* at 1284 ("While it is hard to assess the extent of such competition, it is clear that some vendors have established large HIE networks. For example, Epic's network contains information on nearly 40 percent of the US population . . . .").

[270] *Supra* notes 176-191 and accompanying text.

time deal.[271] Next, while the 2016 program, which provides a 90% match for state Medicaid HIE infrastructure, remains intact for now, that program expires in 2021.[272] The Trump Administration, in turn, put a moratorium on all Medicaid projects seeking federal matches and phased out existing projects.[273] And it is unclear if the Biden Administration will expand funding after the COVID-19 crisis—even Democratic state administrations have called for Medicaid cuts.[274] Thus, three out of the four funding streams to states are likely to dry up.

Some might argue that *ending* subsidies to states should not be treated as displacing state law. After all, states were receiving a benefit that firms were not receiving. On the other hand, others might argue that states were receiving benefits that were their due; as the next Part explains, state networks helped underserved communities and possibly had to reckon with anticompetitive firm behavior.[275] Further, private networks received subsidies from insurance companies who—as we saw above—prefer to keep their data private.[276] One may argue therefore that state HIEs were at a competitive disadvantage, which the federal grants helped ameliorate.[277] And yet others might point out that while states received most of the federal HIE funding, many private HIEs also received funding.[278] Thus, rather than attempt to identify a "fair" baseline, deviation from which constitutes incentivized displacement, I simply look to a departure from the status quo—which involved significant state subsidies that are now ending.

As federal funding dries up, so do state HIEs. A 2014 survey found "[t]he number of planning efforts had declined 60 percent from the 53 that we

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[271] *See supra* notes 176-191 and accompanying text.

[272] *See* Ctrs. for Medicare & Medicaid Servs., *Federal Financial Participation for HIT and HIE*, MEDICAID.GOV, https://www.medicaid.gov/medicaid/data-systems/health-information-exchange/federal-financial-participation-for-hit-and-hie/index.html [https://perma.cc/NR6H-MZ9Y] (last visited Dec. 5, 2021).

[273] Letter from Brian Neale, Dir., Ctrs. for Medicare & Medicaid Servs., to State Medicaid Dir. (Dec. 15, 2017), https://www.medicaid.gov/federal-policy-guidance/downloads/smd17005.pdf [https://perma.cc/KMH5-932T] ("CMS has determined that it will no longer accept state proposals for new or renewing section 1115 demonstrations that rely on federal matching funds . . . ."); *see also* Julia Hirschfield Davis, *Budget Proposal Curtails Efforts Against Poverty*, N.Y. TIMES, May 23, 2017, at A1.

[274] Samantha Young, *California Lawmakers Block Health Care Cuts*, CAL. HEALTHLINE (June 23, 2020), https://californiahealthline.org/news/california-lawmakers-block-health-care-cuts/ [https://perma.cc/CFQ6-VMKU] (discussing Governor Newsom's proposed Medicaid cuts that lawmakers opposed).

[275] *Infra* Section IV.A.

[276] Tom Sullivan, *Is the Future of HIE Private?*, HEALTHCARE IT NEWS (Jan. 27, 2014, 11:11 AM), https://www.healthcareitnews.com/news/future-hie-private-EHR-payers-insurers-hospitals [https://perma.cc/RC44-3BK5].

[277] Off. of the Nat'l Coordinator for Health Info. Tech., *State Health Information Exchange Cooperative Agreement Program*, HEALTHIT.GOV, https://www.healthit.gov/topic/onc-hitech-programs/state-health-information-exchange [https://perma.cc/PXC4-SZ3H] (last reviewed Apr. 29, 2019).

[278] *Private Sector Role*, *supra* note 267.

identified in our 2012 survey. The number of operational efforts had also declined by 11 percent from the 119 such efforts identified in 2012."[279] Further, "[o]nly half of operational efforts reported being financially viable."[280] Another evaluation the same year showed that while HIE performance was improving, most of the improvement came from only a few states.[281] The national HIE use score increased from 36% in 2010 to 79% in 2014; but in 2013, only five states represented 85% of the total directed transactions that go into making the score.[282]

While the federal government takes away support for states on one hand, on the other hand, the federal government has offered regulatory primacy in the field to an oligopoly formed mostly of private entities under the putative authority of the 21st Century Cures Act ("Cures Act").[283] The Cures Act was passed in December 2016 on a bipartisan basis.[284] Among other matters, it seeks to extend federal control over the nation's health data infrastructure—it calls on ONC to "develop or support a trusted exchange framework, including a common agreement among health information networks nationally."[285]

Pursuant to the instructions in the Cures Act, in January 2018, HHS published a draft Trusted Exchange Framework & Common Agreement ("TEFCA").[286] According to this draft, national networks would be unified under the supervision of "a single, industry-based [Recognized Coordinating Entity ("RCE")]." Critically, "*ONC believes that a private-sector organization would be best positioned to serve as the RCE*."[287] This RCE will "onboard[]

[279] Adler-Milstein et al., *supra* note 268, at 1280. The authors suggest that these estimates are optimistic as their data is self-reported. *Id.*

[280] *Id.* at 1278.

[281] PRASHILA DULLABH, SHRIRAM PARASHURAM, LAUREN HOVEY, PETRY UBRI & KATHRYN FISCHER, NORC AT THE UNIV. OF CHI., EVALUATION OF THE STATE HIE COOPERATIVE AGREEMENT PROGRAM 42 (2016), https://www.healthit.gov/sites/default/files/reports/finalsummativereportmarch_2016.pdf [https://perma.cc/JMG6-B6QZ] (noting that Colorado, Indiana, Michigan, New York, and Vermont represented "over 85 percent of the total [directed transactions]" in Q4 2013).

[282] *Id.* at 4, 42.

[283] 21st Century Cures Act, Pub. L. 114-255, 130 Stat. 1033 (2016) (codified as amended at 42 U.S.C. § 300jj-11).

[284] *Id.*

[285] *See* 42 U.S.C. § 300jj-11(c)(9)(A)-(B) ("[T]he National Coordinator shall convene appropriate public and private stakeholders to develop or support a trusted exchange framework for trust policies and practices and for a common agreement for exchange between health information networks.").

[286] *Id.*

[287] OFF. OF NAT'L COORDINATOR FOR HEALTH INFO. TECH., DRAFT TRUSTED EXCHANGE FRAMEWORK 9 (2018) [hereinafter TEFCA DRAFT] (emphasis added). Accordingly, I do not agree with the comment from the American College of Surgeons that purports to find ambiguity in the term "industry-based." Am. Coll. of Surgeons, Comment Letter on Draft Trusted Exchange Framework 3 (Feb. 20, 2018) (on file with author). The College argued

organizations to the final TEFCA, ensur[e] Qualified [networks] comply with the terms and conditions of the TEFCA, address[] non-conformities . . . , develop[] additional use cases," and engage in "day-to-day management and oversight of unaffiliated Qualified [health information networks]."[288] Finally, and critically, the RCE will *itself* have the power to "update[e] the TEFCA over time."[289] While HHS limited the powers of the entity in the most recent draft, as I discuss in the next Section, the RCE will retain these powers in substantial part.[290]

Finally, even as it elevates private entities, TEFCA ignores states. The draft discusses how state HIEs have been weakened.[291] Leaving state HIEs to their own devices, TEFCA envisages that overall, private entities will run the nation's health information networks.[292] Existing state networks will be answerable to these entities, who in turn will be under the "oversight" of the private RCE firm (which, in turn, might be run by a group of firms).[293]

In 2019, HHS awarded the RCE contract to The Sequoia Project.[294] The Sequoia Project began in 2012 as an alliance of industry-based organizations, including insurance companies, EHR developers, healthcare delivery nonprofits, and others, to promote information exchange.[295] Of the nine founding members, two were state HIEs.[296] In the years since, the private-public power balance in The Sequoia Project has tilted. As of 2021, it has sixty-three members, but in the intervening years, only two new state HIEs have become members; one of them is the Indiana entity, which "approach[es]" the project "as a business," rather

that the term "is broad and open to interpretation" and that it could be "a quasi-government entity." *Id.* at 2-3. I think the language of TEFCA here forecloses that interpretation.

[288] TEFCA DRAFT, *supra* note 287, at 9.

[289] *Id.*

[290] Press Release, The Sequoia Project, ONC and The Sequoia Project Announce RCE Efforts Will Continue into Second Year (May 26, 2020), https://www.globenewswire.com/news-release/2020/05/26/2038885/0/en/ONC-and-The-Sequoia-Project-Announce-RCE-Efforts-Will-Continue-Into-Second-Year.html [https://perma.cc/SZ95-873R].

[291] TEFCA DRAFT, *supra* note 287, at 3-4 (noting that network of HIEs has limited interoperability and connectivity).

[292] *Id.* at 9.

[293] *See id.* (noting RCE will be responsible for oversight).

[294] Press Release, U.S. Dep't of Health & Hum. 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), https://www.hhs.gov/about/news/2019/09/03/onc-awards-the-sequoia-project-cooperative-agreement.html [https://perma.cc/9TU2-ZZZK].

[295] *About The Sequoia Project*, THE SEQUOIA PROJECT, https://sequoiaproject.org/about-us/ [https://perma.cc/ZT6J-983B] (last visited Dec. 5, 2021).

[296] *The Sequoia Project's Founding Members*, THE SEQUOIA PROJECT, https://sequoiaproject.org/about-us/members/ [https://perma.cc/2RUX-3DY7] (last visited Dec. 5, 2021) (noting that two state members were Michigan and New York HIEs).

than as a state entity providing services.[297] Admittedly, once HHS decided that the network had to be contracted out rather than run by HHS itself, Sequoia was one of the better choices, as it has at least some public representation.[298]

Nevertheless, TEFCA as it currently stands will further displace state efforts as a practical matter. As the State of Colorado explained in its comment on TEFCA, "The state of Colorado cannot afford the proposed interoperability structure as currently defined."[299] Colorado highlighted that TEFCA imposes an unfunded mandate on state HIEs by requiring "un-funded work for Colorado's health information exchanges to segregate out the non-participating organizations."[300] The State also expressed concerns about "the lack of technical specification for a unique person identifier, scalability of the model, and questioned the many layers of unnecessary fees, organizations, and governance structures."[301] The practical effect of TEFCA, Colorado seemed to argue, would be to burden—even displace—state efforts in this field.[302]

C. *Privately Delegated Preemption*

So far, we have seen how a federal statute, according to the Supreme Court, preempts state law in favor of private contractual arrangements regarding health data collection with respect to most private employers.[303] Next, federal action skews incentives towards private entities with respect to developing health data networks.[304] Finally, the federal government, in its initial pass at TEFCA, sought to give the RCE (before the RCE was known) the power to preempt state privacy law.[305] To be sure, in the very next draft of TEFCA, the federal government pulled back, and instructed that HHS would have control over that aspect of TEFCA.[306] However, the fact that the federal government contemplated delegating to *a private player the power to preempt state regulation of the industry of which it was a member*[307] is worth comment and analysis, which it has not received. And although HHS allegedly retains control over whether to

[297] Miriam Jones, *4 Approaches to Health Information Exchanges*, GOV'T TECH. (Aug. 22, 2012), https://www.govtech.com/health/4-Approaches-to-Health-Information-Exchanges.html [https://perma.cc/9YVZ-STZ8].

[298] Press Release, The Sequoia Project, *supra* note 290 (characterizing The Sequoia Project as a "public-private collaborative").

[299] Colo. Off. of eHealth Innovation, Comment Letter on Draft Trusted Exchange Framework 2 (Feb. 20, 2018) (on file with author).

[300] *Id.*

[301] *Id.*

[302] *See id.*

[303] Gobeille v. Liberty Mut. Ins. Co., 136 S. Ct. 936, 947 (2016).

[304] *See supra* Section III.B.

[305] TEFCA DRAFT, *supra* note 287, at 9.

[306] OFF. OF NAT'L COORDINATOR FOR HEALTH INFO. TECH., TRUSTED EXCHANGE FRAMEWORK AND COMMON AGREEMENT (TEFCA) DRAFT 2, at 16-18 (2019) [hereinafter TEFCA DRAFT 2].

[307] *Id.*

preempt state privacy rules, since the RCE (The Sequoia Project) will be carrying out most functions with respect to the networks, it is unclear to what degree HHS will truly make the determination as to whether state privacy laws will be preempted.

In this Section, I first show how the Cures Act would likely require preemption of state privacy laws, and describe the scope of that preemption, before concluding with how HHS sought to delegate that power.

1. Scope of Preemption

Recall that the Cures Act requires "a common agreement among health information networks nationally."[308] TEFCA envisages several large networks, each with its own common agreement, subject to TEFCA as the master common agreement that will cross numerous state lines. These agreements may take three different approaches to the privacy laws of the states they cover. First, each agreement might simply follow the law of the particular state the data is are in. Second, an agreement might incorporate the state privacy standards from all the states as its minimum—that is, it would effectively adopt a policy that would satisfy all state laws. Third, it could adopt its own standard privacy policy without regard to state law.

The initial draft of TEFCA suggested the first alternative: that the network would follow state privacy laws.[309] With one or two exceptions, every commenter to address the issue, from states to private entities, rejected an approach that varies applicable privacy policy state by state.[310] As the Florida State Agency noted, this would lead to the precise fragmentation that TEFCA

[308] *See* TEFCA DRAFT, *supra* note 287, at 4.

[309] *Id.* at 23. The current TEFCA draft requires entities to follow all "applicable law" which includes state privacy laws. TEFCA DRAFT 2, *supra* note 306, at 60.

[310] *See, e.g.*, Strategic Health Info. Exch. Collaborative, Comment Letter on Draft Trust Exchange Framework 8 (Feb. 20, 2018) (on file with author) ("SHIEC strongly encourages ONC to provide the industry with guidance on addressing variation in state and federal laws related to privacy and consent. TEFCA is silent on how to address this variation, other than to state that all applicable law must be followed. . . . Until there is strong leadership to set a national approach . . . the issue will linger."); Digit. Bridge, Comment Letter on Draft Trusted Exchange Framework 4 (Feb. 20, 2018) (on file with author) ("While the trusted exchange framework highlights the importance of privacy and consent as one of the core principles, the common agreement section of the document seems to pay little specific attention to the reality of inconsistent state, local and tribal patient consent and data sharing laws that are often an obstacle to cross-jurisdiction interoperability."); Greater N.Y. Hosp. Ass'n, Comment Letter on Draft Trusted Exchange Framework 2 (Feb. 20, 2018) (on file with author) ("GNYHA seeks additional detail on how ONC plans to harmonize varying state consent rules for health information exchange. For example, while some states do not require separate patient consent for exchanging patient information unless a patient opts out, others such as New York State require a patient to opt-in to the exchange. How will this be reconciled?").

was meant to avoid.[311] This would present difficulties: as the American Hospital Association noted, "it will be very challenging, if not impossible to know whether responding to a specific request is, in fact, allowed by applicable law" given the multiple laws across the country.[312] Thus, commenters suggested they would not join the network if they had to comply with a patchwork of state privacy law.[313]

Even if the first versions of TEFCA incorporate state privacy law as its current draft demands, that will likely change. As the RCE expands in power and influence, it can use its authority and support to excise this requirement. Indeed, Cerner, the second biggest American EHR provider, noted that TEFCA could be "carefully expand[ed] . . . to include additional permitted purposes," including, possibly, "harmoniz[ing] policies around privacy and security."[314] The biggest American EHR company, Epic, was more direct and advised ONC that the requirement that participants "obey applicable laws [including privacy laws] . . . is extraneous. Remove it."[315] Thus, despite the current version's approach that putatively promises to follow state law, entities from the State of Minnesota to the Mayo Clinic have expressed doubts that this will be the outcome.[316]

[311] Fla. Agency for Health Care Admin., Comment Letter on Draft Trusted Exchange Framework 2 (Feb. 20, 2018) (on file with author) ("Variation in state law surrounding patient authorization remains a significant barrier to exchange. In Florida, this results in a strict inability to exchange with states who do not obtain explicit patient consent to exchange sensitive data. Laws that reach beyond the HIPAA requirements create a landscape where some states are virtual islands . . . .").

[312] Am. Hosp. Ass'n, Comment Letter on Draft Trusted Exchange Framework 5 (Feb. 15, 2018) (on file with author). For example, "an out-of-state HIE seeking to obtain a patient's information from a New York State HIE would need to have that patient's consent in hand in order to access that information . . . , even if the out-of-state HIE properly followed its own states [sic] opt-out rules for consent." N.Y. eHealth Collaborative, Comment Letter on Draft Trusted Exchange Framework 5 (Feb. 20, 2018) (on file with author).

[313] *See* Am. Hosp. Ass'n, *supra* note 312, at 6.

[314] Cerner Corp., Comment Letter on Draft Trusted Exchange Framework 2, 17 (Feb. 19, 2018) (on file with author).

[315] Epic, Comment Letter on Draft Trusted Exchange Framework 15 (Feb. 20, 2018) (on file with author).

[316] Minn. e-Health Initiative, Comment Letter on Draft Trusted Exchange Framework 7 (Feb. 20, 2018) (on file with author) ("What does agreeing to all the permitted purposes mean for Minnesota, which has consent requirements that are more protective than HIPAA?"); *id.* at 8 ("A broad set of permitted purposes are included. It is unclear how the framework will be implemented when different states have different laws either enabling or prohibiting HIE for particular permitted purposes? How will a Qualified HIN or HIN know what data is allowed, for what purposes and how inappropriate secondary uses of data will be avoided?"). The Mayo Clinic expressed similar questions. Mayo Clinic, Comment Letter on Draft Trusted Exchange Framework 2 (Feb. 13, 2018) (on file with author) ("What impact will TEFCA have on our state-based rules for patient consent, HIE accreditation, data sharing requirements, research (IRB process), privacy reporting requirements, etc.?").

The second alternative is impossible because states have different requirements based on different balances they have struck between privacy and other values. Some states, like Maine, seek a freer flow of data and only require individuals to opt out of their data going into an exchange.[317] Others, like New York, place a greater premium on privacy and have an opt-in system.[318] No policy can reconcile these tensions.

Thus, we are left with the third alternative—the agreements will promulgate their own privacy policy, independent of state privacy law. This policy will trump state privacy law.[319] As the Supreme Court has explained, even if Congress does not explicitly preempt a law, state law is *implicitly* preempted if it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."[320] In such cases, the Court first identifies the purposes of the federal scheme, and second, determines the extent to which the state law stands as an obstacle.[321] While there are doctrinal differences, if the Court's reasoning in *Gobeille* is any indication of its understanding, it would hold that state laws that mandate more or less information be exchanged in ways that do not comply with the federal scheme clearly stand as an obstacle to the uniform health data exchange system that the Cures Act seeks to mandate.[322]

Some entities raised this possibility in commenting on TEFCA.[323] The Mayo Clinic simply asked whether "TEFCA policies and procedures supersede . . . state-based rules for patient consent, HIE accreditation, data sharing requirements, research (IRB process), [and] privacy reporting requirements, etc."[324] Some concluded that the Cures Act requires such displacement, suggesting "a national standard for [network entities] that includes clear requirements for privacy and security,"[325] and adopting "a comprehensive approach to defining consent and authorization

[317] HealthInfoNet, Comment Letter on Draft Trusted Exchange Framework 1 (Feb. 20, 2018) (on file with author).

[318] N.Y. eHealth Collaborative, *supra* note 312, at 5; *see also* Greater N.Y. Hosp. Ass'n, *supra* note 310, at 2.

[319] This so-called "obstacle" preemption is one of several approaches. There is express preemption, implied field preemption, and implied conflict preemption, as here. Amanda G. Lewis, Federal Preemption of State and Local Laws 5 (May 5, 2008) (advanced seminar paper, Columbia Law School) (available at https://web.law.columbia.edu/sites/default/files/microsites/career-services/Federal%20Preemption%20of%20State%20and%20Local%20Laws.pdf).

[320] Freightliner Corp. v. Myrick, 514 U.S. 280, 287 (1995) (quoting Hines v. Davidowitz, 312 U.S. 52, 67 (1941)).

[321] *See id.*

[322] 42 U.S.C. § 300jj-11.

[323] This sentence and the next four paragraphs draw from Konnoth, *Regulatory De-Arbitrage*, *supra* note 14, at 148-50.

[324] Mayo Clinic, *supra* note 316, at 2.

[325] HealthShare Exch., Comment Letter on Draft Trusted Exchange Framework 2 (Feb. 20, 2018) (on file with author).

laws/regulations . . . for the TEFCA to be successful."[326] And other commenters threatened not to subscribe to TEFCA unless state laws are displaced.[327] As my own previous work suggests, such threats are not empty.[328]

It seems likely that TEFCA can—if it wants—displace at least some state regulation. What is less clear is the scope of such displacement. Only state laws that get in the way of the "common agreement among health information networks nationally" that the statute mandates could likely be invalidated.[329] This would suggest that the differing consent standards of Maine and New York[330] for transmitting information on health networks can be displaced. But TEFCA could potentially be written to preempt privacy laws more generally—at least when it comes to data on the network.[331] For example, while HIPAA *permits* the authorized sale of protected data,[332] Texas's Bill 300 does not.[333] TEFCA could potentially override Texas's approach at least with respect to data transmitted on the network.[334]

But other health privacy laws would conceivably fall outside the scope of the Act's reach, and therefore, of TEFCA's regulation. For example, Texas and California require covered entities to comply with requests for health data within a shorter period than does HIPAA.[335] A strict reading of the statutory language—

[326] Surescripts, Comment Letter on Draft Trusted Exchange Framework 6, 8 (Feb. 20, 2018) (on file with author) (repeating same language). Further, "local governance [including privately negotiated agreements, one assumes] over data use is eliminated by the Common Agreement." Health Current, Comment Letter on Draft Trusted Exchange Framework 2 (Feb. 20, 2018) (on file with author).

[327] CRISP, Comment Letter on Draft Trusted Exchange Framework 2 (Feb. 15, 2018) (on file with author).

[328] *See generally* Konnoth, *Electronic Health Records*, *supra* note 17 (arguing ONC should control data format standardization and hold primacy on functions involving networking).

[329] 42 U.S.C. § 300jj-11(9)(A).

[330] *See supra* notes 317-318 and accompanying text.

[331] There are other examples. *See, e.g.*, Dignity Health, Comment Letter on Draft Trusted Exchange Framework 5 (Feb. 20, 2018) (on file with author).

[332] Marketing is subject to a different requirement. *See* 45 C.F.R. §§ 164.501, 164.508(a)(3) (2021) (establishing separate consent requirement for marketing that states whether remuneration will be provided).

[333] H.B. 300, § 7, 2011 Leg., 82d Sess. (Tex. 2011) (codified at TEX. HEALTH & SAFETY CODE ANN. §§ 181.153, 181.154 (West 2021)) (prohibiting sale of protected health information with limited exceptions).

[334] Admittedly, the preemption would not apply if an entity chose not to join the network. Yet the American Medical Association ("AMA") and others note that insurers may require providers to link to the TEFCA network. *See* AMA, Comment Letter on Draft Trusted Exchange Framework 6 (Feb. 20, 2018) (on file with author).

[335] *Compare* 45 C.F.R § 164.524(b)(2) (2021) (requiring response within thirty days under HIPAA), *with* Confidentiality of Medical Information Act, CAL. CIV. CODE §§ 56-56.16 (West 2021) (setting California deadline at fourteen days), *and* H.B. 300, § 6 (codified at TEX. HEALTH & SAFETY CODE ANN. § 181.102) (requiring response within fifteen days).

"agreement among health information networks"—would suggest that since this data will be shared outside the nodes of the network (that is, with the patient), it is not subject to TEFCA regulation.[336] But a broad reading of the statute might conclude that it reaches the information sharing practices of any node of the network, even if the information is shared with an entity that is not part of the network.

Finally, there are some provisions that the Cures Act clearly does not allow TEFCA to displace. Texas's H.B. 300, for example, requires that the state attorney general offer "information concerning a consumer's privacy rights" via a website, and also mandates training of state employees.[337] But these provisions do not concern data on the national network and would likely survive.

2. Delegation of Preemptive Power

Having determined the scope of preemption, I turn next to explaining how a private entity might be delegated responsibility for doing so. In TEFCA's initial iteration, discretion was largely left to the RCE as to subsequent iterations of these rules. As it stated, the RCE would *itself* have the power to update the rules of the network over time.[338] Whatever its first iteration, the ideal would be to expand the agreement over time.[339] As commenters pointed out, this meant that the private entity would have been the one deciding whether a state's privacy law should be preempted as an initial matter.

This produced significant negative commentary. As one commenter explained:

> The process for revising the TEFCA appears to be delegated to an ONC grantee, the RCE, who would be a private-sector entity. In this scenario, rules and requirements that affect health information exchange for the country would be modified or updated with no notice and comment process to collect feedback from the stakeholder community in an open and transparent way, no regulatory impact assessment, and no guaranteed feedback loop. This is deeply troubling to the HIE community given the potential impact of the TEFCA on their business models and sustainability.[340]

Other commenters emphasized that the RCE would have great power—plenary authority, or as the State of Colorado put it, "limitless authority,"[341] to develop TEFCA and enforce compliance with it. One commenter registers

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[336] 42 U.S.C. § 300jj-11(c)(9)(A).

[337] Tex. H.B. 300, §§ 6, 8 (codified at TEX. HEALTH & SAFETY CODE ANN. §§ 181.103(a), 181.201(b-1)(3)).

[338] TEFCA DRAFT, *supra* note 287, at 9.

[339] Cerner Corp., *supra* note 314, at 2, 17; Epic, *supra* note 315, at 15.

[340] Direct Tr., Comment Letter on Draft Trusted Exchange Framework 6 (Feb. 20, 2018), https://directtrust.org/wp-content/uploads/2020/02/DirectTrust-TEFCA-comments-1.pdf [https://perma.cc/SQJ5-JLVM].

[341] Colo. Off. of eHealth Innovation, *supra* note 299, at 6.

> concern[] about the level of national control and authority this single entity will have to 1) develop and establish the requirements of a single Common Agreement; 2) operationalize the Trusted Exchange Framework; and 3) monitor and enforce [TEFCA] . . . . The level of control allocated to this central operator seems unnecessary and unparalleled in other sectors where a network-of-networks approach is used (such as banking).[342]

Patient Privacy Rights, a prominent patient privacy advocacy group, similarly cautioned that the RCE should be carefully defined "to make clear that it is controlled by the federal government and subject to the policies of the federal government."[343] A California State agency similarly argued that unless the RCE is a creature of "public-private collaboration . . . . ONC [should] put stringent guidelines on that organization."[344] Others simply argued that the RCE should be a government entity.[345]

After this pushback, HHS changed its mind in the second draft of TEFCA and decided that the private entity would be subject to a set of rules that the agency itself developed: "ONC will maintain the [Trusted Exchange Framework] and will work with an industry-based Recognized Coordinating Entity (RCE) to develop, update, implement, and maintain the Common Agreement."[346] Further, while "[t]he RCE will establish a process to continuously identify new standards and use cases to add to the Common Agreement," nevertheless "ONC will have final approval of the Common Agreement and all subsequent updates."[347] Privacy law compliance would be included in the set of rules that the agency developed rather than in the framework developed by the private entity.[348]

What happens on the ground remains to be seen. However, if past is prologue, the RCE will likely still call the shots. Professor Emily Hammond has looked to other contexts, including securities regulation, hospital accreditation, environmental standards, and workplace safety, where federal agencies have

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[342] Digit. Bridge, *supra* note 310, at 5; *see also* Strategic Health Info. Exch. Collaborative, *supra* note 310, at 5 ("The powers granted to the RCE seem broader and farther reaching than anything that has come before in the healthcare interoperability space.").

[343] Patient Priv. Rts., Comment Letter on Draft Trusted Exchange Framework 4 (Feb. 19, 2018) (on file with author).

[344] Cal. Ass'n of Health Info. Exchs., Comment Letter on Draft Trusted Exchange Framework 3 (Feb. 20, 2018) (on file with author); *see also* Colo. Off. of eHealth Innovation, *supra* note 299, at 6 (making similar suggestion).

[345] *See, e.g.*, Clinical Informatics, Inc., Comment Letter on Draft Trusted Exchange Framework 7 (Feb. 20, 2018) ("Compliance should be performed by complaint to an existing federal agency, most likely the Office of Civil Rights (OCR)."); *id.* at 7-8 ("Updating TEFCA should remain ONC's responsibility to ensure transparency and inclusive participation. If there is no money for ONC to retain this job, where would the money come from to pay the RCE? The open and transparent process that ONC manages in the regulatory review process would be difficult for a private entity to duplicate, let alone improve upon.").

[346] TEFCA DRAFT 2, *supra* note 306, at 8.

[347] *Id.*

[348] *Id.* at 9.

outsourced tasks to private bodies, though they allegedly have the final say over the rules or standards those bodies develop.[349] She finds that "oversight agencies are deferential . . . in practice"[350] to private delegatee rules, and that "even those that do have the full scope of authority rarely reject . . . proposed rules."[351] Professor Sidney Shapiro similarly explains that

> an agency's reliance on private parties creates several important transaction costs for the agency. . . .
>
> . . . .
>
> . . . [T]he agency lacks the expertise to oversee the standards-writing process in an effective manner. Second, to the extent that a politically powerful industry supports private standard setting, the agency may find it politically difficult to engage in extensive rewriting . . . .[352]

Given the cuts to the Office of the National Coordinator for Health Information Technology, the HHS agency responsible for oversight in the last few years, robust oversight of RCE proposals is unlikely.[353] The next Part examines why ONC oversight is unlikely in greater detail.

IV. USING FEDERALISM TO CHECK HEALTH DATA PRIVATIZATION

So far, my story has been primarily descriptive. Yes—the federal government has taken action such that private contracts rather than state law govern health data collection.[354] It has shifted the balance in HIEs towards private entities.[355] It has likely delegated to a private entity substantial say over the applicability of state privacy laws to health data exchange. But some might say that is a good thing. Privatization is the subject of much debate, and as for federalism, two colleagues coauthored an article in which they noted disagreement with *each other* about the bounds of federalism in the same paragraph.[356] This case study presents a concrete application of some of the issues involved.

The first half of this Part focuses on privatization and assesses the choice between private and public regulation of the space. It explains that private

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[349] *See, e.g.*, Emily Hammond, *Double Deference in Administrative Law*, 116 COLUM. L. REV. 1705, 1710 (2016).

[350] *Id.*

[351] *Id.* at 1748.

[352] Sidney A. Shapiro, *Outsourcing Government Regulation*, 53 DUKE L.J. 389, 404, 411 (2003).

[353] *See* Evan Sweeney, *Health IT Winners and Losers in Trump's Budget Proposal: Cybersecurity Gets a Boost, ONC Sees 37% Cut*, FIERCE HEALTHCARE (Feb. 13, 2018, 10:17 AM), https://www.fiercehealthcare.com/regulatory/trump-2019-budget-proposal-onc-ocr-health-it [https://perma.cc/PY8P-DTPV].

[354] Gobeille v. Liberty Mut. Ins. Co., 136 S. Ct. 936, 947 (2016).

[355] *See supra* notes 296-297 and accompanying text.

[356] Stuart Minor Benjamin & Ernest A. Young, *Tennis with the Net Down: Administrative Federalism Without Congress*, 57 DUKE L.J. 2111, 2145 (2008).

delegation is deeply problematic. But this criticism is measured—it concludes by recommending *some* involvement for private entities. The second half of this Part focuses on federalism and assesses the roles of the federal and state governments in partnership with private entities. As the first Section in the previous Part shows, healthcare federalism offers a variety of menu options in determining the scope of federal versus state regulation. Drawing from that Section, I suggest structural solutions that would help address the problem.

A. *Harms of Health Data Privatization*

Fully delegating to private entities oversight over many of the concerns presented here is problematic for a range of reasons. Many private entities use data to make a profit, which means that they may fail to share data when they should and share data when they should not. Such biases may be acceptable if they can be caught and easily corrected. But overseeing private entities is hard for both the government and the public. To be clear, not all private entities should be painted with the same brush, and many entities have done great work. Indeed, some entities may do excellent work on one front, even as they limit data sharing on another. But it is important to be aware of potential biases as the system is built. Finally, to bring home that the delegation to private firms indeed makes the situation worse, I argue that states are not subject to the same biases as private firms.

1. Data Profiteering

The sale of health data—albeit often in deidentified forms—is now a multibillion-dollar enterprise that spans insurance companies, providers, and EHR vendors.[357] Major health systems, from Kaiser to the Mayo Clinic, use health data for internal analyses and sell the data with the appropriate identifiers removed.[358] Google, IBM, United Health, and a recent joint venture by Amazon, JP Morgan, and Berkshire Hathaway, have all entered the multibillion-dollar business of data sales.[359] While leveraging the data for their own uses, these firms do not want to share their data elsewhere.[360]

Profit in this space depends on being able to sell data to those who will pay, and refusing to share it with those who will not. As the CEO for a major nonprofit in this space notes, "In a fee-for-service healthcare system, information isn't just power, it's money, too . . . . So it is natural that we'll get information hoarding, information blocking, and information channeling as

[357] ADAM TANNER, OUR BODIES, OUR DATA: HOW COMPANIES MAKE BILLIONS SELLING OUR MEDICAL RECORDS 3-4 (2017); Enriquez-Sarano, *supra* note 151, at 2321.

[358] Enriquez-Sarano, *supra* note 151, at 2325.

[359] *Id.* at 2325, 2327, 2330.

[360] *Id.* at 2357 (noting "risk that firms become reticent to share data"); *see also infra* Section IV.A.1.

means to an end by some entities."[361] Others have made similar comments.[362] Such behavior allows firms to prevent patient mobility, which may harm health outcomes, manipulate data, and monopolize research breakthroughs.[363]

I consider how the issue plays out in the contexts of data collection, network formation, and privacy laws in turn.

a. *Data Collection*

In *Gobeille*, Liberty Mutual argued that it sought to protect patient privacy and reduce its costs.[364] But Vermont had robust patient privacy protections and, as amici argued, figuring out what data belonged to a self-insured plan and what data did not would likely increase, not decrease, BCBS's costs.[365] The likely reason for Liberty Mutual's claims was to allow it to keep any profits that come from protecting its data.

The focus on the need for uniformity also seemed strained—sharing data based on myriad contracts and on whether plans were self-funded would also likely increase disuniformity. Indeed, ironically, while insurers claimed that state laws introduced disuniformity, the proliferation of different private contracts raise even greater disuniformity concerns. As researchers explain, even "worse than" the possibility that all insurers have exited APCDs is the possibility that "the proportion of commercial enrollees included in the APCD may vary over time in different states depending on how insurers in that state responded to the ruling."[366] Disuniformity decreases the robustness of research. Further, for third-party administrators like BCBS, determining which of its customers want it to submit data to states, and which, like Liberty Mutual, do not, is likely to be a greater administrative headache.[367]

At least part of the reason for this strained focus, therefore, likely lay elsewhere. Take Liberty Mutual's district court complaint, where it did not foreground privacy arguments or costs.[368] After arguing for ERISA preemption, it explained: "the Plan *owns the claims data* that [the state] seeks, and Liberty

[361] Paul Cerrato, *Healthcare Data Blocking: Fact or Fiction?*, MEDPAGE TODAY, https://www.medpagetoday.com/resource-centers/osteoporosis/healthcare-data-blocking--fact-fiction/455 [https://perma.cc/DC4M-683F] (last visited Dec. 5, 2021) (alteration in original).

[362] *See* Konnoth, *Health Information*, *supra* note 13, at 1330 (discussing "inherent wealth" in health data).

[363] *See infra* note 395-399.

[364] Brief for Respondent, *supra* note 228, at 14.

[365] *See* N.Y. Amicus Brief II, *supra* note 133, at 32 ("On the other hand, excluding data from self-funded plans will likely increase administrative costs for health care payers.").

[366] Gordon, *supra* note 265.

[367] Brief for Petitioner, *supra* note 101, at 54 ("[Liberty Mutual] suggested to the Second Circuit that providing information is '*per se* burdensome' because 'all regulations have their costs.'").

[368] *See* Joint Appendix at 24, Gobeille v. Liberty Mut. Ins. Co., 136 S. Ct. 936 (2016) (No. 14-181), 2015 WL 5159115, at *12.

Mutual Group Inc. . . . has designed the Plan to meet its own competitive needs in the marketplace."[369] To maintain these competitive needs, Vermont and its amici, including the American Medical Association, alleged insurers *would* share their plan data with each other.[370] But as the New York Attorney General found after an investigation, insurer submitted data suffers from "conflicts of interest from top to bottom."[371] Insurers would "manipulate the data they provided . . . so that the pooled data would skew reimbursement rates downward," such that "insurers systematically under-reimburs[ed] New Yorkers" up to 20%.[372]

But skewing the APCD database would create significant problems, as explained in an amicus brief filed by an institute at Harvard Law School on behalf of numerous medical researchers.[373] For example, if the amount of employer submitted data were reduced, the relative amount of Medicaid/Medicare data would increase—and that would present problems. In one study, Medicaid data suggested that a drug caused medical harms, but research using a less biased dataset showed that the study using only Medicaid data was incorrect.[374] Similarly, as of 2018, in Vermont, 59% of non-elderly women are covered by employer-sponsored plans but only 55% of men are.[375] As amici noted, nearly 60% of private companies are self-insured, and "companies with young, healthy employees are especially likely to opt for self-funding, while traditional commercial insurers are increasingly likely to cover a disproportionately older workforce."[376] Voluntary databases just did not work.[377]

Thus, the evidence seems to suggest that Liberty Mutual's goals were not to create uniformity or reduce costs of sending in data. Rather, its goal was to retain the competitive advantages of refusing to share the data, even if that came at a cost to the public. As the New York Attorney General suggested, retaining a data

[369] *Id.* at 25.

[370] AMA Brief, *supra* note 230, at 13.

[371] *Deceptive Health Insurance Industry Practices: Are Consumers Getting What They Paid For?—Part 1, Hearing Before the S. Comm. on Com., Sci. & Transp.*, 111th Cong. 6 (2009) (statement of Linda A. Lacewell, Counsel for Economic and Social Justice and Head of the Healthcare Industry Taskforce, Office of the New York State Att'y Gen.).

[372] *Id.* at 8.

[373] Brief of Amici Curiae Harvard Law School Center for Health Law & Policy Innovation, et al. in Support of Petitioner at 11-12, *Gobeille*, 136 S. Ct. 936 (No. 14-181).

[374] *Id.* at 13-14.

[375] Maura Calsyn, *Policy Options to Encourage All-Payer Claims Databases*, CTR. FOR AM. PROGRESS (Apr. 20, 2018, 9:02 AM), https://www.americanprogress.org/issues/healthcare/reports/2018/04/20/449602/policy-options-encourage-payer-claims-databases/ [https://perma.cc/L5P2-YDRE].

[376] *See* N.Y. Amicus Brief I, *supra* note 130, at 7; Hosp. Ass'n Brief, *supra* note 131, at 19.

[377] *See* NAHDO Brief, *supra* note 137, at 16.

monopoly allowed Liberty Mutual to skew reimbursement rates.[378] Retaining control over data also allows entities to gain a "monopolistic position of power over health analytics," which would allow them to retain the profit from (and monopoly control over) treatments that come from analyzing data.[379]

b. *Data Networks*

Entrusting private entities with HIEs would also present problems—though some federal rulemaking has been put into place to counteract these concerns.[380] The key problem is that private entities appear to engage in information blocking, which HHS defines as "a practice . . . likely to interfere with access, exchange, or use of electronic health information."[381] In short, developers seek to make it difficult to exchange data with the networks and systems of other EHR developers in order to control market share.[382] While controversy has raged over whether this is indeed a problem, after significant investigation, Congress has decided that it is.[383] Accordingly, the Cures Act tasked HHS with developing rules to prevent the practices.[384] Providers similarly appear to have engaged in blocking "to control referrals and enhance their market dominance."[385]

While HHS, pursuant to congressional command, issued a robust rule to prevent this practice in 2020,[386] it is unclear how robust *enforcement* of the rule will be. As scholars have noted, blocking may occur simply when private entities fail to prioritize data—there may be no smoking gun.[387] Finally, as I explain

[378] *See supra* note 371 and accompanying text.

[379] Véliz, *supra* note 34, at 312.

[380] *See* 42 U.S.C. § 300jj-11.

[381] Off. of the Nat'l Coordinator for Health Info. Tech., *Information Blocking*, HEALTHIT.GOV, https://www.healthit.gov/topic/information-blocking [https://perma.cc/6QS6-XY5H] (last reviewed Mar. 19, 2021). For a more detailed definition, see 42 U.S.C. § 300jj-52(a)(1)(A) (defining "information blocking" as a practice "likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information").

[382] For a summary, see OFF. OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., REPORT TO CONGRESS: REPORT ON HEALTH INFORMATION BLOCKING 15-16 (2015) [hereinafter HEALTH INFORMATION BLOCKING]. Many other sources including congressional testimony exist, but I do not seek to belabor the point.

[383] *See* 42 U.S.C. § 300jj-11.

[384] 42 U.S.C. § 300jj-52(a)(3).

[385] HEALTH INFORMATION BLOCKING, *supra* note 382, at 16.

[386] For some of the controversy around the rule, see Lucas Mearian, *Fed Rule on Patient Access to Healthcare Data Gets EMR Vendor Pushback*, COMPUTERWORLD (Jan. 30, 2020, 3:00 AM), https://www.computerworld.com/article/3518401/fed-rule-to-open-patient-access-to-healthcare-data-gets-emr-vendor-pushback.html [https://perma.cc/7VYY-LBJ5].

[387] Adler-Milstein & Pfeifer, *Information Blocking*, *supra* note 16, at 118 (distinguishing between weak and perverse incentives). It appears that intent may help determine violations. *See* Fred Bazzoli, *Final Rules on Info Blocking Pose Multiple Challenges—but Also Big Opportunities*, HEALTHCARE IT NEWS (May 1, 2020, 11:56 AM), https://www.healthcareitnews.com/news/final-rules-info-blocking-pose-multiple-challenges-also-big-opportunities [https://perma.cc/744U-339C].

below, it will be hard to monitor the actions of private entities to get evidence of information blocking malfeasance. Additionally overall HHS enforcement in other areas, including pursuing privacy violations, has slacked.[388]

The TEFCA oligopoly can enhance this bias.[389] The American Academy of Family Physicians expressed "concern[s] that a single RCE might function as a monopoly."[390] Others voiced concern about—possibly unintentional—bias or favoritism on the part of the RCE.[391] Another organization suggested that there should be many RCEs who could compete for health data networks.[392] While awarding the RCE position to The Sequoia Project alleviated some of these concerns, as there are several nonprofits among its members and it constitutes a group of organizations, for-profit industry remains heavily represented.[393]

Finally, private HIEs do not promote data exchange where there is no profit. Thus, in underserved or rural areas, it is public HIEs—which might now fail—that bear the brunt of the work.[394] Thus, once more, HIEs will be loath to promote data exchange where they will not retain profit.

c. *Privacy Regulation*

Turning ultimately to health privacy concerns—while entities will hoard data to preserve their profit motives, maintaining patient privacy also costs money. Historically, private entities have engaged in numerous privacy violations. The last few years have seen record breaking settlements: 2018 saw Anthem, a health insurer, pay $16 million in fines for security violations to HHS, which dwarfed

[388] *See* Konnoth, *Privatization*, *supra* note 21, at 2014.

[389] Private firms have an interesting relationship with TEFCA. On the one hand, they oppose government regulation. *See*, *e.g.*, athenahealth, Inc., Comment Letter on Draft Trusted Exchange Framework 1 (Feb. 20, 2018) (on file with author) ("True private sector leadership must materialize as a cornerstone of the framework . . . ."). But they are as afraid of a competitor getting an advantage by being designated as the RCE. Many firms envisage a private oligopoly of entities that can preserve the interests of specific health sectors (most prominently, their own), while remaining independent from government intervention. *See, e.g.*, AMA, *supra* note 334, at 5 (suggesting oversight from "provider community, patient/non-covered entity community, and public health community," while also demanding "independence from ONC").

[390] Am. Acad. of Fam. Physicians, Comment Letter on Draft Trust Exchange Framework 1 (Feb. 14, 2018) (on file with author).

[391] Mich. Health Info. Network Shared Servs., Comment Letter on Draft Trust Exchange Framework 14 (Feb. 20, 2018) (on file with author).

[392] La. Pub. Health Inst., Comment Letter on Draft Trusted Exchange Framework 2 (n.d.) (on file with author).

[393] *See The Sequoia Project's Founding Members*, *supra* note 296.

[394] *See* SPOTLIGHT, *supra* note 223, at 2, 6; Mike Miliard, *State and Regional HIEs: 'Don't Count Us Out Just Yet!,'* HEALTHCARE IT NEWS (Jan. 28, 2019, 9:51 AM), https://www.healthcareitnews.com/news/state-and-regional-hies-dont-count-us-out-just-yet [https://perma.cc/PL6G-Y9WK] ("[I]f you go looking for the people that have the last mile wired and/or have the data available—and in some cases have it in normalized, curated repositories, ready to be exchanged—it's the HIEs.").

the prior 2016 record of $5.5 million.[395] In 2019, Aetna, another payer, entered settlements after accidentally disclosing that 12,000 individuals lived with HIV.[396] Despite these prominent settlements, overall, HHS enforcement has been increasingly lax—and indeed, some of these actions were state-initiated as I describe below.[397] Even if the privacy rules that the RCE writes are robust, there is no reason to believe that enforcement of those rules would be stringent if private entities are left at the helm—it is often simply not in their interest.[398] Such privacy risks can result in discrimination, blackmail, and identity theft.[399] By contrast, state enforcement of privacy violations has been increasingly robust, as the next Section discusses.

2. Lack of Oversight

When private entities engage in biased behavior, there is little oversight. When it comes to data collection, *Gobeille* left Liberty Mutual to do as it wished.[400]

But similar problems arise when it comes to the lack of oversight of the data networking and privacy issues raised by delegating control to a private RCE. Commenters have offered concerns over the RCE-ONC oversight mechanism: "If a private entity does the monitoring, who monitors the monitor? There would be a greater risk of conflict of interest and a higher cost due to the need for additional oversight of the RCE."[401] The lack of oversight arises for several reasons. First, as I discuss in the previous Part, oversight by ONC is likely to be limited, and even if ONC finds malfeasance, it is unlikely to be able to do much. Second, public oversight of government contractors like the RCE will be

[395] Press Release, U.S. Dep't of Health & Hum. Servs., Anthem Pays OCR $16 Million in Record HIPAA Settlement Following Largest U.S. Health Data Breach in History (Oct. 15, 2018), https://www.hhs.gov/about/news/2018/10/15/anthem-pays-ocr-16-million-record-hipaa-settlement-following-largest-health-data-breach-history.html [https://perma.cc/UAD8-U7TN].

[396] Shelby Livingston, *Aetna Settles California Lawsuit over HIV Privacy Breach*, MOD. HEALTHCARE (Jan. 31, 2019, 12:00 AM), https://www.modernhealthcare.com/article/20190131/NEWS/190139978/aetna-settles-california-lawsuit-over-hiv-privacy-breach [https://perma.cc/NL3G-9SDA] (describing Aetna's $935,000 settlement with California's Attorney General following Aetna's accidental mailing of letters revealing patients' use of HIV medicine).

[397] *E.g.*, *id.*; *see also infra* notes 499-501 and accompanying text.

[398] For a full list of breaches, see *Breach Portal: Notice to the Secretary of HHS Breach of Unsecured Protected Health Information*, U.S. DEP'T OF HEALTH & HUM. SERVS. OFF. FOR C.R., https://ocrportal.hhs.gov/ocr/breach/breach_report.jsf/ [https://perma.cc/8WAB-NTT4] (last visited Dec. 5, 2021). While most of these are private health systems and payers, note that some of them are public entities.

[399] *See* Véliz, *supra* note 34.

[400] *See supra* Section III.A.

[401] Clinical Informatics, Inc., *supra* note 345, at 7.

curtailed. And third, the kinds of organizations that form The Sequoia Project RCE generally have rejected oversight.

Turning first to ONC's oversight, the TEFCA draft leaves the oversight plans over the RCE murky.[402] But by contracting out data management functions, the federal government will have outsourced much of the expertise involved in a complex technical area. Even to the extent the federal government retains some expertise, monitoring will be in the hands of procurement personnel, not individuals with actual expertise (though this depends in part on how the administration actually enforces TEFCA).[403] ONC will also lack the resources to engage in close oversight of private entities—ONC has faced severe budget cuts in the last few years.[404]

Further, even if ONC discovers egregious malfeasance, there is a lack of competition: the transaction costs that come with switching out contractors will make it hard to act on the information, rendering accountability even harder to achieve.[405] Thus, a patient rights organization "encourage[s] ONC to develop an approach that does not vest significant power in one organization, an RCE, that once selected, and TEFCA implemented, will risk cementing current approaches and not make way for innovation."[406] First, private firms face transaction costs in submitting bids, and in developing the resources that render them eligible to submit bids—only firms with a certain range of resources would be eligible to apply to run a national health data network.[407] The government also faces transaction costs. It must share some of a contractor's start-up costs.[408] Thus, as David Super explains, these costs have "forced several states to keep [technical] contractors [who] were causing chaos in the administration of their programs. The states reasoned that switching contractors would cause considerable disruption and that any new contractor's system might have comparable

[402] Thus, the AMA requested "clarity from ONC on where it believes its oversight role intersects with a QHIN's oversight and/or that of a Recognized Coordinating Entity (RCE)." AMA, *supra* note 334, at 3.

[403] JON D. MICHAELS, CONSTITUTIONAL COUP: PRIVATIZATION'S THREAT TO THE AMERICAN REPUBLIC 133-34 (2017).

[404] Heather Landi, *ONC Budget Cut by 29 Percent in FY2019 Draft Bill, NIH Gets $1.25B Boost*, HEALTHCARE INNOVATION (June 19, 2018), https://www.hcinnovationgroup.com/policy-value-based-care/news/13030445/onc-budget-cut-by-29-percent-in-fy2019-draft-bill-nih-gets-125b-boost [https://perma.cc/8KMV-KVWS].

[405] We see this dynamic in the federalism context as well. Jessica Bulman-Pozen, *Federalism as a Safeguard of the Separation of Powers*, 112 COLUM. L. REV. 459, 477 (2012) ("[O]nce the federal executive has been assigned a function—and the states have not—it will be practically quite complicated to switch this function to the states, which likely will not have built up the requisite capacity. Indeed, the reverse is also true and is a well-known source of state power in cooperative federalism schemes . . . .").

[406] PatientRightsAdvocate.org, Comment Letter on Draft Trusted Exchange Framework 2 (Feb. 20, 2018) (on file with author).

[407] *See* David A. Super, *Privatization, Policy Paralysis, and the Poor*, 96 CALIF. L. REV. 393, 414 (2008) (discussing how firms must build up resources to submit bids on contracts).

[408] *Id.* at 420.

problems."[409] The problem is limited in the case of easily available, fungible products: states could switch out the supplier of floor mopping liquid for their janitorial staff, for example. But swapping out a provider for a national health data network would be hard.

Next, there will also be less public oversight. Courts have held that private contractors are subject to neither Freedom of Information Act rules[410] nor Administrative Procedure Act procedures,[411] which means that others in civil society cannot monitor what contractors do.[412] Private health IT firms are unlikely to demonstrate particular solicitude for the concerns and interests of their competitors, or for the individuals from whom they collect data. In particular, a single private entity would be far less accountable than state entities. The administration of policy might reside in remote corporate headquarters, quite apart from local contexts where it is administered.[413] As privatization scholars note, contractors' employees do not need to attend those local town halls that federal congressmen found particularly fractious when discussing plans to repeal the ACA.[414]

Finally, EHR vendors and private HIEs have resisted attempts at transparency. They might seek to escape responsibility in case of deliberate or inadvertent malfeasance, of course, but their key goal is to keep proprietary

[409] *Id.*; *see also* Michele Estrin Gilman, *Legal Accountability in an Era of Privatized Welfare*, 89 CALIF. L. REV. 569, 599 (2001) (noting that contractors "gain specific expertise and develop close relationships with government officials"). One study shows how the Massachusetts Department of Mental Health's contracting process lacked competition in its bidding because the "'goal of maintaining continuity of care,' economies of scale, and the difficulties associated with evaluating providers without 'track record' . . . led to an increasing concentration of contracts with large organizations." JOEL F. HANDLER, DOWN FROM BUREAUCRACY: THE AMBIGUITY OF PRIVATIZATION AND EMPOWERMENT 89 (1996) (quoting Janet Rothenberg Pack, *The Opportunities and Constraints of Privatization*, *in* PRIVATIZATION AND ITS ALTERNATIVES 281, 302 (William T. Gormley, Jr., ed., 1991)). Private contractors thus, in time, become "public monopolies." *Id.* at 217.

[410] *E.g.*, Lombardo v. Handler, 397 F. Supp. 792, 802 (D.D.C. 1975) (holding that private entity that "merely contract[s] with the government to conduct studies" is not an agency and not subject to FOIA).

[411] *E.g.*, Perry v. Delaney, 74 F. Supp. 2d 824, 839 (C.D. Ill. 1999) (finding APA does not apply to private firm that provides services to federal agency).

[412] *See* Jon Michaels, *Deforming Welfare: How the Dominant Narratives of Devolution and Privatization Subverted Federal Welfare Reform*, 34 SETON HALL L. REV. 573, 600 (2004).

[413] As Jon Michaels explains, a contracting firm's "Vice President . . . is less likely than a state [or, for that matter, federal] legislator or city alderman to run into . . . ordinary taxpayers . . . in the local supermarket and get an earful." *Id.* at 638. To be sure, a federal entity would also be less accountable than state entities, but that cost by itself is acceptable, in my opinion, with the benefits that accrue from interoperability.

[414] *See, e.g.*, Seung Min Kim, *Moran Gets an Earful on Obamacare Repeal at Town Hall*, POLITICO (July 6, 2017, 3:40 PM), https://www.politico.com/story/2017/07/06/jerry-moran-gop-health-care-bill-townhall-240268 [https://perma.cc/2V8H-X3Q2].

various kinds of algorithms and technology.[415] Thus, as a government primer for providers of EHRs explains, EHR contracts

> define confidential information expansively to include almost everything the EHR technology developer discloses or provides to [the provider] . . . . The definition of confidential information may be broad and could restrict [the provider's] ability to share access to the EHR technology developer's software in order to compare different EHR technology developer systems, provide access to researchers, or even address possible patient safety concerns.[416]

Further, vendors require clients who notify them of defects to "sign non-disclosure agreements that prevent the provider organization from even disclosing the fact that a defect exists."[417] Again while the proposed information blocking rule seeks to limit such practices, the final limitations might be narrowly interpreted, and enforcement of the rule will likely be spotty.[418]

3. Comparing Firms to States

State engagement in health data regulation has not been perfect, but there have been bright spots. As should be clear by now, the field consists of numerous players—ranging from providers to EHR developers, payers, patients, and others. State oversight may present issues, but states are relatively insulated from capture, simply because of the numerous sets of conflicting interests involved.[419] In *Gobeille*, for example, the American Hospital and Medical Associations were on opposite sides from Liberty Mutual and BCBS.[420] It would be hard for states to favor one powerful group over another without consequences, and, as described above, states have incorporated private and public entities within their organizations to ensure feedback from their stakeholders.[421] Agency heads often sit on the boards of these organizations.[422] And most importantly, no one vendor

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[415] W. Nicholson Price II, *Regulating Black-Box Medicine*, 116 MICH. L. REV. 421, 436 & n.75 (2017).

[416] WESTAT, EHR CONTRACTS: KEY CONTRACT TERMS FOR USERS TO UNDERSTAND 7 (2013), https://www.healthit.gov/sites/default/files/ehr_contracting_terms_final_508 compliant.pdf [https://perma.cc/NL44-3D4R].

[417] OFF. OF NAT'L COORDINATOR FOR HEALTH INFO. TECH., EHR CONTRACTS UNTANGLED: SELECTING WISELY, NEGOTIATING TERMS, AND UNDERSTANDING THE FINE PRINT 12 (2016), https://www.healthit.gov/sites/default/files/EHR_Contracts_Untangled.pdf [https://perma.cc/6ZTE-86ER].

[418] *See supra* note 381 and accompanying text.

[419] *See* AMA Brief, *supra* note 230, at 16-17; Am. Med. Ass'n v. United Healthcare, 588 F. Supp. 2d 432, 438 (S.D.N.Y. 2008) (noting AMA's opposition to United Healthcare's reliance on database).

[420] Gobeille v. Liberty Mut. Ins. Co., 136 S. Ct. 936, 941-42 (2016).

[421] *See supra* notes 125-130 and accompanying text.

[422] *See, e.g.*, Del. Health & Soc. Servs., *Who Serves on the Delaware Health Care Commission?*, DELAWARE.GOV, https://dhss.delaware.gov/dhss/dhcc/serve.html [https://perma.cc/UF69-MND8] (last visited Dec. 5, 2021).

has a monopoly in any state. Because states are smaller, unlike a potential RCE, they can (and have) switched out vendors that do not do the job well.[423]

The federal government has recognized state capability. As HHS has noted in the context of developing payment models based on data the state collects,

> States are key partners in developing and testing community-centered health systems and proving that they can deliver significantly improved cost, quality, and population health performance results for Medicare, Medicaid, and CHIP beneficiaries. States have policy and regulatory authorities, as well as ongoing relationships with private payers, health plans, and providers, that can help drive and accelerate performance of payment and service delivery models across the spectrum of public and private payers.[424]

Delegating power to firms thus makes the situation worse.

4. The Importance of Private Involvement

So far, I have made the case that complete delegation to firms is problematic. But at the same time, firms *must* be included in any solution. First, at this point in time, substantial expertise lies with firms. States themselves have realized many of their strengths by determining that they lack expertise in certain contexts and that reliance on private industry can be useful. However, where the privately delegated function can be specified, where performance can be appropriately evaluated, when competition exists in the award and maintenance of the contract, and when private and government interests are aligned, there might be great benefits to privatization.[425] Where the field is technical, private entities may be better situated to create novel solutions.[426]

Further, as enforcement scholarship suggests, engaging private entities in enforcement can help entrench the values from within the organization through compliance officers and the like. Compliance will come from within—firms will follow the law because that becomes part of their culture, rather than trying to

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[423] *See* Mary Sell, *Health Insurance Provider Changes Approved by State Employees' Insurance Board*, ALA. DAILY NEWS (July 21, 2019), https://www.aldailynews.com/health-insurance-provider-changes-approved-by-state-employees-insurance-board/ [https://perma.cc/ABH9-RQ8U].

[424] U.S. DEP'T OF HEALTH & HUM. SERVS., CTR. FOR MEDICARE & MEDICAID INNOVATION, FUNDING OPPORTUNITY NO. CMS-1G1-12-001, STATE INNOVATION MODELS: FUNDING FOR MODEL DESIGN AND TESTING ASSISTANCE 2 (2012), https://innovation.cms.gov/files/x/stateinnovation_foa.pdf [https://perma.cc/6BDF-BYNH]; *see also* AMANDA VAN VLEET & JULIA PARADISE, KAISER FAM. FOUND., THE STATE INNOVATION MODELS (SIM) PROGRAM: AN OVERVIEW 1 (2014), http://kff.org/medicaid/fact-sheet/the-state-innovation-models-sim-program-an-overview [https://perma.cc/3JC8-95SV] ("The State Innovation Models (SIM) initiative provides federal grants to states, under cooperative agreements, to design and test innovative, state-based multi-payer health care delivery and payment systems.").

[425] JOHN D. DONAHUE, THE PRIVATIZATION DECISION: PUBLIC ENDS, PRIVATE MEANS 10 (1989); Shelley Welton, *Public Energy*, 92 N.Y.U. L. REV. 267, 282-85 (2017).

[426] Martha Minow, *Public and Private Partnerships: Accounting for the New Religion*, 116 HARV. L. REV. 1229, 1243-46 (2003) (pointing to "competition and incentives for improvement" and development of "new knowledge" and infrastructure).

get away with what they can.[427] Thus, there is no one answer, whatever the mode of privatization or nationalization, that can tell us how all these calculations come out as a general matter.

Finally, in certain policy contexts, private checks on government power are also desirable. Most recently, for example, Apple and Google, which have proposed using smartphones for COVID-19 tracking—presenting some surveillance concerns by itself—have refused requests from public officials for even more pervasive tracking.[428]

B. *Structural Solutions*

Transferring control to private entities altogether is undesirable—even though I end the previous Section by suggesting they should be involved in the process. But even if private entities are involved, how should we organize the public participation by the federal and state governments? In so choosing, we can pick from the menu of federalism structures that Part I outlines: separate spheres, cooperative, and interstitial federalism. I begin this Part by explaining why the separate spheres and interstitial approaches are of limited promise.

I therefore recommend a cooperative approach, where the federal government and states partner up. Private entities will—as the last Section recommends—also be involved. Such joint solutions may take three forms. First, states can be given powers ex ante—they will act as contractors for the federal government, which may then involve subdelegations and contracting with private entities. This tracks what federal health law already *does* in the ACA and Medicaid contexts.[429] Next, states and private entities might be treated as partners in building national programs. Finally, states might be given, with the federal government, ex post enforcement powers, to check malfeasance by private entities. I offer a sketch of how each of these solutions should work.

One final note: these changes will likely have to be achieved through agency action.[430] Thus, I consider agency authority closely where relevant. Absent

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[427] *See* Michael J. Trebilcock & Edward M. Iacobucci, *Privatization and Accountability*, 116 HARV. L. REV. 1422, 1447-48 (2003); Christopher Serkin, *Public Entrenchment Through Private Law: Binding Local Governments*, 78 U. CHI. L. REV. 879, 886 (2011).

[428] Reed Albergotti & Drew Harwell, *Officials Downplay Efficacy of Virus Apps*, WASH. POST, May 16, 2020, at A1 ("The struggle for effective digital contact tracing is reshaping the debate over the trade-offs between privacy and public health when lives are immediately at stake.").

[429] Konnoth, *Privatization*, *supra* note 21, at 2005-07.

[430] An evenly divided Senate will make going through Congress hard, while going through courts will likely not prove productive. The Supreme Court purported to be interpreting congressional command in *Gobeille*. Gobeille v. Liberty Mut. Ins. Co., 136 S. Ct. 936, 943 (2016). Additionally, arguing that the Cures Act does not permit the privatized delegation in TEFCA, while a colorable argument, would likely not work. To be sure, one might argue that where Congress intended to allow *privatized* delegation with respect to the tasks involved, it clearly provided for it in the statute. For example, it directs that "the Secretary . . . , directly

further instruction from Congress, agencies should be particularly disposed to federalism-respecting solutions, as they are bound by a range of executive orders to adopt federalism-promoting solutions where possible. The details of this regime are described elsewhere.[431]

1. The Problem with Separate Spheres and Interstitial Approaches

The last Section concludes by recommending that, while private entities should not be delegated primary control over the health data space, they should somehow still be involved in partnership with *public* entities. But what should those public entities be and how should they be organized?

Under the separate spheres approach, we could either award authority entirely to the federal government or to states. Neither alternative is ideal. Purporting to create state primacy in the field of health data regulation is subpar, even though states are superior to firms. Liberty Mutual was not wrong in *Gobeille* when it noted that disuniformity still exists among states: for example, states may require reporting based on different criteria, or for different individuals as they define state "resident" differently.[432] Some central coordination is required.

At the same time, the federal government should not hold unilateral power. Regulatory capture by a private entity of a federal agency for example, will likely lead to even more regulatory capture unless states can step in to limit the tilt.[433] And with fifty states, at least some have differing party allegiances and local commitments than the federal government. They can thus act as an effective check on federal delegation to private entities.[434]

At the same time, a non-coordinated, interstitial model where the federal government goes its own way and the states fill in the gap in an ad hoc manner is problematic for similar reasons I describe above.

Thus, a cooperative solution where all three entities have a voice is preferable, in the ways I describe in the introduction to this Part.

or through a partnership with a private entity, establish a provider digital contact information index to provide digital contact information for health professionals." 42 U.S.C. § 300jj-11 (emphasis added). Indeed, it carefully circumscribes private influence. The Health Information Technology ("HIT") Advisory Committee has private representation on it—at least twelve members of the twenty-five-member advisory committee are government officials, while two others should be patient or consumer advocates. 42 U.S.C. § 300jj-12(d)(2). Of the remainder, there must be "balance among various sectors." *Id.* § 300jj-12(d)(3). But other statutes where Congress has delegated to private entities take similar approaches, and agencies still delegate. *See* Konnoth, *Privatization*, *supra* note 21, at 1977 (discussing statutes in which Congress has delegated authority to private entities). This argument would face an uphill battle.

[431] Konnoth, *Privatization*, *supra* note 21, Part III.

[432] Brief for Respondent, *supra* note 228, at 40.

[433] Konnoth, *Privatization*, *supra* note 21, at 2003 ("[I]t might be hard for the federal government to summon the political will and strength to fight back against private entities. States, however, will be able to exercise appropriate oversight . . . .").

[434] *Id.* at 2001-02.

2. States as Contractors for National Health Data Regulation

I first explain how the ACA creates a partnership federalism framework for federal and state governments, and then show how federal and state entities can adopt that framework in the context of health data regulation.

a. *Existing Contractor Models*

The ACA adopts a cooperative federalism model.[435] Like various cooperative federalism models, the ACA seeks to devolve power to the states in developing health insurance exchanges. However, the matter is not left entirely up to the states. The ACA gives states right of first refusal: if a state declines to run an exchange, the federal government then uses a federal contractor to run much of the exchange in that state.[436] As health data interaction is similarly important, we cannot have states that "opt out" of data exchange—it is more appropriate to look to a model that gives states the right of first refusal rather than the right to opt out.

The ACA states engaged with and learned from each other in this process. Connecticut's exchange—in part, perhaps, informed by the high concentration of health insurance industry in the state—created a model system and "package[d] [its] services and expertise and [made] them available to other states, . . . avoiding a duplication of effort."[437] States collaborated in other ways: through learning collaboratives,[438] or even using the same contractors or consulting firms, such as Deloitte.[439] And there is evidence to suggest that the states-as-contractors did a better job than the private contractors the federal government hired. As one nonprofit notes, "the administration turned the task of building its futuristic new health care technology planning and programming over to legacy contractors with deep political pockets."[440] This produced "[p]roblem-plagued online exchanges that make it all but impossible for consumers to buy insurance and hundreds of millions of dollars in the coffers of some of the biggest lobbying powerhouses in Washington."[441] On the other

[435] Gluck & Huberfeld, *supra* note 6, at 1774.

[436] 42 U.S.C. §§ 18041(c)(1), 18031(b)(1). *See generally* King v. Burwell, 135 S. Ct. 2480, 2487 (2015) (describing federal and state exchanges).

[437] Gluck & Huberfeld, *supra* note 6, at 1774-75 (quoting Robert Pear, *Connecticut Plans to Market Health Exchange Expertise*, N.Y. TIMES, Feb. 25, 2014, at A17).

[438] *Id.* at 1772-73. These networks included the "Center for Consumer Information and Insurance Oversight (CCIIO); the Health Care Reform Regulatory Alternatives Working Group of the National Association of Insurance Commissioners; the State Health Exchange Leadership Network of the National Academy for State Health Policy; the National Governors Association; . . . the National Conference of State Legislatures (NCSL)[; and] . . . . the National Association of Insurance Commissioners." *Id.* (footnotes omitted).

[439] *Id.* at 1775.

[440] Bill Allison, *Good Enough for Government Work? The Contractors Building Obamacare*, SUNLIGHT FOUND. (Oct. 9, 2013, 3:34 PM), https://sunlightfoundation.com/2013/10/09/aca-contractors/ [https://perma.cc/73JX-VBZJ].

[441] *Id.*

hand, many states waited to see how a private contractor performed in other states before hiring them—and those contractors would have been incentivized to perform well, knowing that other states out there might hire them, instead of a one-time contract with the federal government.[442]

This cooperative-contractor model can be used to create a framework for state involvement in the health data regulation process.

b. *APCDs*

In the context of APCDs, the Court said that authority lay with federal agencies.[443] These agencies should coordinate with, and delegate a substantial amount of the task to, states as contractors. As a practical matter, states have historically cooperated with each other and would be able to take on the task.[444] In 2007, northeastern states convened the Regional All-Payer Healthcare Information Council, which became the national All-Payer Claims Database Council in 2010.[445] States assist each other with selecting vendors, providing support and analytics, finding common solutions to problems, and creating model legislation.[446]

As a legal matter, in *Gobeille* itself, Justice Breyer raised the possibility that the federal government could officially designate states as contractors of the federal government for data collection purposes.[447] Recall that one of the reasons the Court held that the state APCDs were preempted was because they interfered with "core" ERISA functions—ERISA required plans to report data to the federal Department of Labor ("DOL"); since states also required data reporting (albeit of a different kind), there was preemption.[448]

Concurring with the Court, Justice Breyer—himself a former administrative law professor—explained that "pre-emption does not necessarily prevent Vermont or other States from obtaining the self-insured, ERISA-based health-plan information that they need"—all states need to do is "ask the Federal Government for appropriate approval."[449] As the majority says, he notes, the statute gives the "Secretary of Labor . . . authority to establish additional reporting and disclosure requirements" and to "undertake research and surveys and in connection therewith to collect, compile, analyze and publish data,

[442] Gluck & Huberfeld, *supra* note 6, at 1774-75.

[443] Gobeille v. Liberty Mut. Ins. Co., 136 S. Ct. 936, 945 (2016) ("The Secretary of Labor, not the States, is authorized to administer the reporting requirements of plans governed by ERISA.").

[444] Gluck & Huberfeld, *supra* note 6, at 1774-75.

[445] Brief for Nat'l Governors Ass'n, *supra* note 101, at 8.

[446] *Id.* at 9-10.

[447] *Gobeille*, 136 S. Ct. at 949 (Breyer, J., concurring).

[448] *Id.* at 944 (majority opinion).

[449] *Id.* at 949 (Breyer, J., concurring).

information, and statistics relating to employee benefit plans, including retirement, deferred compensation, and welfare plans."[450]

The DOL could use this power to use states as contractors: "the Department could . . . delegate to a particular State the authority to obtain data related to that State, while also providing the data to the Federal Secretary for use by other States or at the federal level."[451] To be sure, this does not allow the states to retain the same degree of power as it otherwise would without ERISA preemption, as it must get "federal approval or authorization."[452] But, as Justice Breyer rightly points out, this allows us to create a national perspective on health data, and avoids conflict by creating some degree of national coordination, just as we see to some degree in the ACA health exchanges and Medicaid programs; the federal government can determine the extent to which state efforts should be uniform.[453] And, much like the ACA, if states decline, the federal government can step in and collect the data itself: the Secretary "could . . . develop [federal] reporting requirements that satisfy the States' needs"—and presumably any federal needs as well.[454]

A few months after *Gobeille* was decided, in the waning months of the Obama Administration, the DOL sought comment on data collection in light of *Gobeille*.[455] Historically, as the United States noted in its amicus brief in *Gobeille*, which was signed by the DOL, the federal government did not collect claims data.[456] But now, it proposed to do so. Comments on the notice of proposed rulemaking closed about a month before the end of the administration, and the Department did not take further action under the Trump Administration.[457]

However, the DOL should reopen the matter in 2021, and revisit its approach. Rather than seek to collect the data itself, it should take heed of the

[450] *Id.* (quoting 29 U.S.C. § 1143(a)(1)).

[451] *Id.* at 950.

[452] *Id.*

[453] *Id.* ("The federal agencies are more likely to be informed about, and to understand, ERISA-related consequences and health-care needs from a national perspective. Their involvement may consequently secure for the States necessary information without unnecessarily creating costly conflicts—particularly when compared with such alternatives as giving each State free rein to go its own way or asking nonexpert federal courts to try to iron out, regulation by regulation, such conflicts.").

[454] *Id.* at 949-50. Justice Scalia expressed some reservations about this at oral argument, but I agree with commentators that such reservations appear to be baseless. Nicholas Bagley, *The Labor Department and* Liberty Mutual v. Gobeille, INCIDENTAL ECONOMIST (Jan. 6, 2016), https://theincidentaleconomist.com/wordpress/the-labor-department-and-liberty-mutual-v-gobeille/ [https://perma.cc/4BBK-UTYU].

[455] Annual Reporting and Disclosure, 81 Fed. Reg. 47,496, 47,500 (proposed July 21, 2016) (to be codified at 29 C.F.R. pts. 2520, 2590).

[456] U.S. Merits Stage Brief, *supra* note 135, at 22.

[457] *See* Annual Reporting and Disclosure, 81 Fed. Reg. at 47,496 (setting comment collection deadline of October 4, 2016).

recommendation of some entities to work with state APCDs. As one commentator notes, a joint

> federal-state . . . approach is attractive because it allows DOL to leverage existing state APCD data collection and analytic capacity, reduces administrative burden and duplication, and leaves APCD investments intact. States would be granted authority to collect a uniform dataset from self-funded plans on a monthly or quarterly basis that would be aggregated into an annual report to the DOL to provide more robust data . . . .[458]

Beyond these reasons, the DOL only has power under ERISA to collect data from self-funded plans.[459] If the federal government continues to collect the data itself, there will likely be more fragmentation: states will collect data from the remaining employers that are not self-funded.[460] It is possible that the federal government can collect the data and then feed it to states for self-funded plans, but resituating existing state-based APCD data collection modalities within a new federal framework would help reduce data duplication and maintain data integrity as well. Finally, as commenters note, likely because of the DOL's limited experience in this area, the data collection efforts of the DOL may be problematic in other ways.[461]

c. *HIEs and Privacy Laws*

The context of state HIEs and privacy laws do not allow for such a neat ending. The fundamental problem here is delegation of the RCE role to an entity dominated by private firms, but delegating to states to the same degree as with APCDs is not viable because state HIEs have not engaged in the same level of coordination as we see with state APCDs.[462] Further, states-as-contractors in the context of the ACA and Medicaid do not run programs that are completely similar.[463] But with respect to data transmission and HIEs—where the fundamental rationale of the system is interconnectedness and linkages—

[458] NASHP Staff, *Next Steps for APCDs: US Department of Labor (DOL) Rulemaking*, NAT'L ACAD. FOR STATE HEALTH POL'Y (Oct. 4, 2016), https://www.nashp.org/next-steps-for-apcds-us-department-of-labor-dol-rulemaking/ [https://perma.cc/7VYY-WUFM].

[459] Brief for Nat'l Governors Ass'n, *supra* note 101, at 16-17.

[460] *See supra* note 261 and accompanying text.

[461] Carmel Shachar, Aaron S. Kesselheim, Gregory Curfman & Ameet Sarpatwari, *Potential Roadblocks in Healthcare Big Data Collection*, *in* BIG DATA, HEALTH LAW, AND BIOETHICS 112, 120 (I. Glenn Cohen et al. eds., 2018).

[462] *Compare supra* notes 437-442 and accompanying text (arguing that there was some benefit to decentralizing the creation of HIEs to states, and that states used private contractors well in some circumstances), *with supra* notes 287-292 (discussing overreliance of federal government on private sector).

[463] *See* Konnoth, *Privatization*, *supra* note 21, at 2005-07.

disuniformity is not acceptable.[464] Firmer federal control does make more sense in that context. Finally, the TEFCA contract has been awarded to the new RCE—The Sequoia Project—and it would likely be counterproductive to restart the process, even with the possible harms of privatization.[465]

At the same time, however, it is important to create a role for the states. How can we do so? The answer lies in the fact that the RCE is not the only player in town.[466] The RCE will operate through several Qualified Health Information Networks ("QHINs") that perform the task of actually connecting entities, including providers, payers, and other health information networks.[467] They will ensure that these entities comply with the rule of data exchange, technical specifications, privacy, and the like.[468] Indeed, in some ways, QHINs will operate like health insurance exchanges: much like insurance exchanges marshal insurance companies within a particular network subject to certain rules regarding insurance coverage within a state, so too will QHINs marshal health entities within a region subject to certain rules regarding data exchange.[469]

The second draft of TEFCA appears to permit any existing networks, including state networks, to apply for QHIN status.[470] But HHS should, again, seek to give the right of first refusal to states to act as contractors to the RCE.[471] The RCE can set base rules, and a few states or group of states can come together to form a QHIN, depending on the number of QHINs desired.[472] This limits duplication of efforts and addresses concerns that QHINs might act in a biased way among participants.[473] Even in the early draft, commenters read such collaborations as possible: "two single state HIEs [could] collaborate as a QHIN."[474] HHS should also follow the approach the federal government adopts in other areas of health law, and assist states with the process of becoming

[464] *See* Konnoth, *Electronic Health Records*, *supra* note 17 (arguing that FDA should refrain from regulating aspects of EHRs that directly implicate data networks because of their interconnectedness).

[465] Rajiv Leventhal, *ONC Awards The Sequoia Project as TEFCA's Recognized Coordinating Entity*, HEALTHCARE INNOVATION (Sept. 3, 2019), https://www.hcinnovationgroup.com/interoperability-hie/trusted-exchange-framework-and-common-agreement-tefca/article/21095350/onc-awards-the-sequoia-project-as-tefcas-recognized-coordinating-entity.

[466] TEFCA DRAFT 2, *supra* note 306, at 11.

[467] *Id.*

[468] *Id.* at 11, 35-37.

[469] *See id.*

[470] *Id.* at 11.

[471] While the QHIN selection process is laid out in TEFCA, HHS appears to retain control to modify the terms of TEFCA at any time. *See id.*

[472] *See* The Sequoia Project, Comment Letter on Draft Trusted Exchange Framework 6-7 (Feb. 16, 2018) (on file with author) [hereinafter Sequoia Project Letter].

[473] *Id.*

[474] *Id.* (critiquing TEFCA DRAFT 1).

QHINs.[475] This could involve giving states the right of first refusal to the state to form QHINs and/or assisting states with funding and support in the QHIN application process.[476]

This is not to say that there should be fifty QHINs. The number of QHINs has not been specified.[477] HHS may determine that states below a certain size might have to collaborate with another state's QHIN to provide the support TEFCA demands of QHINs, or choose to participate in other ways, including via a private contractor.[478]

Apart from promoting federalism for those who care about that particular value, such an approach would permit economies of scale—many states already control vast aspects of health coverage in the state, including ACA exchanges and Medicaid coverage.[479] QHINs could be administered as part of a holistic set of regulations that apply to those contexts, rather than as a standalone set of requirements administered by a private entity. Further, there will be data synergies—the first draft of TEFCA contemplated that QHINs might maintain data "repositor[ies]" formed through data exchange on its network.[480] It would be more efficient to integrate such repositories with the APCDs that states already have.

Finally, state dominance of QHINs would also allow them to maintain some degree of control over how their privacy laws will be altered. As The Sequoia Project noted in its comments on TEFCA Draft 2, compliance with state data consent laws should be a matter left to the internal workings of each QHIN that operates within a particular jurisdiction.[481] States will be better able to modulate their privacy laws to allow for data exchange, instead of being subject to preemption at the behest of primarily private action.

3. Private-State Consults and Partnerships

If the federal government does not contract the task of health data regulation out to states, it should at least bring states, formally or informally, into the decision-making process. At the informal end of the spectrum, states should be brought in as part of roundtable processes; APCD-federal roundtables have already occurred, where federal entities discussed with states the common efforts the states could undertake, ways in which the federal government can

[475] *See supra* notes 49-54 and accompanying text (discussing existing models of cooperative federalism in healthcare, including Sheppard-Towner Act of 1921, Hill Burton Act of 1946, Medicaid, and ACA).

[476] *Id.*

[477] Noam Arzt, *ONC Gets It Mostly Right with TEFCA 2.0 [Updated]*, HLN CONSULTING (Apr. 24, 2019), https://hln.com/onc-gets-it-mostly-right-with-tefca-2-0/index.html [https://perma.cc/9R2Z-AC68].

[478] Over time, the federal government might offer its own public option for networks.

[479] *See supra* notes 49-54 and accompanying text.

[480] TEFCA DRAFT 1, *supra* note 287, at 28.

[481] Sequoia Project Letter, *supra* note 472, at 7.

provide Medicare data, and ways in which state data could support federal initiatives such as drug safety.[482] Such consultation is the bare minimum to comply with existing legal requirements that agencies consult with states on issues affecting their interests; for example, the Federalism Executive Order 13,132 requires agencies to consult with states on issues in various contexts.[483]

But such consultations could be further formalized through a committee-system. When it comes to building health networks, the national health data world has long relied on advisory committees. The Cures Act, for example, required the creation of a Health Information Technology Advisory Committee ("HITAC"), which required federal agency representatives and representation from health systems stakeholders, including those of medical providers, payers, and the like.[484] The HITAC in turn replaced two other committees, the Health Information Technology ("HIT") Policy Committee and the HIT Standards Committee, which were established in 2008 and had similar requirements.[485] While the Cures Act imposes no such requirement, compliance with the Federalism Executive Order suggests appointing representatives of states to the HITAC.[486] The HHS Secretary and Comptroller General of the United States, who have some discretion over whom to appoint, should ensure state representation on the HITAC.[487]

The HITAC provides reports to the relevant agency, but has no binding authority.[488] Thus, at an even higher level of formalization, other organizational forms would better represent state interests. In the APCD context, if the DOL and HHS decide not to contract out APCD tasks to states, they might instead create hybrid state-private entities subject to review by the secretaries of the

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[482] *Expanding and Enhancing All Payer Claims Database System Capacity in States*, AGENCY FOR HEALTHCARE RSCH. & QUALITY, https://www.ahrq.gov/data/apcd/confrpt.html [https://perma.cc/Q76B-4VHH] (last visited Dec. 5, 2021) (describing schedule for and highlights from roundtable).

[483] Exec. Order No. 13,132, 64 Fed. Reg. 43,255, 43,256 (Aug. 10, 1999) (requiring that state and local officials be consulted in order to abide by "Federalism Policymaking Criteria").

[484] 42 U.S.C. § 300jj-12.

[485] Off. of Nat'l Coordinator for Health Info. Tech., *Health IT Policy Committee*, HEALTHIT.GOV, https://www.healthit.gov/hitac/committees/health-it-policy-committee [https://perma.cc/P9GD-A55R] (last reviewed Jan. 8, 2020); Off. of Nat'l Coordinator for Health Info. Tech., *Health IT Standards Committee*, HEALTHIT.GOV, https://www.healthit.gov/hitac/committees/health-it-standards-committee [https://perma.cc/6HWV-S3DB] (last reviewed Jan. 8, 2020); Health Information Technology for Economic and Clinical Health Act, Pub. L. No. 111-5, sec. 13101, §§ 3002, 3003, 123 Stat. 226, 234-39 (2009) (codified at 42 U.S.C. §§ 300jj-12 to -13).

[486] *See* Exec. Order No. 13,132, 64 Fed. Reg. 43,255, at 43,256.

[487] *See* Off. of Nat'l Coordinator for Health Info. Tech., *Health Information Technology Advisory Committee (HITAC)*, HEALTHIT.GOV, https://www.healthit.gov/hitac/committees/health-information-technology-advisory-committee-hitac [https://perma.cc/5TRJ-RH34] (last reviewed July 14, 2020).

[488] *See id.* (noting that HITAC makes "recommendations").

relevant agencies.[489] These hybrid entities could absorb the tasks of existing APCDs. In the context of HIEs, The Sequoia Project is already somewhat on its way to forming such a hybrid, with approximately seven of its sixty-three members consisting of state entities.[490] HHS should exert informal pressure, and, in the long run, formally require as a condition of renewing the RCE contract that The Sequoia Project incorporate more states within its membership to ensure federalism interests are sufficiently represented. Similar bodies could be created both at the QHIN level, or if the DOL proceeds with APCD-related action.

Within these formalized advisory or policy-making entities, states can be given different types of roles. As I describe elsewhere, apart from their powers simply of advice or persuasion, proposals from any advisory body might *require* buy-in from a certain number of states: "[s]tates may only have an advisory role, may have veto power, may have the sole power to initiate, but not adopt, proposals (or vice versa), or may have power over only certain kinds of programs."[491]

The federal government should look to models that states have already developed in this space that I describe above. Many states rely primarily on government entities in this context.[492] Several states also required nongovernment members of the advisory council to come from certain industries—providers, payers, heads of state medical societies—and both the executive and legislative branches, including the innovative power sharing mechanism adopted by the University of Connecticut.[493] Similarly, a future RCE's actions could be vetoed by a majority of *states* on its board, in which case HHS would be required to step in.

4. Enforcement Authority over Private Entities for Health Data Regulation

Finally, if the federal government chooses to use private entities to fulfill policy objectives, states should be given enforcement authority if existing statutes permit. Of course, states have enforcement authority over their own laws. In this case, however, ERISA preempts APCDs, and the Cures Act

[489] It is possible to create some kind of commission with this power. *See* Konnoth, *Privatization*, *supra* note 21, at 1960. However, that would require congressional intervention as the Committee is set by statute.

[490] *See The Sequoia Project's Founding Members*, *supra* note 296 (listing all members, including the following state entities: Agency for Health Care Administration for State of Florida, California Primary Care Association, Delaware Health Information Network, East Tennessee Health Information Network, Indiana Health Information Exchange, North Dakota Health Information Network, and United States SSA).

[491] Konnoth, *Privatization*, *supra* note 21, at 2009.

[492] *See supra* note 116 and accompanying text.

[493] *See supra* notes 116-120 and accompanying text.

preempts state privacy laws[494] but in various situations, states have been given enforcement authority with respect to various areas of federal law as well.[495]

To take an example that those engaged with health data regulation would be most familiar with, consider HIPAA privacy enforcement. As I note above, private entities have had numerous data breaches in the last few years.[496] Originally, the HIPAA privacy and security regulations could only be enforced by the federal government.[497] In 2009, along with its first forays into health IT improvement, and its grants to the states in the HITECH Act for state HIEs, Congress also gave states enforcement authority over HIPAA: "the attorney general of the State, as *parens patriae*, may bring a civil action" to enforce HIPAA, through both injunctions and damages, though such action is paused if the federal government is also pursuing action.[498] State attorneys general "ramp[ed] up" enforcement after federal training.[499] Some of the largest payouts HHS received were the result of state attorney general investigations.[500] Thus, even as federal HIPAA enforcements have been "slumping," states "pick[] up slack."[501]

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[494] *See supra* notes 234-242 and accompanying text (explaining why APCDs are preempted by ERISA); *supra* notes 319-328 and accompanying text (explaining why Cures Act would likely preempt state privacy laws).

[495] Professor Margaret Lemos has documented numerous instances of such delegated enforcement authority. Margaret H. Lemos, *State Enforcement of Federal Law*, 86 N.Y.U. L. REV. 698, 708-10 (2011); *see also* 18 U.S.C. § 248(c)(3) (allowing for state enforcement to ensure access to abortion clinics); 15 U.S.C. § 2073(b)(1) (allowing for state enforcement with respect to consumer products); Clean Water Act, 33 U.S.C. § 1365 (allowing states to commence civil actions); Clean Air Act, 42 U.S.C. § 7604 (allowing "any person" to "commence a civil action on his own behalf"); Philip J. Weiser, *Towards a Constitutional Architecture for Cooperative Federalism*, 79 N.C. L. REV. 663, 672-673 (2001) (discussing state enforcement).

[496] For a discussion of these data breaches, see *supra* notes 395-398.

[497] Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462, 82,472 (Dec. 28, 2000).

[498] Health Information Technology for Economic and Clinical Health Act, Pub. L. No. 111-5, § 13410(e), 123 Stat. 226, 274-75 (2009) (codified at 42 U.S.C. § 17939).

[499] U.S. Dep't of Health & Hum. Servs., *State Attorneys General*, HHS.GOV, https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/state-attorneys-general/index.html [https://perma.cc/44PE-YR6Y] (last reviewed July 28, 2021); Mary Chaput, *State Attorney General HIPAA Enforcement Ramps Up*, CLEARWATER (June 27, 2019), https://clearwatercompliance.com/blog/state-attorney-general-hipaa-enforcement-ramps-up/ [https://perma.cc/ZS4P-GVRH].

[500] Chaput, *supra* note 499 (discussing data breach settlements); Brian Annulis, Ryan Meade & Benjamin D. Bresnick, *12 State Attorneys General Unite in the First Multi-State Enforcement of Alleged HIPAA Privacy Breach*, ANKURA (Dec. 19, 2018), https://ankura.com/insights/12-state-attorneys-general-unite-in-the-first-multi-state-enforcement-of-alleged-hipaa-privacy-breach/ [https://perma.cc/P478-TLJU].

[501] Marianne Kolbasuk McGee, *Are State AGs Picking Up Slack in HIPAA Enforcement?*, CAREERS INFO. SEC. (Sept. 14, 2018), https://www.careersinfosecurity.com/are-state-ags-picking-up-slack-in-hipaa-enforcement-a-11516 [https://perma.cc/TR5U-25G6].

Accordingly, State enforcement schemes present several advantages, as I document elsewhere.[502] First, these schemes are particularly helpful in situations where the federal government may have suffered capture or otherwise lacks incentives to enforce certain laws, as states whose executives belong to the opposing political party have both the will and the expertise to enforce these laws.[503] Second, the Court has recognized the greater constitutional standing of states to enforce federal law.[504] Third, the risk of overenforcement is likely lower than if enforcement power were delegated to private individuals.[505] Finally, state health data agencies often have close relationships with industry, with whom they must work formally and informally, according to state regulation, but *enforcement* authority is usually delegated to state attorneys general, who are far less likely to have deep relationships with health entities that might deter enforcement and are independently elected.[506]

In the context of health data regulation, such enforcement authority can exist whether or not the government chooses to use states as contractors. Take APCD enforcement authority first, where, in *Gobeille*, the Supreme Court held that enforcement power lay with the DOL.[507] Failure to file the appropriate reports comes with steep penalties, and the Secretary of Labor has the power to bring enforcement actions (as do individuals in limited circumstances, and, in even more limited circumstances, states).[508] Whether or not the DOL delegates powers to states to carry out APCD data collection, it could also allow states to bring enforcement actions against private entities that *fail* to provide the appropriate data to the relevant entities—be that the federal or state governments.[509]

Unlike with the previous structural solutions, however, there may be a question of the agency's authority here to delegate enforcement authority to states. Consider whether the DOL can delegate APCD data collection enforcement to states. Unlike in the case of HIPAA, the federal statute here, ERISA, does not authorize state enforcement.[510] Litigants might argue that only Congress—not the DOL—can create a cause of action for enforcing regulations

[502] *See* Konnoth, *Privatization*, *supra* note 21, at 2013-15.

[503] *Id.* at 2014.

[504] *Id.* ("The second benefit arises from the possibly greater constitutional standing of states to enforce federal law when compared to private entities.").

[505] *Id.* at 2015.

[506] *Id.*

[507] Gobeille v. Liberty Mut. Ins. Co., 136 S. Ct. 936, 947 (2016).

[508] 29 U.S.C. § 1132(a) (granting Secretary of Labor and individuals power to bring civil actions in a number of circumstances but only granting states power "to enforce compliance with a qualified medical child support order").

[509] In particular, litigants might argue that since the statute delegates certain powers to states, it implicitly prohibits the agency from delegating further power to states, under the *inclusio unius* principle. But the distinction here is that Congress created interests for states as states; here, I am advocating for the federal executive delegating part of its interest to states.

[510] 29 U.S.C. § 1132(a).

pursuant to federal law. In *Alexander v. Sandoval*[511] and related cases, the Supreme Court held that "private rights of action to enforce federal law must be created by Congress," rather than agency regulation.[512] In *Sandoval*, a plaintiff sued a federal grantee under a statute that prohibited race discrimination by federal grantees.[513] The Court noted there that Congress had entrusted enforcement to the agency, and had created a series of steps the agency had to follow to fulfill its mandate.[514] Accordingly, it would go against congressional intent to allow the agency to also create an additional cause of action in states.[515]

There is an important distinction, however. *Sandoval* prevents agencies from creating causes of action that allow non-federal entities to sue in their *own* right, but it does not explicitly prohibit agencies from delegating to a nonfederal entity the right to sue on behalf of the *agency* itself.[516] Indeed, under current law, agencies have delegated broad swaths of agency functions to private organizations including drafting regulations and determining policy.[517] It would be strangely asymmetrical to permit delegation in those vast areas of agency function but prohibit such delegation here.[518] Finally, as Leah Litman documents, the Court has been particularly deferential to arrangements where *states* enforce federal law, even as it has acted increasingly hostile to private enforcement—though I note that in those situations, again, Congress has entrusted states with enforcement authority.[519]

To be sure, a federal agency could not simply delegate in ways that would cause an end run around statutory requirements. For example, in *Sandoval*, the agency had to communicate with the grantee before bringing enforcement action.[520] A contractor or agency delegate standing in the agency's shoes would

[511] 532 U.S. 275 (2001).

[512] *Id.* at 286; *see id.* at 291 ("[W]hen a statute has provided a general authorization for private enforcement of regulations, it may perhaps be correct that the intent displayed in each regulation can determine whether or not it is privately enforceable. But it is most certainly incorrect to say that language in a regulation can conjure up a private cause of action that has not been authorized by Congress. Agencies may play the sorcerer's apprentice but not the sorcerer himself.").

[513] *Id.* at 275 (arguing that Alabama Department of Public Safety—a recipient of federal financial assistance—violated § 602 of Title VI by administering English-only driver's license tests).

[514] *Id.* at 278; *see also* Armstrong v. Exceptional Child Ctr., Inc., 135 S. Ct. 1378, 1386 (2015) (addressing similar issue regarding Medicaid remedies).

[515] *Sandoval*, 532 U.S. at 286-87.

[516] *See id.* at 275.

[517] *See* Konnoth, *Privatization*, *supra* note 21, at 1975-81.

[518] Pamela Karlan recognizes the distinction. *See* Pamela S. Karlan, *Disarming the Private Attorney General*, 2003 U. ILL. L. REV. 183, 198 ("[T]he Court's decision essentially disarms private attorneys general.").

[519] Leah M. Litman, *Taking Care of Federal Law*, 101 VA. L. REV. 1289, 1308-12 (2015) (using several Supreme Court cases to demonstrate that where Congress "carve[s] out a role for the states in implementing a federal scheme" courts honor states' ability to do so).

[520] *Sandoval*, 532 U.S. at 289.

have to satisfy similar steps, presumably under the agency's oversight as specified by its arrangement with the agency.

Turning to data transfer and privacy laws in the case of TEFCA: HHS could allow states to bring suit (whether states have QHIN status) against government contractors, such as the RCE, who fail to live up to their obligation. The federal agency here possibly has greater leeway than in the case of APCDs. TEFCA will produce a *contract* between the federal government and states. The RCE here is not a regulatee—rather it will stand in the position of a regulator.[521] Thus, one of the provisos of the contract might be that the RCE lacks immunity against state enforcement; states can explicitly be recognized as third-party beneficiaries in the contract. States would then be in a position to take enforcement action if they could show not that the RCE itself violated any regulations but that the RCE *failed to enforce* regulations against entities that it regulated, meaning it had violated the contract with the federal government. This distinction would likely pass constitutional muster.

CONCLUSION

Without access to health data, the healthcare system would grind to a halt. The COVID-19 response would have long ago been stymied. More generally, providers would be unable to diagnose or treat patients or collect payments. Insurance companies could not be able to pay providers for services. Who has custody over the system is therefore essential. Rendering custody over health data regulation to the private sphere, thereby displacing state regulation, harms the viability of the system itself. Even when private entities act in an unbiased and impartial manner, the priorities they set may still undermine data connectivity and collaboration and fail to achieve the public interest that states seek. And indeed, to some degree, to the extent that data tells the story of who someone is, rendering control to private entities may present dignitary concerns for some.

At the same time, the health data regulation world acts as a cautionary tale—a case study—regarding private engagement in the healthcare space more generally. It is possible that private entities may act more efficiently than states as guardians of certain areas, and concerns regarding privatized preemption might sound more in general, theoretical concerns regarding federalism or privatization.[522] But this Article shows how, in practice, privatized preemption can cause mischief in at least a particular area of regulation in a very real way. Policy makers would do well to draw from this example when considering private engagement in programs like Medicaid, Medicare, and the ACA.

Practical problems call for practical solutions. Data regulation cannot be fully fragmented—or else data will never be collected or exchanged. But it also

[521] TEFCA DRAFT 2, *supra* note 306, at 8.

[522] *See* Konnoth, *Privatization*, *supra* note 21, at 1990 (articulating precisely such theoretical concerns).

cannot be fully entrusted to private industry, nor does the federal government seem willing or equipped to carry out the job without the risk of private capture. Given the situation, creating a framework balancing all stakeholders will ensure a system that will properly regulate this essential healthcare resource.

GLOSSARY OF TERMS

ACA	Affordable Care Act
AMA	American Medical Association
APCD	All-Payers Claims Database
BCBS	Blue Cross Blue Shield
CHIP	Children's Health Insurance Program
CMS	Centers for Medicare and Medicaid Services
DOL	Department of Labor
FDA	Food & Drug Administration
FOIA	Freedom of Information Act
EHR	Electronic Health Record
EMR	Electronic Medical Record
ERISA	Employee Retirement Income Security Act of 1974
HHS	Health & Human Services
HIE	Health Information Exchange
HIPAA	Health Insurance Portability & Accountability Act of 1996
HIPAA COW	HIPAA Collaborative of Wisconsin
HIT	Health Information Technology

HITAC	Health Information Technology Advisory Committee
HITECH Act	Health Information Technology for Economic & Clinical Health Act
HMO	Health Maintenance Organization
ONC	Office of the National Coordinator for Health Information Technology
NAHDO	National Association of Health Data Organizations
NCSL	National Conference of State Legislatures
NCVHS	National Committee on Vital and Health Statistics
QHIN	Qualified Health Information Network
RCE	Recognized Coordinating Entity
SHIEC	Strategic Health Information Exchange Collaborative
TEFCA	Trusted Exchange Framework & Common Agreement