A Proposed National Healthcare Information Network Architecture and Complementary Preemption of State Health Information Privacy Laws

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Abstract

The U.S. is currently experiencing a healthcare crisis including problems of quality and affordability. A national health information network (NHIN) holds great potential for reducing these problems by linking healthcare-related entities and patients to provide real-time information flow. The current evolutionary strategy for NHIN development is resulting in an unaffordable delay. NHIN architecture and patient privacy laws are interdependent, and information flow is impeded by disparate state privacy laws layered onto federal law. We propose a revolutionary NHIN architecture and a complementary framework for preemptive federal law that will allow a true NHIN to develop much faster.
I. Introduction

As evinced by the current national debate, the U.S. faces a healthcare crisis of monumental proportions with complex issues of access, quality, and affordability.\(^1\) In terms of its cost, politics, quality, and efficiency, healthcare is no longer a state and local issue but rather a national one\(^2\) - and one that seriously threatens the U.S. economy.\(^3\) Electronic healthcare (e-health) applications have been suggested as a partial solution to these problems, and the increased use of health information technology (HIT) is a common element of virtually all serious U.S. healthcare reform proposals.\(^4\) At their zenith, such applications would include a national health information network (NHIN) argue holds great potential for improving the quality and efficiency of healthcare while lowering its cost.\(^5\) When it comes to healthcare reform, however, questions of policy and law often overlap, and such is the case with a NHIN.\(^6\)

Two major, interdependent impediments to a fully operational NHIN are (a) the lack of rapid progress given the current evolutionary approach to NHIN architecture and (b) the tension between operational efficiency and patients’ privacy rights with respect to their health information, the resolution of which depends upon the rationalization of myriad and disparate

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\(^1\) See, e.g., John W. Hill, Arlen Langvardt & Anne Massey, Law, Information Technology, and Medical Errors: Toward a National Healthcare Information Network Approach to Improving Patient Care and Reducing Malpractice Costs, 2 J. L. TECH. & POL’Y 159, 159-165 (2007) (discussing problems with medical errors, healthcare cost, medical malpractice, and archaic health information systems).


\(^5\) See, e.g., Hill, Langvardt & Massey, supra note 1, at 204-10.

\(^6\) Connors & Westmoreland, supra note 2, at 1.
state privacy laws layered upon federal law. Electronic health information exchange holds great potential for improving the flow of information necessary for quality healthcare. As Congress and the Administration struggle to find cost savings in healthcare expenditures while increasing access for the uninsured and improving quality through healthcare reform, a NHIN should play an integral role.

A NHIN has been described as the relatively seamless electronic flow of patient information such that there is national interoperability among hospitals, outpatient clinics, and external laboratories allowing clinicians to have access to patients’ longitudinal test results on a 24-hour/7-days-a-week basis from office, hospital, or home. The benefits include reducing redundant tests, delays, costs associated with results reporting, and errors attending oral reporting. Interoperability with pharmacies would enable the formation of complete medication lists and reduce duplicate therapy, drug interactions, and other adverse drug events. It would bring attendant benefits of automated refill alerts, easy clinician access to information regarding patients' of refilling prescriptions, identification of patients affected in the event of drug recalls, and detection of new drug side effects across a broader patient population. Provider-provider interoperability would save time associated with the handling of referrals and chart requests, and interoperable electronic medical records (EMRs) could become the building blocks in a nationwide network for assembling and distributing up-to-the-minute health studies showing researchers and physicians what treatments work best for patients with similar characteristics.

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8 Connors & Westmoreland, supra note 2, at 12.
Despite these enormous potential benefits, progress toward a NHIN has been slow for two reasons. First, past and present national administrations have embraced a bottom-up, evolutionary approach to the development of NHIN architecture - an approach that has yet to prove efficacious or resolve privacy law/interoperability tensions.\(^{11}\) Second, for a NHIN to be effective it must be accompanied by other reforms,\(^ {12}\) and among these reforms is the need to revise the various federal and state laws pertaining to the privacy of patients’ protected healthcare information (PHI)\(^ {13}\) which impose one of the greatest legal barriers to a NHIN.\(^ {14}\) There is general consensus that the movement toward widespread implementation of e-health must be attended by appropriate protections for privacy and security of personal health information, and most states have enacted health information privacy laws.\(^ {15}\) Already there is evidence that the complexities of and disparities in state laws is impeding the advance of e-health as exemplified by states with more stringent privacy laws layered upon federal law experiencing lower rates of adoption of (EMRs),\(^ {16}\) a critical prerequisite for NHIN enablement.\(^ {17}\) As argued

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\(^{11}\) Hill, Langvardt & Rinehart, supra note 7, at 41-43.

\(^{12}\) John W. Hill, Angela N. Aneiros, & Paul R. Hogan, Law and the Healthcare Crisis: The Impact of Medical Malpractice and Payment Systems on Physician Compensation and Workload as Antecedents of Physician Shortages – Analysis, Implications and Reform Solutions, 1 J. L. TECH. & POL’Y (forthcoming Spg. 2010) (discussing the need for various types of reforms to include new delivery and HCOP reimbursement systems).

\(^{13}\) Hill, Langvardt & Rinehart, supra note 7, at 23-24.


\(^{15}\) Mcgraw, supra note 4, at 33.

infra, NHIN architecture and privacy law protection are non-recursive due to interdependencies. The need for privacy protection affects the choice of architecture which, in turn, affects how privacy laws should be written to complement the architecture.

In this study we argue that a revolutionary federal blueprint for NHIN construction is integral to achieving the realization of a NHIN in a timely manner. This study proposes a framework for NHIN construction coupled with complementary federal privacy protection regime. Section II briefly reviews some critical elements of the national healthcare crisis, discusses the potential benefits of a NHIN in its resolution, and lays a foundation for subsequent discussion of NHIN architecture by examining the flawed current strategy to build regional health information organizations (RHIOs) as precursors to a NHIN. Section III discusses current federal privacy laws and model statutes proposed for adoption by the states to promote uniformity across states as a foundation for alter discussion of a new federal privacy law regime. It also analyzes certain key elements of state privacy laws and discusses why such disparate laws are incompatible with a smoothly functioning NHIN. It concludes with recommendations for new, preemptive federal privacy legislation. Section IV proposes a revolutionary, cloud-based-computing architecture for a NHIN that satisfies the need for protecting patient privacy while meeting the criterion of affordability. Section V examines legal issues that represent constraints on the federal government from taking a more assertive role in fostering the development of a NHIN and our counterarguments for the legal inferiority of those constraints. Section VI summarizes our thoughts.

II. Why a NHIN?

(citing Amalia R. Miller & Catherine Tucker, Privacy Protection and Technology Diffusion: The Case of Electronic Medical Records, 55 MANAGEMENT SCIENCE 1077 (July 2009)).

The healthcare crisis has been described as extraordinarily complex, costly, and seemingly intractable. Among the most important of the many facets of the healthcare crisis are (a) a grossly inefficient, antediluvian care delivery system, (b) an unacceptable rate of medical errors, and (c) an increasingly unaffordable cost of healthcare at the macro level that is exacerbated by a complex, convoluted payment system. One of the major culprits is the organizational structure of U.S. healthcare which contributes greatly to both quality and cost problems. Healthcare processes are often unconnected to one another in any real-time fashion and care is frequently delivered unevenly. If the error rates in intensive care units were acceptable in the airline and banking industries, for example, the result would be two dangerous landings per day at O’Hare International Airport and 32,000 checks deducted from the wrong accounts every hour. In the era of total-quality-management and six-sigma thinking in many business organizations that strive to limit errors to 3.4 defects per million opportunities, high U.S. healthcare error rates, especially when one considers what is at risk, seem absurdly unconscionable, but nonetheless

18 Hill, Aneiros, & Hogan, supra note 12.
20 Hill, Aneiros, & Hogan, supra note 12.
21 See Hill, Langvardt & Massey, supra note 1, 197-204. “Many medical errors are traced to gaps in the flows of necessary information.” Sidney Taurel, Chairman & CEO, Eli Lilly & Co., Remarks at the Indiana University Kelley School of Business Annual Business Conference, The Health Care Conundrum: A Call for Leadership, Indianapolis, IN (March 8, 2006) (hereinafter Health Care Conundrum Conference) (notes on file with authors). A lack of understanding of patterns of error resulting from shared information is often the culprit in causing medical errors as opposed to purely individual human mistakes. Tom Murphy, Clarian Plans Training Center, INDIANAPOLIS BUS. J., Apr. 3-9, 2006, at 46A.
22 David K. Ahern et al., What Is e-Health (6): Perspectives on the Evolution of eHealth Research, 8 J. MED. INTERNET RES. 9, 9 (2006) (“e-Health has the capacity to address health disparities among traditionally underserved populations due to its scalability, potential to target specific groups and conditions, and ability to be tailored and customized to culturally and linguistically diverse users”).
23 Id.
persistent with adoption rates for new health information technologies that hold promise of reducing errors being slow.\textsuperscript{25} Physicians’ acceptance of quality improvement tools is sometimes slow\textsuperscript{26} due to cost, fear of legal liability, and physician reluctance to system checks on medical decisions.\textsuperscript{27}

E-health technology has been proposed as a partial solution to problems of healthcare cost and quality with technologies falling in a spectrum ranging from localized EMRs to RHIOs to the possibility of a NHIN.\textsuperscript{28} Patient demographics and past medical history, progress notes, problems, medications, vital signs, immunizations, laboratory data, and radiology reports are examples of information that can be collected in an EMR.\textsuperscript{29} More powerful and flexible than paper systems, EMRs offer improved methods of storing, manipulating and communicating medical information including text, images, sound, and video.\textsuperscript{30} Healthcare is one of the most technologically intense\textsuperscript{31} and data-rich industries,\textsuperscript{32} and empirical evidence strongly suggests that the incidence of medical errors can be reduced through the ability of e-health technologies to

\textsuperscript{25} Blackford Middleton et al., \textit{Accelerating U.S. EHR Adoption: How to Get There From Here; Recommendations Based on the 2004 ACMI Retreat}, 12 J. AM. MED. INFORMATICS ASS’N 13, 14-15 (2005).

\textsuperscript{26} R. Nat Natarajan & Amanda Hoffmeister, \textit{Do No Harm: Can Health Care Live Up to It?}, (undated working paper) (noting that it is important to distinguish between active errors, which occur at the frontline provider level, and latent errors which are systemic are removed from the direct control of individuals – with the implication that error prevention must focus on the entire system), http://www.tntech.edu/mayberry/2001N-DoNoHarm.htm.


\textsuperscript{28} Hill & Powell, \textit{supra} note 17, at 265, 267-68.


\textsuperscript{31} Rainu Kaushal et al., \textit{The Costs of a National Health Information Network}, 143 ANNALS INTERNAL MED. 165, 165 (2005).

provide more complete, current, and integrated healthcare information to HCPs.33 One source has estimated the annual cost savings potential from the widespread use of e-health technologies to be in the range of $142-371 billion annually.34 Despite this potential for e-health to improve the effectiveness and efficiency of healthcare by facilitating the flow of patient-related information,35 the industry invests only about 2 percent of its revenues in IT, compared with 10 percent for other information-intensive industries.36

Further, if restricted only to primary providers such as individual physicians and hospitals, the full potential of e-health technologies to improve healthcare and lower its cost will remain unfulfilled37 because medical records restricted to single providers cannot be used effectively to coordinate care and measure quality across multiple HCPs.38 If the goal of creating a life-long medical record that moves with the patient and is accessible by all authorized participants in the healthcare process is to be realized,39 a much more sweeping system is required that provides connectivity and interoperability with other systems – a NHIN. The purposes of a NHIN are as follows: “…inform clinical practice with the use of EHRs [electronic health records], interconnect clinicians so that they can exchange health information using secure electronic communication, personalize care with consumer-based health records and better information for consumers, and improve population health through advanced bio-surveillance methods and

34 Hillestad, et al., supra note 29, at 1103.
35 Edward H. Shortliffe, Strategic Action in Health Information Technology: Why the Obvious Has Taken So Long, 24 HEALTH AFFAIRS (2005), 1227.
36 IT in the Health-Care Industry, ECONOMIST, April 30, 2005, at 72.
37 Hillestad, et al., supra note 29, at 1103-04.
38 Id.; David W. Bates et al., A Proposal for Electronic Medical Records in U.S. Primary Care, 10 J. AM. MED. INFORMATICS ASS’N 4, 4 (2003).
streamlined collection of data for quality measurement and research.” In order to have universal connectivity and interoperability among health IT systems, such systems would need to capture whatever data are needed including interfacing with pharmacy systems, specialists, hospitals, insurance billing systems, and even governmental entities engaged in the clinical and administrative care of individual patients as well as monitoring care of entire patient populations. Such connectivity between networks is essential for rapid coordination of care and seamless sharing of healthcare information. A high level of interoperability is required so that connected data are accessible, consistent, and decipherable wherever used.

Although the focus of attention on a NHIN has been on these justifications, its salutary aspects extend beyond to include the acceleration of medical research through the creation of large databases containing data on patient symptoms, personal characteristics, and treatment outcomes. Such data could greatly enhance medical research as is the case with genomics.

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42 Mary Mosquera, DHHS Proposes Health IT Exception to Anti-Kickback Laws, NEWSBYTES NEWS NETWORK, Oct. 5, 2005. Citing Michael Leavitt, Secretary of U.S. Department of Health and Human Services, the author notes that computer-assisted drug prescriptions result in a 70 percent reduction in prescription errors versus handwritten prescriptions. Id.

43 Rogerson, supra note 30, at 2000; Walker et al., supra note 10, at W5-14.

44 Charles M. Kilo, Transforming Care: Medical Practice Design and Information Technology, 24 HEALTH AFF. 1296, 1300 (2005).


48 See, e.g., Edward H. Shortliffe, Strategic Action in Health Information Technology: Why the Obvious Has Taken So Long, 24 HEALTH AFFAIRS 1, 6 (2005). (“The human genome project clearly demonstrated that modern molecular biology research has become impossible, given the amount of data that must be gathered, managed, and analyzed, without major computational support.”).
One source of commentary states, “The promise of the NHIN is the delivery of better health and a better healthcare system through seamless knowledge and information sharing….the NHIN must address the entire system through enhancing the exchange of information among the domains of personal health management, healthcare delivery, public health, and medical research.”

Two mutually exclusive strategies are plausible for the development of a NHIN with this high degree of connectivity and interoperability. One is to allow a NHIN to evolve bottom-up through the eventual aggregation of RHIOs. A second is for the federal government to encourage creation of a NHIN in a more revolutionary manner by pushing top-down legislation. Serious attention to accelerating NHIN development is paramount given its potential for improving healthcare quality and availability while reducing its costs. The current vision for a NHIN does not include a national data store. We argue this is a mistaken philosophy that has an unacceptably high price tag for the nation. As a foundation for this discussion, the remainder of this section deals with the slow development of RHIOs and the reasons that a top-down approach may be preferable.

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49 Faster Cures, supra note 46, at 5.
50 See Barney Corwin, D.C. RHIO: 5 Lessons Learned, GOVERNMENT HEALTH IT 50, 50 (Nov. 2007) (noting that all parties to HIE must see the benefits to be willing participants).
51 See, e.g., Hill, Langvardt & Massey, supra note 1, at 236-37 (calling “…for a top-down, federal legislative agenda top-down, federal legislative agenda to (a) establish sound parameters for HCP malpractice liability consistent with technological capabilities, (b) complete the process of dealing with still-too-restrictive physician referral and anti-kickback laws, and (c) create one set of privacy standards to override conflicting and unduly restrictive state patient privacy laws.”).
A RHIO “…is a multi-stakeholder organization that enables the exchange and use of health information.” The path currently being taken, relying upon healthcare-provider-centric, regionalized networks through the formation of RHIOs, sometimes (mistakenly) treated as synonymous with health information exchanges (HIEs), represents an evolutionary step toward a NHIN. The vision is that, through a nationwide “network of networks,” health information will be exchanged by state and RHIOs, health plans, integrated delivery systems, federal

54 Chheda, supra note 40.
57 A RHIO is a formal, geographically defined organization designed to carry out health information exchange. See Wikipedia, available at http://en.wikipedia.org/wiki/RHIO. See also, Daigrepont, supra note 10, at 240 (noting that RHIOs are usually multi-stakeholder organizations requiring clinical integration and typically include payers, hospitals, and physicians. Although HIEs are similar to RHIOs, master patient/person index software is always required which allows health information to move across multiple locations of care and disparate information systems. Thus, a HIE can form the systems backbone for a RHIO and can be thought of as a component of a RHIO.). Consequently, for purposes of our discussions, we consider HIEs as necessarily being subsumed into RHIOs in order to arrive at a NHIN in an evolutionary manner.
58 Brett Griffith, Backing Up EHRs, ADVANCE, available at http://health-information.advanceweb.com/common/Editorial/Editorial.aspx?CC=68423. For an example of a RHIO can be found in pharmacies in several states creating a network linking pharmacies with online information regarding patient medical histories, drugs, dosage, and patient compliance, see Bill Alpert, At Last, Digital Doctors, BARRON’S, at 43 (Feb. 13, 2006). See also Blue Cross Blue Shield Association to Create Database of Member Claims, MED. NEWS TODAY, Aug. 10, 2006, available at http://www.medicalnewstoday.com/printerfriendlynews.php?newsid=49054 (noting that insurance companies may become the catalyst for inter-operative electronic health systems). However, some practitioners are suspicious of insurance companies having unfettered access to patients’ health records for fear that they would use these records to deny coverage to patients. Interviews with Mark R. Neaman (CEO, Evanston Northwestern Healthcare, past Chairman, Healthcare Leadership Council, and past Chairman, National Committee for Quality Healthcare), Jeffrey H. Hillebrand (Chief Operating Officer, Evanston Northwestern Healthcare), Thomas H. Hodges (Chief Financial Officer, Evanston Northwestern Healthcare), Joseph Golbus (President, ENH Medical Group), Peggy King (Senior Vice President, Quality and Risk Management, Evanston Northwestern Healthcare), and Dr. Ned Wagner (Medical Director of Medical Informatics, Evanston Northwestern Healthcare), Evanston, IL (April 19, 2006) (notes on file with authors). If such process improvements can have such a significant effect on one facility’s costs, the implication for process improvement on a national scale are profound. See James Pope, Implementing EHRs Requires a Shift in Thinking, DISEASE MGMT., Jun. 6, 2006, at 24 (discussing disease management companies as another source of RHIO development); Stephen Barlas, Bill Allows for Reporting of Medical Errors, PSYCHIATRIC TIMES, Dec. 2005, at 78, available at http://psychiatrictimes.com (suggesting that patient safety organizations authorized under the Patient Safety and Quality Improvement Act of 2005 may also play a role in the development of IT interoperability among HCPs).
agencies and other networks.\textsuperscript{59} It is hoped that these networks eventually consolidate over time in a “rollup” fashion.\textsuperscript{60}

A major stumbling block to this evolutionary strategy is that RHIOs have not met with universal success for many reasons. RHIOs involve joint ventures which often entail myriad configurations without common IT infrastructures making consolidation challenging.\textsuperscript{61} It generally requires a lengthy time period to build consensus, a critical success factor, among RHIO members on important decisions.\textsuperscript{62} There is the further problem of misaligned incentives. Many HCPs operate in settings where they compete with one another making them suspicious of data sharing. The entities that benefit most from information provided by RHIOs are not always the parties expected to pay for them, and interoperability standards are lacking.\textsuperscript{63} Hundreds of parties have to be comfortable with data use and sharing agreements necessitating significant legal expense.\textsuperscript{64} As a consequence, NHIN development under the RHIO-evolutionary approach depends as much on consensus as it does technology.\textsuperscript{65} As a result of these and other obstacles, a disproportionate many RHIOs are not expected to achieve long-term viability.\textsuperscript{66} In one study of 138 “surviving” RHIOs, only 2 were considered functioning and only 12 of these were self-

\textsuperscript{60} Patty Enrado, \textit{Perspective: States Hold the Key to RHIO/HIE Expansion, HEALTHITNEWS} (Aug., 17, 2007) (noting the analogy to development of a national highway system first requires local roads), \textit{available at} http://www.nhinwatch.com/news.cms?newsId=2751.  
\textsuperscript{61} Daigrepont, \textit{supra} note 10, at 241.  
\textsuperscript{63} David E. Garets, \textit{supra} note 53, at 102-03.  
\textsuperscript{65} Shepherd, \textit{supra} note 59.  
\textsuperscript{66} John Smaling, \textit{A Dose of RHIOlity: The Toughest RHIO Integration Challenges Are Not Technology-Based, HEALTH MGT. TECH.} (Dec. 2005), \textit{available at} http://findarticles.com/p/articles/mi_m0DUD/is_12_26/ai_n15979867/.
sustaining financially. Another study of 38 RHIOs determined that the majority had heavy reliance on grant funding at all stages of development, and achieving critical mass continues to plague even the most well-established RHIOs. Consequently, as one commentator notes, “RHIOs as aggregators of geographically closely related providers are a great idea but not realistic in the near future.”

To summarize, only a NHIN would enable the nation to realize the maximum benefit of the potential for e-health to improve the quality of healthcare while making significant inroads toward cost control. Although some commentators call for the establishment of a NHIN within the next three years, it appears that an evolutionary approach to developing one will take far too long to realize these benefits. A revolutionary approach in contrast raises major questions about the role of the federal government. One involves creating an architecture and a second a complementary removal of privacy law barriers to the smooth flow of health information across state lines. These barriers help slow NHIN advancement because of questions such as which state laws are applicable and what party is responsible in the event of a security breach resulting from information exchange. The following section examines these barriers, briefly reviewing current federal privacy law and model statutes before turning to difficulties presented by state laws and then to recommended criteria for inclusion in preemptive federal law.

III. Privacy Laws

68 Id.
70 Faster Cures, supra note 46, at 16.
71 Although a few RHIOs have been successful in developing privacy law agreements, others have not. Manos, supra note 64 (noting that in November 2008 in what was supposed to be a National Coordinator for Health Information Technology demonstration of health information systems interoperability for 19 organizations using real patient data, fear of violating privacy laws caused all participants to use fictitious data).
Current privacy law is built upon three basic frameworks: state law, federal law, and the model statutes. State laws add an additional layer of privacy regulations; with the net result a patchwork of state and federal laws that convolute and obstruction the construction of a NHIN. The authors of a recent empirical study of the effects of medical information privacy protection of the diffusion of e-health technology note, “Privacy protection may affect the network benefit….In many cases, policy makers have enacted privacy protection without careful quantification of the potential costs in terms of inhibiting technology diffusion.”

Similarly, the American Clinical Laboratory Association has stated that “…the patchwork of state privacy laws is an impediment to health information exchange” and noted that HCPs regard fear of legal action as one of the greatest deterrents to the adoption of e-health technologies despite the ability of these technologies to make healthcare “better, faster, and cheaper.”

Despite previous attempts to address this issue through such proposals as so-called “model statutes,” such efforts fall short of resolving the tension between privacy of patient information and a fully interoperable NHIN. Consequently, states’ ability to provide greater privacy protections must be revisited so that privacy concerns, despite their importance, do not become an undue barrier to the creation and operability of a NHIN.

A. Federal Law

Federal health privacy law is largely captured in the Health Insurance Portability and Accountability Act (HIPAA), the Health Information Technology for Economic and Clinical

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72 Miller & Tucker, supra note 16, at 1077-78.
74 Hill, Langvardt & Rinehart, supra note 7, at 35-45.
75 See infra text accompanying notes 135-211.
Health (HITECH) Act, and the Model and Turning Point Acts. These are discussed briefly in turn in the following subsection.

**HIPAA’s Privacy Rule**

The first major federal health privacy regulations came in 1996 with HIPAA’s Privacy Rule which regulates health plans, health care clearinghouses, and HCPs who electronically transmit protected health information in connection with transactions covered under HIPAA.

Prior to the HITECH Act, HIPAA regulated business associates only through contractual relationships between regulated entities and their business associates. The final Privacy Rule was similar to its predecessors in that covered entities are generally prohibited from using or disclosing an individual’s protected health information. The intent was to limit the scope and access to health information to the minimum necessary to achieve the intended use while permitting certain uses and disclosures incidental to other allowable uses or disclosures.

The minimum-necessary standard requires that a covered entity make reasonable efforts to limit the use of protected health information to the minimum necessary to accomplish the

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76 As defined, a business associate is a person or entity whose function involve the use or disclosure of protected health information on behalf of or to a covered entity. 45 CFR 164.502(e), 164.504(e), 164.532(d)-(e).
78 See Citizens for Health v. Thompson, 2004 WL 765356 (E.D. Pa., 2004); 45 C.F.R. § 160.103.
79 45 C.F.R. § 162.923(c).
81 45 C.F.R. §§ 160.103.
82 Id. § 164.502(b).
intended purpose of the use, disclosure, or request. This standard does not generally apply for treatment purposes, and incidental uses are allowed for allowed uses and disclosures. Under the standard, a use is considered incidental if it occurs as a result of an allowable use and could not be reasonably prevented.

Generally for a covered entity to use PHI, it first must obtain patient authorization unless an exception applies. The final Privacy Rule includes routine uses in the course of treatment and seems to better balance the interests between patient privacy and covered entity’s needs for routine uses. Patients are allowed to request restrictions on the uses and disclosures of their health information, but this right extends only as far as health care providers are willing to enforce it inasmuch as covered entities are not required to agree to any patient request to restrict disclosure.

HIPAA and the Privacy Rule only supersede state laws that directly contradict it or provide less protection. State laws that are more restrictive typically require patient consent for some disclosures and limit the HCPs who can access PHI, though not always in an identical manner.

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84 45 C.F.R. § 164.508(b)(1).
85 Id. § 164.508(b)(2).
86 45 C.F.R. 164.530.
87 Id.
88 45 C.F.R. § 164.508(a)(1).
89 45 C.F.R. § 164.506 (“[A] covered entity may use or disclose protected health information for treatment, payment, or health care operations as set forth in paragraph (c) of this section”). Some of the important exceptions contained in paragraph C includes exceptions for “treatment, payment, or health care operations,” “treatment activities of a health care provider,” and “the payment activities of [another covered entity].” The rule also provided an exception for “health care operations,” as defined in the code. See 45 CFR § 164.501, .504.
90 Id. § 164.522(a).
91 Id.
92 42 U.S.C. § 1320d-7(a)–(b); 45 C.F.R. § 160.203. However, if DHHS concludes that certain state laws prevent fraud or serve as key components of the state’s insurance regulation system, the federal provisions do not preempt the state laws. Neither is there preemption of state laws dealing with controlled substances and with the reporting of injuries, diseases, other public health matters, and vital statistics. 42 U.S.C. § 1320d-7(a)(2), (b); 45 C.F.R. § 160.203. The same is true of state standards and information-gathering efforts that relate to audits, licensure, or certification. 42 U.S.C. § 1320d-7(a)(2), (b); 45 C.F.R. § 160.203.
States’ layering of protection on top of HIPAA is understandable given the less than enthusiastic use of the civil and criminal penalties provided under the act. To date, DHHS has demonstrated a decided preference for encouraging voluntary compliance and informal resolution of complaints as opposed to the imposition of such penalties. Of approximately 14,000 complaints filed by patients through June 2006, none had resulted in penalties.94

**Health Information Technology for Economic and Clinical Health Act (‘‘HITECH Act’’)**

Attached to the American Recovery and Reinvestment Act of 2009 was a statement of goals with respect to healthcare information technology known as the HITECH Act.95 Recognizing the importance of consistent standards and represents an important step forward in developing a NHIN,96 the federal government hopes to take a leadership role in developing nationwide electronic exchange standards, invest in infrastructure, and strengthen privacy and security laws.97 The HITECH Act expands the reach of current federal privacy laws beyond the HIPAA Privacy Rule.98 Patients must now be notified when their PHI is either disclosed or used without their authorization.99 The HITECH Act also closed the loophole for business associates,100 established the rights of patients to access and control of their PHI including the right to request

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94 Rob Stein, *Medical Privacy Law Nets No Fines*, WASH. POST, June 5, 2006, at A01 (noting that during the first three years of privacy protections put in place by HIPAA and the Privacy Rule (the period of 2003 through 2006), DHHS almost always engaged in informal resolution when patients filed grievances).


96 See American Recovery and Reinvestment Act § 13003 (establishing a HIT Standards Committee to recommend a set of standards, implementation specifications, and certification criteria for exchanging health information electronically).


100 American Recovery and Reinvestment Act § 13402(a).
an audit trail showing all electronic disclosures, and prohibits companies from selling PHI without proper authorization. HCPs now need patient authorization to use PHI for marketing or fundraising functions. Finally, there are increased penalties for violations and unauthorized disclosures, but the practical effect of these regulatory penalties is still uncertain.

**The Model and Turning Point Acts**

When HIPAA was passed in 1996, Congress did not explicitly promulgate a Privacy Rule. Recognizing the issues involved with a patchwork of disparate state laws regulating PHI, there have been two noteworthy subsequent initiatives aimed at harmonizing state privacy law by providing guidance to states on how to structure legislative reform of privacy law - the Model State Health Privacy Act (“Model Act”) and the Turning Point Model State Public Health Act (“Turning Point Act”). The Model Act provided a set of guidelines for state law to protect PHI during its acquisition, use, and disclosure by public health agencies at the state and local levels with the goal of balancing privacy and operational concerns. It segments health information regulation into laws governing the acquisition, the use, and the subsequent disclosure of PHI. The Model Act also addresses security safeguards, record retention practices and fair information practices including patient access to individual medical records.

The Model Act includes regulations relating to the acquisition of PHI and stipulates that public health agencies limit their acquisition of PHI to a legitimate public health purpose, a

102 American Recovery and Reinvestment Act § 13405(d).
103 Id.
104 American Recovery and Reinvestment Act § 13401.
107 See generally THE MODEL STATE PUBLIC HEALTH PRIVACY ACT.
108 See id. § 5-102; id. § 5-101; id. § 6-101; id. § 6-102; id. § 6-103.
109 See id. § 2-101 to -102.
limitation that has implications for NHIN architecture. To help limit the number of entities holding sensitive patient information (thereby decreasing the number of opportunities for improper disclosure), the Model Act restricts entities from acquiring PHI if inconsistent with its operational needs, effectively limiting acquisition to those situations where it is reasonably likely to achieve the legitimate health purpose. So, for example, if there is no reasonably likely chance for a HCP to treat a patient, acquisition is disallowed. Also, if the legitimate public health purpose can be achieved with non-identifiable versus identifiable information, then public health entities are required to use the former.

The Model Act also treats the proper use of PHI post-acquisition. A public health agency can only use PHI for legitimate public health purposes directly related to the reason the information was acquired. Any other use must survive the above analysis to determine whether any new use constitutes a legitimate purpose that would have originally warranted acquisition. For example, if a public health agency acquires PHI related to sexually-transmitted diseases for the purpose of monitoring their transmission, the agency is allowed to use that information for other activities directly related to surveillance. This inevitably raises the issue of what constitutes a “direct” use.

The Model Act also proposes regulations for uses not related to treatment. Research disclosure must include, among other things, the minimum amount of information necessary to

110 See id. § 2-101(a)(1).
111 See id. § 2-101(a)(2).
112 See id. § 2-101(a)(3).
113 See id. § 3-101(a).
114 See id. § 3-101(b).
115 See id. § 2-101.
116 The use of protected health information is limited “solely for public health purposes that are directly related to the purpose for which the information was acquired.” Id. § 3-101(a) (emphasis added).
conduct the research.\textsuperscript{118} PHI must also be made non-identifiable as soon as possible and expunged after the research project concludes.\textsuperscript{119} It also prohibits public health agencies from using PHI for commercial purposes.\textsuperscript{120} A health agency, then, would not be allowed to sell or allow access to PHI for use in a pharmaceutical company’s research study without obtaining informed consent from each patient.\textsuperscript{121}

Part of the Model Act governs the subsequent disclosure of PHI. Generally, PHI is not public information and cannot be disclosed unless it falls under one of two types of exceptions:\textsuperscript{122} (1) medical reasons for the benefit and treatment of the patient, and (2) certain non-medical reasons. Once an exception has been determined to exist, HCPs can disclose only the minimum amount of information necessary, and, when possible, must disclose information in a non-identifiable form.\textsuperscript{123} Notice is to be provided to third parties so that they are aware of the confidential nature of the information.\textsuperscript{124}

The Model Act would also afford patients the right to request review of their own PHI.\textsuperscript{125} HCPs must provide, without charge, printed copies of a patient’s medical record\textsuperscript{126} subject to reasonable time and place restrictions on access. Access can be denied only under a limited set of circumstances.\textsuperscript{127} The Act also grants patients a right to correct and amend their health records.\textsuperscript{128}

\textsuperscript{118} See id. § 3-101(c)(1).
\textsuperscript{119} See id. § 3-101(c)(5).
\textsuperscript{120} See id. § 3-103.
\textsuperscript{121} See discussion of informed consent at note 221.
\textsuperscript{122} The Model State Public Health Privacy Act, § 4-101.
\textsuperscript{123} See id. § 4-103(d).
\textsuperscript{124} See id. § 4-103(a)-(c).
\textsuperscript{125} See id. § 7-102.
\textsuperscript{126} See id. § 6-101(a).
\textsuperscript{127} See id. § 6-101(b).
\textsuperscript{128} For example, health care providers are allowed to deny access if that access would reasonably cause substantial and identifiable harm to the person requesting the information. See id. § 6-102.
\textsuperscript{128} See id. § 6-104.
The second model statute, the Turning Point Act, borrowed heavily from the Model Act in fashioning a more comprehensive set of suggested statutes that address strategic issues aimed at facilitating coordination of state-based initiatives for developing public health infrastructure, fostering relationships between the public and private sector, and managing emergencies. The Turning Point Act is not as comprehensive a treatment of health information privacy as is the Model Act, but addresses the amount of information acquired and subsequently disclosed in emergency situations, imposes security standards related to information retention, and grants rights of self-remediation for medical record errors.

Although both the Model and Turning Point Acts represent progress toward statutory uniformity, there remains what has been termed “a messy legal environment in which differing privacy-preserving obligations exist.” Variation in state privacy laws has been cited by multiple sources to be a barrier to NHIN development. The further proliferation of piecemeal legislation will only complicate the current patchwork of state and federal law and delay the development of a NHIN with its attendant benefits. Before these benefits can be realized, a uniform legal framework needs to be created conducive to the transference of PHI across state lines in a seamless fashion. The following section analyzes the current patchwork of state laws that represent a barrier to such seamless transference and NHIN development.

B. An Analysis of States’ Health Information Privacy Law and NHIN Development

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129 Hill, Langvardt & Rinehart, supra note 7, at 36.
130 See THE TURNING POINT MODEL STATE PUBLIC HEALTH ACT, § 7-101 to -103.
131 See id. § 7-104 to -105.
132 Hill, Langvardt & Rinehart, supra note 7, at 36.
134 Hill, Langvardt & Massey, supra note 1, at 159-65.
Although a complete analysis of state privacy laws is beyond the scope of our examination, this subsection focuses on several aspects of state privacy laws that appear most threatening to NHIN development. It first highlights certain state attempts to augment and strengthen federal security requirements for PHI. It next deals with state laws restricting access to medical records followed by an examination of state requirements regarding retention of medical records. It then discusses certain definitional and procedural ambiguities in state laws that have the potential of impeding the transmission of medical information across state lines. Finally, it describes how these concerns collectively threaten to impede the interstate electronic transmission of health information necessary for a smooth-functioning NHIN.

Disclosure of Protected Health Information

Because HIPAA’s privacy provisions were intended to be only a floor for protection of PHI, a profusion of state privacy laws has been layered on top of HIPAA.¹³⁵ Interplay between state and federal law is problematic for two reasons. First, any balance achieved at the federal level between patients and HCPs can be upset by more stringent state law. Second, determining when HIPAA or the HITECH Act preempts state law can be difficult.

Overall, states are fairly protective of patient’s medical records, generally prohibiting disclosure unless it fits in one of the exceptions listed in federal statutes. The problem, therefore, is not the level of protection afforded patients, but rather the uneven landscape of state laws. Some states place more reliance upon federal law and have fewer state regulations.¹³⁶ Others take a more comprehensive approach, detailing disclosure procedures for various scenarios.¹³⁷

¹³⁵ Hill, Langvardt & Rinehart, supra note 7, at 34.
¹³⁶ See generally ALA. CODE § 27-21A-25 which regulates the dissemination of health information obtained by a HMO; see ALA. CODE § 34-8A-21 (regulating the communication between counselors and their patients); ALA. CODE § 34-26-2 (protecting the communications between psychologists and their patients).
¹³⁷ See, e.g., Alaska which has a number of statutes, each covering a specific area in which health information could be disclosed. For more thorough coverage, see ALASKA STAT. § 08.80.315 (pharmacists); ALASKA STAT. §
Yet others attempt an all-inclusive approach, preferring a few general statutes. States with all-inclusive statutes often have mechanisms for physician override in cases where patients do not want to disclose healthcare information but the physician deems it in the patient’s best interest.

Each state’s law generally covers the same issues, but there is a tendency toward specific construction begging the question of whether such differences are necessary. Not every state seems to find an appropriate balance between competing interests. For example, some states have no provisions allowing for “routine use” exception making them more stringent than federal statute. A NHIN requires sufficient flexibility to allow HCPs exceptions for routine uses. In a

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08.63.200 (family therapists); ALASKA STAT. § 08.29.200 (licensed professional counselors); ALASKA STAT. § 08.86.200 (psychologists); ALASKA STAT. § 09.25.400 (sexual assault counselors); ALASKA STAT. § 47.37.210 (records of alcoholics, drug abusers, and intoxicated persons). Alaska is not the only state with this type of framework. See N.J. STAT. ANN. § 17:23A-13 (insurance institutions); N.J. STAT. ANN. § 26:2J-27 (HMOs); N.J. STAT. ANN. §17:48D-21 (dentists); N.J. STAT. ANN. § 26:2H-12.8 (general hospitals); N.J. STAT. ANN. § 45:14B-28 (psychologists); N.J. STAT. ANN. § 45:8B-29 (marriage and family therapists).

See R.I. GEN. LAWS § 5-37.3-4(a) (generally requiring that “a patient's confidential health care information shall not be released or transferred without the written consent of the patient or his or her authorized representative.”); WIS. STAT. § 146.82(1) (“All patient health care records shall remain confidential. Patient health care records may be released only to the persons designated in this section or to other persons with the informed consent of the patient or of a person authorized by the patient.”).

See R.I. GEN. LAWS § 5-37.3-4(b) (“No consent for release or transfer of confidential health care information shall be required in the following situations…[t]o a physician, dentist, or other medical personnel who believes, in good faith, that the information is necessary for diagnosis or treatment of that individual in a medical or dental emergency”); WIS. STAT. § 146.82(2).

For example, compare a number of state’s statutes disclosure requirements for health information. Colorado has specific disclosure requirements for health insurance companies. See COLO. REV. STAT. § 10-16-1003 (2009). On the other hand, a state like Delaware has a more comprehensive state statute covering the disclosure of health information. See DEL. CODE ANN. tit. 16, § 1232 (2009). Take, for example, rules that want to prohibit disclosure without patient authorization. Colorado prohibits disclosure except for those circumstances where “[d]isclosures [are] explicitly authorized through written informed consent procedures by an individual.” COLO. REV. STAT. § 10-16-1003(1)(b). Delaware, similarly, states that “[p]rotected health information shall be disclosed with the informed consent of the individual who is the subject of the information to any person and for any purpose for which the disclosure is authorized pursuant to informed consent.” See DEL. CODE ANN. tit. 16, § 1232(b). Compare these with Illinois, whose statutes state that “[n]o member of a hospital's medical staff and no agent or employee of a hospital shall disclose the nature or details of services provided to patients, except that the information may be disclosed to the patient, persons authorized by the patient…” 210 ILL. COMP. STAT. 85/6.17 (2009). Compare these with the law in Maine, which states “[a] health care practitioner or facility may disclose health care information pursuant to a written authorization signed by an individual for the specific purpose stated in the authorization.” 22 ME. REV. STAT. ANN. tit 22 § 1711-C (2009).

The HIPAA “routine use” exception allows the disclosure of protected health information when the disclosure is for treatment, payment, or health care operations. 45 C.F.R. § 164.506(c). A covered entity is allowed to disclose information from one covered entity to another covered entity for any one of these three purposes. Id. § 164.506(c)(3). Minnesota state law is different than HIPAA. Minnesota law states that a patient's “health record…used in assessing the patient's condition…shall promptly be furnished to another provider upon the written
similar vein, disparate enforcement penalties imposed by states for wrongful disclosure could have a chilling effect on interstate transmission of health information and discourage sufficient disclosure.\(^\text{142}\)

Another concern involves states with more modern, comprehensive health privacy laws versus those with legacy laws. States such as Minnesota have revised prior laws, opting for a comprehensive health privacy statute that covers many of the concerns addressed herein.\(^\text{143}\) In 2007, the Minnesota state legislature passed the Minnesota Health Records Act designed to address the most significant privacy and security barriers to the electronic exchange of health information.\(^\text{144}\) The legislature identified several impediments for electronic health information exchange. For example, consent requirements did not clearly define the circumstances when and how information exchange should occur, and prior statutes were not clear and consistent in their terms and concepts\(^\text{145}\) creating uncertainty that made electronic exchange nearly impossible.\(^\text{146}\)

request of the patient.” \(^\text{142}\) MINN. STAT. § 144.293 (2009). So, HIPAA would allow a routine use disclosure in transmitting patient data from one covered entity to another, but the Minnesota statutes would allow the same disclosure only upon patient authorization. There are also states whose laws would give rise to a preemption analysis. Illinois’ routine use law excepts “those parties directly involved with providing treatment to the patient or processing the payment for that treatment,” 410 ILL. COMP. STAT. 50/3Those parties who are ‘directly involved’ could be both more stringent and more liberal than the HIPAA rule depending on the analysis.\(^\text{142}\) HIPAA disparities have negatively affected research. Cancer researchers have remarked that HIPAA is derailing the progress of knowledge. Charles Bankhead, \textit{Privacy Regulations Have Mixed Impact on Cancer Research Community}, Journal of the National Cancer Institute 96(23):1738-1740 (2004). Surveys conducted by the National Academies have noted that HIPAA’s effect on research has: increased the cost and time to conduct a research project, made the conducting of research more difficult, made the recruitment of subjects more difficult, increased the confusion among subjects as to their rights, led to the abandonment of certain studies, and created new barriers to research. The National Academies, \textit{Effect of the HIPAA Privacy Rule on Health Research}, available at: http://www.ncbi.nlm.nih.gov/bookshelf/br.fcgi?book=nap12458&part=a20016f79dd0129&rendertype=box&id=a20016f79b00128. \textit{See also} Sara Rosenbaum, Phyllis C. Borzi, Taylor Burke, and Sonia W. Nath, \textit{Does HIPAA Preemption Pose a Legal Barrier To Health Information Transparency and Interoperability?}, BNA’s Health Care Policy Report, Vol. 15, No. (2007).\(^\text{143}\) MINN. STAT. § 144.291 et seq.

\(^\text{144}\) Minnesota Health Records Act – HF 1078. For example, the new statute defined key terms like “health information exchange,” “health record,” “identifying information,” “medical emergency,” “patient,” and “provider.” MINN. STAT. § 144.291. The statute also made clear what the patient’s access rights were with respect to medical records. Patients could retrieve a copy of their health record subject to certain exceptions. If the release of the health record were likely to cause detrimental effects to the patient’s health, then the record could not be released to the patient but an appropriate third party. \textit{See} MINN. STAT. § 144.292.

In contrast, states lacking comprehensive statutes such as Arkansas\textsuperscript{147} are likely to experience difficulty with the issues presented by the interstate electronic exchange of PHI.

**Patient Access to Medical Records**

As with PHI disclosure rules, states vary widely in their laws governing access to records.\textsuperscript{148} Accuracy of PHI is critical, and providing patients with the right to inspect and alert HCPs of the need to correct their medical records can potentially improve accuracy. Patients often have information about themselves not possessed by HCPs such as their dietary and exercise habits and family histories of illness. Further, in the future it is likely that patients will have multiple HCPs entering information into their EMRs, and astute patients have an incentive to help ensure the accuracy of their PHI across HCPs.\textsuperscript{149} States may feel the need to address patient access because such rights are relatively circumscribed at the federal level. Federal law currently provides patients the right to inspect their health records, but does not provide for patient-initiated correction of erroneous records.\textsuperscript{150} As noted previously, the HITECH Act grants patients the right to request an audit trail of electronic disclosures.\textsuperscript{151} In addition, the Federal Privacy Act of 1974 affords individuals the right to review non-exempt records about

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\textsuperscript{146} Id.

\textsuperscript{147} Although Arkansas (as of this writing) does not have a comprehensive statute, it is currently in an information gathering phase in preparation for the development of a comprehensive statute. See Arkansas Center for Health Improvement, Health Information Security & Privacy Collaboration, available at http://www.achi.net/HISPC.asp.

\textsuperscript{148} Some states afford patients a right to inspect their medical records. See e.g. ARK. CODE ANN. § 25-19-105 (2009); CONN. GEN. STAT. § 4-104; Other statutes provide patients the right to inspect and amend their medical records. See e.g. COLO. REV. STAT. § 10-16-1003(3)(b); It is presumed that those states with a more restrictive approach to patient rights are preempted by HIPAA. See State v. La Cava, 2007 WL 1599888, Conn.Super. Ct. (2007). Still other states take a shotgun approach to legislation, segmenting inspection rights across a number of statutes. See, e.g. FLA STAT. ANN. § 394.4615 (mental health procedures); § 395.3025 (hospitals); § 400.611 (long-term care facilities).

\textsuperscript{149} See Benjamin M. Bluml and Glenna M. Crooks, Designing Solutions for Securing Patient Privacy: Meeting the Demands of Health Care in the 21st Century, Journal of the American Pharmaceutical Association, 39:402–7 (1999) (noting the role that patients will provide in this system; patients will be able not only contribute information to bolster their current EMR, but will be able to help correct factual errors in their records).

\textsuperscript{150} See 45 C.F.R. § 164.524 (granting patients the right to inspect their medical records); 45 C.F.R. § 164.526 (granting patients the right to amend their medical records).

\textsuperscript{151} See discussion \textit{supra}. 
themselves, to discover if that information has been disclosed, and to request amendments or corrections to that information.\(^{152}\) HIPAA generally provides patients a right to access one’s medical records, but the right is not absolute inasmuch as covered entities are permitted to deny requests to access under certain conditions.\(^{153}\)

Under HIPAA states are permitted to grant patients an absolute right of access to medical records,\(^{154}\) and most states have laws enabling patients to inspect and copy their records.\(^{155}\) Some states circumscribe access when the information disclosure would negatively impact the health of the patient.\(^{156}\) Some states vest ownership of the medical record with HCPs\(^{157}\) while

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\(^{152}\) Privacy Act of 1974, 5 U.S.C. § 552a. This act also covers medical records. Patients can request that the federal government disclose his medical records to “an individual” (presumably health-care providers). However, this act only pertains to federal files, not to the files of a private health care provider. See Privacy Act of 1974, 5 U.S.C. § 552a(f)(3).

\(^{153}\) 45 C.F.R. § 164.524(b)(2)(i)(B) (requiring the covered entity to provide written notice as to the reasons why it denied access under the statute).

\(^{154}\) According to the department of Health and Human Services (DHHS), a state law is \textit{more stringent} than HIPAA if it: prohibits or restricts a use or a disclosure when HIPAA would allow it; provides a patient with greater rights of access or amendment to his or her medical records than afforded under HIPAA; provides a patient with a greater amount of information about a use, a disclosure, rights, and remedies; narrows the scope or durations, increases the privacy protections afforded, or reduces the coercive effect of the circumstances surrounding express legal permission; provides for the retention or reporting of more detailed information or for a longer duration; or the state law provides greater privacy protection for the individual who is the subject of the individually identifiable health information. 45 C.F.R. § 160.202 (2002).


\(^{156}\) COL. REV. STAT. § 25-1-801(1)(a) (preventing disclosure to mental health patients when, in the opinion of their doctor, disclosure of that information would negatively impact the mental health of that patient); HAW. REV. STAT. § 622-57 (allowing access unless “in the opinion of the health care provider, it would be detrimental to the health of the patient to obtain the records.”); IND. CODE 16-39-1 (denying access if the disclosure is either “detrimental to the physical or mental health of the patient” or “likely to cause the patient to harm the patient or another”); ME. REV. STAT. ANN. tit. 22, § 1711 (denying access to patient when determined detrimental to patient’s health but allowing an “authorized representative” access); MASS. GEN. LAWS ch. 112, § 36 (restricting mental health patient’s access altogether, unless the mental health commissioner allows it because it is in the interest of the patient); MINN. STAT. § 144.335; NEB. REV. ST. § 71-8403; W. VA. CODE § 16-29-1.

Beyond the plausibly sound reason for limiting patient access when it is likely to have adverse consequences on patients’ health, striking the appropriate balance between access and protection of what should arguably be private information is important in a different context. Physician notes entered into EMRs are often speculative in nature, and physicians may fear that disclosure of these notes would provide fertile fishing grounds for case-finding medical malpractice attorneys. Larry Garber, Panel Discussion Remarks, “Health Information Exchanges,” Harvard Seminar, \textit{supra} note 10 (notes on file with authors). See, however, Tom Delbanco, “Through the Patient’s Eyes: Time,
others place ownership with the patient.158 Yet others are more restrictive in granting access, particularly to certain types of records. Oklahoma, for example, generally grants access to medical records, but denies access to "psychological, psychiatric, mental health or substance abuse treatment records."159 Some states require access requests to be in writing.160 Maine denies patient access, but allows access by the patient’s authorized representative.161

The issue of whether HIPAA overrides Rhode Island’s statute is an example of the uncertainty and ambiguity about consonance among PHI privacy laws. Although HIPAA permits providing patients a summary of health records, it does so if the individual agrees to pay the associated fees.162 In contrast, Rhode Island does not grant patients an explicit right to access medical records163 making this the discretion of the attending physician.164 In addition, Rhode Island drafted and passed its own comprehensive legislation to reduce the difficulties associated with health information exchange,165 but compliance is voluntary. If HCPs choose not to

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157 IOWA CODE § 135.154.4.c; TENN. CODE ANN. § 68-11-304;
158 N.H. REV. STAT. ANN. § 332-I:1 (“All medical information contained in the medical records in the possession of any health provider shall be deemed to be the property of the patient.”).
159 OKLA. STAT. tit. 76, § 19-1-3;
160 TENN. CODE ANN. § 68-11-304; R.I. GEN. LAWS, § 5-37-22(c) (1956).
161 ME. REV. STAT. ANN. tit. 22, § 1711.
162 45 C.F.R. § 164.524(c)(2)(ii).
163 R.I. GEN. LAWS § 5-37-22(d) (“Every physician or medical practice group shall, upon written request of any patient…at the option of the physician or medical practice group either permit the patient (or his or her authorized representative) to examine and copy the patient's confidential health care information, or provide the patient (or his or her authorized representative) a summary of that information.”)
164 R.I. GEN. LAWS § 5-37-22(d). Patients desiring to transfer their health records from one doctor to another must request the transfer in writing. R.I. GEN. LAWS § 5-37-22(c) (“When a patient requests, in writing, that his or her medical records be transferred to another physician or medical practice group, the original physician or medical practice group shall promptly honor the request.”).
participate, they are subject to a different set of rules\footnote{R.I. GEN. LAWS § 5-37-4(c)-(d) (\textquotedblleft Patients and health care providers shall have the choice to participate in the HIE...[p]articipation in the HIE shall have no impact on the content of or use or disclosure of confidential health care information of patient participants that is held in locations other than the HIE.	extquotedblright).} creating even more difficulty for both intrastate and interstate information exchange.

**Records Retention**

Ideally, in a patient-centric healthcare system, a patient’s health record should reside with the patient from cradle to grave. This would allow for the accumulation of a great deal of information, however, much of which may become dated over time.\footnote{One’s health record could also possibly last longer than the grave. For example, one’s health record could be used in research or next of kin could use it for determination what, if any, diseases they are at greater risk for.} Periodic review and purging are necessary to de-clutter records and limit the potential damage in the event of inadvertent disclosure.\footnote{Purging information prevents opportunities for inadvertent disclosure. \textit{See e.g.}, Melinda Rogers, \textit{U of U medical records stolen, 2.2 million patients' data at risk}, The Salt Lake Tribune, June 10, 2008 (reporting of a theft of 2.2 million billing records that were stolen out of a courier’s personal vehicle); Carol M. Ostrom, \textit{Patients' information stolen in 3 thefts}, Seattle Times, January 26, 2006, \textit{available at}: http://seattletimes.nwsource.com/html/localnews/2002762444_recordtheft26m.html http://seattletimes.nwsource.com/html/localnews/2002762444_recordtheft26m.html (noting that a thief stole over 350,000 patients’ data from an employee’s car); Gary Delsohn, \textit{Laptop Stolen; State Fears ID Theft}, Sacramento Bee, May 28, 2005 (noting that a laptop containing the information from more than 20,000 patients’ was stolen out of the trunk of a car).} Some states require records to be retained for ten years while others require shorter periods.\footnote{See e.g., ALASKA STAT. § 18.20.085; ARIZ. REV. STAT. § 12-2297; CAL.BUS. & PROF.CODE § 2919; MD. CODE ANN., HEALTH–GEN., § 4-403; MINN. STAT. § 145.32; MISS. CODE ANN. § 41-9-69; S.C. CODE ANN. § 44-115-120; WASH. REV. CODE 70.41.190; \textit{See e.g.,} ALASKA STAT. § 18.20.085 (\textquotedblleft Unless specified otherwise by the department a hospital shall retain and preserve records that relate directly to the care and treatment of a patient for a period of seven years following the discharge of the patient ... Records consisting of X-ray film are required to be retained for five years.	extquotedblright) \textit{Code Ann., Health–Gen.} § 4-403.} Some states require different retention periods for different types of PHI contained in the same EMR. For example, records related to general care are sometimes treated differently than source data, such as X-rays or MRIs. Alaska records relating to treatment and care are retained for a period of seven years following discharge of a patient while x-rays are retained for only five years.\footnote{See e.g., A.LASKA S.TAT. § 18.20.085 (\textquotedblleft Unless specified otherwise by the department a hospital shall retain and preserve records that relate directly to the care and treatment of a patient for a period of seven years following the discharge of the patient ... Records consisting of X-ray film are required to be retained for five years.	extquotedblright)} Maryland requires HCPs to retain x-rays, medical records, and lab reports for five years \textit{after the record or report was made},\footnote{\textit{Code Ann., Health–Gen.} § 4-403.} but requires a
holding period of three years beyond the age of majority for minors.\textsuperscript{172} Obviously, such disparities would greatly complicate the periodic review of EMRs and purging of outdated information in a NHIN environment.\textsuperscript{173}

Some retention statutes like those of Mississippi are ambiguous and complex.\textsuperscript{174} New Mexico allows HCPs the option of destroying records four years after the date of exposure\textsuperscript{175} creating confusion by, in effect, permitting retention policies to be made on a HCP-by-HCP basis. A number of states have no records retention laws leaving HCPs without guidance. Alaska’s retention statute is aimed specifically at EMRs and affords HCPs the option of preserving records in an electronic as opposed to paper format.\textsuperscript{176} The statute, however, provides no guidance regarding the required holding period for electronic records versus paper records.\textsuperscript{177} Complicating the situation even further, most state statutes implicitly assume that PHI will not be consolidated into one EMR in which all of a patient’s health information resides. Such consolidation, although providing HCPs more complete patient information, also begs the question as to which HCP is responsible for information correctness, completeness, retention,

\textsuperscript{172} Id.
\textsuperscript{173} There is a disparity among laws at the federal level and at the state level. Medicare requires hospitals to retain records for five years, while HIPAA mandates a six-year retention period. \textit{Compare} 42 C.F.R. § 482.24(b)(1) with 45 C.F.R. § 164.530(j)(2). The patchwork is even worse at the state level. \textit{See e.g.}, 18 VA. STAT. ANN. §1905(8) (requiring hospitals to retain records for ten years after patient discharge; R.I. GEN. LAWS §23-3-26(d) (mandating that vital records must be kept for 5 years).
\textsuperscript{174} MISS. CODE ANN. § 41-9-69 (“However, complete hospital records shall be retained for a period after discharge of the patient of at least (a) seven (7) years in cases of patients discharged at death, except as may be otherwise hereinafter provided; (b) ten (10) years in cases of adult patients of sound mind at the time of discharge, except as may be otherwise hereinafter provided; (c) for the period of minority or other known disability of the patient plus seven (7) additional years, but not to exceed twenty-eight (28) years, in cases of patients under disability of minority or otherwise; or (d) for the period of minority or other known disability of any survivors hereinafter mentioned plus seven (7) additional years, but not to exceed twenty-eight (28) years, in all cases where the patient was discharged at death, or is known by the hospital to have died within thirty (30) days after discharge, and the hospital knows or has reason to believe that such patient or former patient left one or more survivors under disability of minority or otherwise who are or are claimed to be entitled to damages for wrongful death of the patient under Section 11-7-13, or laws amendatory thereof. Upon the expiration of the applicable period of retention, any hospital may retire the hospital record.”). Its retention statutes for minors and for source data are just as complicated. \textit{See generally} MISS. CODE ANN. § 41-9-69.
\textsuperscript{175} N.M. STAT. § 14-6-2.
\textsuperscript{176} ALASKA STAT. § 18.23.100; \textit{see also} MO. ANN. STAT. 334.097.
\textsuperscript{177} \textit{See} ALASKA STAT. § 18.23.100; ALASKA STAT. § 18.20.085.
periodic review and purging.\footnote{Floor comments, Harvard Seminar, supra note 10 (notes on file with authors). Another physician concern relates to the fact that once an error is introduced into an EMR and signed over, it cannot be erased.} Electronic PHI exchange would obviously be facilitated by a set of common standards.

**Definitional and Procedural Ambiguities**

Clear definitions are critical to any harmonization of laws because such definitions affect disclosure rules, consent requirements, and patient access rights.\footnote{These three attributes were selected for the following reasons. One, the definition of a health record is relevant because it defines the scope of what is to be regulated. Two, the definition of a provider is important as it determines who will be regulated. Finally, the definition of what is and what is not identifying information is important as health information networks will strip data of identifying information for purposes of research. Obviously without a common definition of what constitutes identifying information will make data collection for research that much more difficult.} This subsection examines variances in definitions among state privacy laws.

A major definitional ambiguity is that of what constitutes a “covered entity.” Generally, covered entities under HIPAA include health plans, HCPs, health care clearinghouses, and business associates.\footnote{Health plans are defined as individual and group plans that provide or pay the cost of medical care. The group includes most all types of health insurers, but provides an exception for group health plans administered and maintained by an employer with less than 50 participants. C.F.R. §§ 160.102, 160.103. Health care providers include all “providers of services” like hospitals and “providers of medical or health services” like private practice doctors or dentists and anyone who bills or is paid for health care. 45 C.F.R. §§ 160.102, 160.103. Healthcare clearinghouses are entities that process nonstandard information they receive from another entity into a standard format or vice versa. For example, this could include billing services, information systems, or networks. 45 C.F.R. § 160.103. Finally, business associates include those entities that perform services for a covered entity that involve the use of or disclosure of identifiable health information. 45 C.F.R. § 160.103.} In contrast, Minnesota defines covered entities by reference to other pre-defined and regulated entities listed in separate statute,\footnote{According to the statute, a provider is defined as “any person who furnishes health care services and is regulated to furnish the services under chapter 147, 147A, 147B, 147C, 147D, 148, 148B, 148C, 148D, 150A, 151, 153, or 153A”; or “a home care provider licensed under section 144A.46” or “a health care facility licensed under this chapter or chapter 144A”; or “a physician assistant registered under chapter 147A”; or “an unlicensed mental health practitioner regulated under sections 148B.60 to 148B.71.” MINN. STAT. § 144.291(h). Looking through some of the chapters referred to, this appears to include: physicians licensed by the state of Minnesota, physicians assistants, acupuncture practitioners, respiratory care practitioners, traditional midwives, etc.} taking a specific approach compared to HIPAA’s categorical approach.\footnote{For example, for a list of the regulated Minnesota entities, see generally MINN. STAT. § 144.291(h); MINN. STAT. §§ 147, 147A, 147B, 147C, 147D, 148, 148B, 148C, 148D, 150A, 151, 153, and 153A. Compare this to HIPAA, which defines covered entities (at least with respect to those providing health care services) as all health care providers, health plans, and business associates.} This degree of specificity is not replicated, however, in
Minnesota’s definition of a “health record” where it is less specific than HIPAA in generally defining a health record as any patient information.  

Rhode Island recently enacted an electronic information exchange statute that takes an all-encompassing approach to defining what it calls “confidential health care information”, but the statute’s construction is more ambiguous than either federal or Minnesota law. Rhode Island’s covered entities fall under the definition for a “provider participant,” a catch-all covering all pharmacies, laboratories, and HCPs. The state also lacks a definition for individually identifiable health information and is therefore silent as to how PHI should be extracted for research and data gathering purposes.

Maryland has also passed an electronic information exchange statute, and it too has widely varying definitions among these key terms. Similar to Rhode Island, it embodies a narrower construction of what information constitutes a medical record and lacks any provision for defining individually identifiable information, again creating uncertainty as to how to extract and providers who electronically transmits health information. 45 C.F.R. §§ 160.102, 160.103. While HIPAA only covers those providers who electronically transmit health information, one could easily imagine a broader statute to cover any HCP who uses, handles, stores, or transmits electronic health information.

Compare Minn. Stat. § 144.291 (defining health record as “any information, whether oral or recorded in any form or medium, that relates to the past, present, or future physical or mental health or condition of a patient; the provision of health care to a patient; or the past, present, or future payment for the provision of health care to a patient.”) with 45 C.F.R. § 160.103 (“Health information means any information, whether oral or recorded in any form or medium, that: Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and [r]elates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.”). See also Minn. Stat. § 144.291; 45 C.F.R. § 160.103.

See R.I. Gen. Laws § 5-37.7-1.

See R.I. Gen. Laws § 5-37.7-3(e) (“‘Confidential health care information’ means all information relating to a patient participant’s health care history, diagnosis, condition, treatment, or evaluation.”). I consider this more ambiguous because there could be categories of health records than do not fall into one of those explicit categories. For example, are doctor’s notes included in the Rhode Island statute? Under the Minnesota construction, it appears they would, but it isn’t as clear a case under Rhode Island law.

See R.I. Gen. Laws § 5-37.7-3(s).

See generally MD Code, Health–Gen., § 19-142.

See MD Code, Health–Gen., § 19-142(c) (defining an electronic health record as one that “Includes patient demographic and clinical health information; and [h]as the capacity to: (i) Provide clinical decision support; (ii) Support physician order entry; (iii) Capture and query information relevant to health care quality; and (iv) Exchange electronic health information with and integrate the information from other sources.”). This is a narrower construction than Minnesota’s “any information” approach to defining what constitutes a health record.
information and data for medical research. Maryland takes a specific approach similar to Minnesota’s for defining covered entities under the statute.\textsuperscript{189}

\textit{The Consequences of Disparities in Federal and State Patient Privacy Law}

The current system of patchwork privacy laws is wastefully inefficient requiring HCPs in different states to maintain knowledge of multiple legal regimes. When PHI is transmitted electronically across state lines, HCPs need to be familiar with three sets of laws: federal law, laws of the state where the transmission originates, and laws of the destination state.\textsuperscript{190} Even when electronic transmissions are intrastate, whether federal or state law is operative is dependent upon which set of laws is most stringent on a particular point. Utah’s legislation was drafted, at least in part, with concern for a possible HIPAA override,\textsuperscript{191} but this is not always the case. For example, unlike HIPAA,\textsuperscript{192} Arkansas does not give patients an explicit right to copy their medical records unless the matter involves a legal proceeding,\textsuperscript{193} but Arkansas is more restrictive with respect to disclosure. State law is more stringent if, among other reasons, the state law either prohibits or restricts a use or a disclosure when HIPAA would allow it or provides a patient with greater rights of access or amendment to his or her medical records than

\begin{footnotesize}
\begin{enumerate}
\item See MD CODE, HEALTH–GEN., § 19-142(d)-(e).
\item UTAH CODE ANN. 1953 § 78B-5-618 (stating that “a patient … may inspect or receive a copy of the patient's records from a health care provider … when that health care provider is governed by the provisions of 45 C.F.R., Parts 160 and 164 … [w]hen a health care provider … is not governed by 45 C.F.R., Parts 160 and 164 … a patient or a patient's personal representative may inspect or receive a copy of the patient's records unless access to the records is restricted by law or judicial order.”); WASH. REV. CODE 70.02.030 (“Unless disclosure without authorization is otherwise permitted under … the federal health insurance portability and accountability act of 1996 and its implementing regulations…”).
\item 45 C.F.R. § 164.524(b)(1).
\item Compare ARK. CODE ANN. § 23-76-129 with § 16-46-106. Section 23-76-129 holds medical information in confidence and prevents disclosure to any person except with the express consent of the enrollee or applicant. Section 16-46-106 allows persons involved in a legal proceeding to obtain copies of their medical records. Read together, it appears that in Arkansas, unless you are involved in a legal proceeding, you may view, but not copy, your medical records.
\end{enumerate}
\end{footnotesize}
afforded under HIPAA.\textsuperscript{194} Arkansas law thus provides more protection to patients,\textsuperscript{195} but federal law affords patients more rights.

A group of healthcare-related organizations has stated that a NHIN will be virtually impossible as a result of HCPs being required to comply with complex and disparate federal and state privacy laws.\textsuperscript{196} To date DHHS has declined to provide a comprehensive preemption analysis,\textsuperscript{197} and there is no national coordination on the issue of preemption. The determination of which laws are applicable to specific situations requires time consuming and costly comprehensive preemption analyses in each jurisdiction in which HCPs do business. A related issue involves conflicts and overlaps between HIPAA and other federal laws dealing with privacy including the Family Educational Rights and Privacy Act.\textsuperscript{198}

Perhaps no situation exemplifies the complexities surrounding disclosure and consent laws – and concomitantly the difficulties in taking a bottom-up approach to harmonizing healthcare privacy law - as well as Hawaii. In 1999, Hawaii passed the Privacy of Health Care Information Act\textsuperscript{199} addressing consent and disclosure guidelines and granting patients a limited right to

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\textsuperscript{194} 45 C.F.R. § 160.202 (2002).
\textsuperscript{195} At least under the reasoning that excess copies of medical records creates a great opportunity for unwanted disclosure.
\textsuperscript{196} AdavaMed, et al., letter to Dr. David J. Brailer, Office of the National Coordinator for Health Information Technology, DHHS 4,5 (Jan. 18, 2005), available at http://www.hlc.org/FINAL.pdf. It noted the following:

State health privacy protections vary widely and are found in thousands of statutes, regulations, common law principles, and advisories. Health information privacy protections can be found in a state’s health code as well as laws and regulations governing criminal procedure, social welfare, domestic relations, evidence, public health, revenue and taxation, human resources, consumer affairs, probate and many others. The rules typically apply either to specific entities – such as hospitals or county health departments – or to specific health conditions, and no two states are the same in this regard. Virtually no state requirement is identical to the federal rule.

\textsuperscript{197} See 65 Fed. Reg. 82, 462, 82, 481 (Dec. 28, 2000).
\textsuperscript{198} National Committee on Vital and Health Statistics letter (Nov. 25, 2002), available at www.ncvhs.DHHS.gov/021125lt.htm.
inspect their health records.\textsuperscript{200} Although the bill expanded HIPAA’s coverage to a wider range of entities, some citizens opposed portions of the bill that allowed limited disclosures of health information, arguing insurers would take advantage of the loopholes.\textsuperscript{201} Insurance companies opposed the bill as well, and were subsequently provided more exceptions under the legislation.\textsuperscript{202} The bill passed with little opposition,\textsuperscript{203} but unfortunately Hawaii had implementation difficulties, in part due to conflicting opinions issued by lawyers representing HCPs in Hawaii.\textsuperscript{204} Expanded exceptions for insurers led some attorneys to advise insurance clients that they were covered as an “agent” under the new regulations, while other attorneys advised their insurance clients differently.\textsuperscript{205} Further, insurance companies were uncertain as to when they needed to obtain patient authorization to use PHI for litigation purposes.\textsuperscript{206} The result was uneven application of the laws with some medical records not being released, some patients not receiving care, some being denied benefits, and providers not being paid.\textsuperscript{207} Physicians, concerned about the penalties, resisted releasing information as a precautionary measure.\textsuperscript{208} Many parties were upset about unnecessary paperwork and additional costs, and ultimately Hawaii’s privacy legislation was repealed.\textsuperscript{209}

Difficulties in NHIN development increase as legal ambiguity increases,\textsuperscript{210} and Hawaii’s attempt at disclosure legislation portend the difficulties associated with attempting to harmonize
federal and state privacy laws as opposed to a single, preemptive legal regime. Systems architects and designers need bright line privacy rules in order to design safeguards into their operating systems. HCPs need greater simplicity and clarity in order to better comply with requirements and speed the transmission of PHI. There is also the question of whether it is socially desirable to expend political and judicial resources to clarify ambiguities between HIPAA and state law. Although a number of states have passed laws authorizing the creation of commissions or exploratory committees to identify issues and problems and provide guidance to the drafting of each state’s electronic exchange statutes,\footnote{211} to the extent the aforementioned disparities are a portent of what is to come from these initiatives, it seems safe to conclude that a bottom-up approach to harmonizing privacy laws promises to be highly problematic.

C. Some Recommended Criteria for Federal Privacy Law

The previous subsections reflect two fundamental privacy law problems that must be resolved to facilitate a smooth-functioning NHIN. First, disparities between federal and state laws must be eliminated.\footnote{212} Federal law should, in effect, be the ceiling, not the floor, for PHI security. Second, holes in existing federal laws need to be closed to bolster security of PHI. Helping to guide the resolution of these two problems should be the principle that privacy law should largely be patient centric whereas current federal regulations are focused on covered entities, not personal health records (PHRs).

\footnote{211}{See e.g. TEX. HUM. RES. CODE ANN. § 32.151 - .154 (establishing the Electronic Health Information Pilot Program); TEX. HUM. RES. CODE ANN. § 531.02175 (Pilot Program for Telehealth or Telemedicine Consultations for Certain Medicaid Recipients); 22 VT. STAT. ANN. § 903 (establishing a plan for exploring HIT); WASH. REV. CODE ANN. § 41.05.035 (creating exchange of health information pilot project); R.I. GEN. LAWS § 5-37.7-6 (Rhode Island Health Information Exchange Act of 2008); N.J. STAT. ANN. 17:1D-1 (establishing Office for e-HIT to explore and implement healthcare IT); MD. CODE ANN. HEALTH–GEN. § 19-209 (creating a health information exchange project).}
\footnote{212}{See Section II, supra.
As addressed supra, it is unlikely that harmonization of privacy laws will occur at the state level in an expeditious fashion. Current laws are too disparate, and it is unlikely that enough political capital exists in each to state to pass a set of model statutes. A more promising solution is to create federal law that preempts state laws allowing for common privacy standards. Such federal law should embody provisions that clarify what entities are regulated under the law, regulate the acquisition of healthcare information, provide for certain exceptions for family members in special situations, and standard record retention requirements.

To date, federal law has manifested a piecemeal approach to legislation regarding what entities are covered by privacy law. Initially only HCPs, health care plans, and health care clearinghouses were included. As noted supra, the HITECH Act later included business associates, but a major loophole still exists in the exclusion of entities that compile PHRs into databases allowing for the massive accumulation of PHI without federal regulation. National databases as proposed infra would probably be excluded under current federal law as are current private databases captured in GoogleHealth and Microsoft HealthVault. Instead, all entities involved with PHI should be covered with coverage segmented based upon distinguishing specific usage.

213 See supra text accompanying notes 199-209.
214 Include a discussion about the chart that is so freaking confusing?
216 See id. These entities are also not subject to the notice requirements for unauthorized disclosures. See American Recovery and Reinvestment Act § 13402.
219 For example, laws could segment between those entities who store identifiable health information for treatment and those who may need temporary use and those who may need part of the health record. But a system like this could only be done through a top-down approach with a common framework for patient health records.
Another issue is determining what information should be covered and under what specific circumstances should exceptions be provided. Federal law currently regulates the use and subsequent disclosure of PHI reasonably well.\textsuperscript{220} It adequately covers informed consent, breach notification, and patients’ rights to review their records,\textsuperscript{221} but an exception should be added permitting access by immediate family members in emergency situations. Federal law currently only covers identifiable information,\textsuperscript{222} but as some scholars have noted, reassembling de-identified information in an identifiable manner is becoming easier than once believed.\textsuperscript{223} Patient confidence is critical to participation in a NHIN,\textsuperscript{224} and privacy law should encompass use of anonymized information as well as identifiable information.\textsuperscript{225}

With respect to records retention, federal and state laws collectively are another legal patchwork.\textsuperscript{226} The problem with records retention in a NHIN environment is that two interests are inherently in tension. First, patients, their HCPs, and the public may benefit from inferences drawn from trends based upon historical information contained in PHRs. This suggests retention

\textsuperscript{220} 45 C.F.R. § 164.508; 45 C.F.R. § 164.501.
\textsuperscript{221} See 45 C.F.R. § 164.502(a)(1); 45 C.F.R. § 164.506(b)-(c); 45 C.F.R. § 164.501; 45 C.F.R. § 164.510(a)-(b); 45 C.F.R. § 164.512; American Recovery and Reinvestment Act § 13402; 45 C.F.R. § 164.524; 45 C.F.R. § 164.501.
\textsuperscript{222} 45 C.F.R. § 160.103; Milt Freudenheim, \textit{And You Thought a Prescription Was Private}, N.Y. TIMES, Aug. 8, 2009.
\textsuperscript{224} See Blum, \textit{supra} note 149, at 403; (noting the importance of security to protect patient records from errant disclosure). A follow-up survey found that 67 percent of respondents are either “somewhat” or “very concerned” about the privacy of their health information. \textit{CALIFORNIA HEALTH CARE FOUNDATION, NATIONAL CONSUMER HEALTH PRIVACY SURVEY 2005: EXECUTIVE SUMMARY} 3 (2005). Even more disturbing was the finding that some patients were willing to skip doctor’s visits or request that the doctor diagnose a less serious condition for privacy health concerns. \textit{Id.} at 4. Assuming patients are given a choice, patient buy-in is obviously necessary in order for a NHIN to be effective. Some argue that no one should be able to opt out of a NHIN because doing so will degrade its effectiveness and raise healthcare costs for all. Others argue vociferously that healthcare consumers should be given a choice. \textit{See} Testimony of Pam Dixon, Executive Director, World Privacy Forum, “Electronic Health Records and the national Health Information network: Patient Choice, Privacy, and Security in Digitized Environments,” before the Subcommittee on Privacy and Confidentiality, National Committee on Vital and Health Statistics (NCVHS), San Francisco, CA, Aug. 16, 2005, at 5, 7 available at http://www.worldprivacyforum.org/pdf/pamdixonNCVHSTestimonyfinal.pdf (also noting that during one period of seven and a half months there were 94 known security breaches in the digital medical environment impacting potentially 56 million patients and providing numerous specific examples of security breaches).
\textsuperscript{225} \textit{Id.} at 25-26.
\textsuperscript{226} See text accompanying notes 167-78.
of as much information as possible. Conversely, retention of greater amounts of information creates greater opportunity for damages resulting from its improper disclosure, theft, or misuse. Consequently, a bright line distinction is difficult, especially considering that even if there is no longer a personal need for information, it may be useful for purposes of medical research and public health studies. Individual preferences will therefore likely conflict with social welfare needs in many cases. Information acquisition and retention are currently inadequately regulated at the federal level and are differentially regulated at the state level.\textsuperscript{227} New federal legislation would need to address these current loopholes and eliminate disparities.

As discussed both supra and infra, privacy law and NHIN architecture are non-recursive in nature impacting upon one another. In the following section we propose an architecture that simultaneously addresses the unaffordable, sluggish pace of NHIN development and provides hope for addressing effectively many PHI security concerns.

IV. NHIN Architecture

A NHIN has been described as the cornerstone for interoperable HIT. Given that some commentators argue that there is no generally held optimal model for a NHIN and no “nirvana” for how to develop one,\textsuperscript{228} this section first examines the characteristics of a highly effective NHIN with regard to protecting patient privacy. It then briefly critiques four proposed, prototypes of a privately developed, NHIN architecture that rely upon evolutionary rollup, and discusses key attributes of these prototypes. It concludes with a proposal for a revolutionary, hybrid centralized/decentralized architecture based upon cloud computing and discusses why this

\textsuperscript{227} While acquisition is not regulated, unauthorized acquisition of PHI is subject to the breach disclosure rules under the HITECH Act. American Recovery and Reinvestment Act § 13402. The problem with the current set of laws is that, as long as you are an authorized entity, there is no limit to your acquisition of PHI. Some of the model statutes discourage indiscriminate acquisition of health information if it is not tied to a legitimate health purpose. See THE MODEL STATE PUBLIC HEALTH PRIVACY ACT § 2-101.

architecture offers a far greater hope for realizing the full potential of a NHIN within a reasonable timeframe.229

A. Characteristics of an Effective NHIN with Respect to Safeguarding Patient Privacy

Section II described how an optimally designed NHIN would greatly improve healthcare quality and efficiency. In achieving this improvement, as noted previously it is necessary that the NHIN protect patient privacy to a high level in order to inspire both patient and provider confidence in it. Longitudinal patient information is one of the most temporally and spatially complex information sets in existence,230 and security is a major concern.231 The exchange of personal information across a NHIN will require, at a minimum, laws that ensure privacy and

229 Observation of the evolution other networked technologies such as cellular telephone and electronic funds transfer may provide a crude idea of the time necessary for the evolutionary diffusion of a NHIN. For example, automated teller machines (ATMs) first came into being in the mid-1960s. By 1978 there were fewer than 10,000 terminals. By 2001 the number had grown to approximately 324,000 with the number of access cards having increased from 60 million in 1982 to 236 million in 2001. As is likely with NHIN technology, ATMs growth was impeded by state laws, in that case laws restricting interstate expansion. See Stan Sienkiewicz, The Evolution of EFT Networks from ATMs to New On-Line Debit payment Products, discussion paper, Federal Reserve Bank of Philadelphia (Apr. 2002), available at http://www.philadelphiafed.org/payment-cards-center/publications/discussion-papers/2002/EFTNetworks_042002.pdf. Similarly, the first handheld mobile phone was introduced in 1983. See Benj Edwrads, Evolution of the Cell Phone, PCWORLD (Oct. 4, 2009), available at http://www.pcworld.com/article/173033/evolution_of_the_cell_phone.html. Although cell phone testing had begun much earlier by , it was not until 1981 that federal restrictions on their manufacture by producers of terminal phones was lifted. Robert D. Keith, In the Kingdom of Cell Phones (2005), available at http://iml.jou.ufl.edu/projects/fall04/keith/history1.htm. From 1983 to 1993, there was relatively low diffusion in the U.S., in part because technological competition actually slowed diffusion due to the use of multiple standards. From 1993 to 1999, the diffusion rate increased markedly. Ex ante (de jure) standards have the advantage of faster adoption. See, generally, Heli Koski & Tobias Kretschmer, Entry, Standards and Competition: Firm Strategies and the Diffusion of Mobile Telephony, 26 REVIEW OF INDUSTRIAL ORGANIZATION (2005), 89, 91-92. In contrast to U.S. cellular service which remain woefully behind that of much of the world, the diffusion of fixed- line telephony provides an excellent example of a top-down strategy that resulted in rapid diffusion of networked technology. See, generally., International Telecommunications Union, World Telecommunication/ICT Indicators Database, 13th ed.(2009), available at http://www.itu.int/ITU-D/ict/publications/world/world.html; International Telecommunications Union, World Telecommunication Union, Market Information and Statistics (2008), available at http://www.itu.int/ITU-D/ict/statistics/ict/index.html. The inescapable conclusion that one draws from the evolution of these networked technologies is that, to the extent that NHIN realization mimics them, it is likely to take a number of years to achieve a universal and smoothly functioning NHIN using an evolutionary strategy. Taking a revolutionary approach would not only speed NHIN development but would also have the collateral, salutary benefit of attracting more users early on thereby intensifying usage. See, generally, Michal Grajek & Tobias Kretschmer, Usage and Diffusion of Cellular Telephony, 1998-2004, 27 INT’L J. IND. ORG. (2008), 238, 240.


231 Relay Health Whitepaper, Selecting a Results Distribution Service (undated), at 1 (copy on file with authors).
security of patient data, protecting at all times the confidentiality of health information. This leads to several requirements in addition to those enumerated in Section II.

A 2007 study prepared for the Office of the National Coordinator for Health Information Technology developed a set of 14 functional requirements for a NHIN to increase information accuracy and protect against fraud. Prominent among these with respect to patient privacy were such attributes as structured and coded data, transmission integrity, patient-identity proofing, and accurate linkage to claims data. The report notes that, “Because the HIPAA Privacy Rule allows for disclosure of personal health information with the individual’s signed authorization for purposes of treatment, payment, and health care operations, special consideration must be given to scenarios involving some level of access by groups other than the primary user, such as the patients themselves, visiting physicians, and payers.” Ensuring traceability of EMRs, secure messaging, and making data anonymous for use in medical research are also considerations. Because fraud continues to be a major factor in the rising cost of healthcare, a NHIN should be constructed so as to reduce fraud to include patient involvement in anti-fraud efforts. Consequently, provisions for the maintenance of data audit logs and access by auditors to deter healthcare payment fraud should be incorporated into a NHIN.

What is abundantly clear is that the success of a NHIN depends upon two frequently conflicting considerations: the public’s confidence that PHI will be well guarded against unauthorized use and disclosure and a high level of connectivity and interoperability that will allow interfaces among an entire set of health-related entities including physicians, hospitals,

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233 Id. at 4-5.
234 Id. at 5-2.
235 See, e.g., Hill, Langvardt & Rinehart, supra note 7, at 41.
clinics, pharmacies, insurance billing systems and government agencies necessary for rapid coordination of care and seamless sharing of PHI.\textsuperscript{236} This tension between interoperability and privacy of PHI must be resolved.\textsuperscript{237} One difficulty in its resolution is that consumer acceptance of e-health technology is dynamic due to the rise of healthcare consumerism and growing patient demands for greater participation in their health decision and access to their health records. As some commentators have noted, a balance between competing interests, such as that between privacy and interoperability, requires a fulcrum, but dynamism makes achieving this balance in a highly precise manner difficult.\textsuperscript{238} In light of this moving target, what is needed is a set of general guiding principles by which to assess the efficacy of alternative NHIN architectures in protecting PHI.

The World Privacy Forum, a nonpartisan, public-interest research group focused on privacy issues,\textsuperscript{239} and the Electronic Frontier Foundation, a nonprofit organization dedicated to defending citizens rights with respect to electronic information,\textsuperscript{240} have listed seven general principles for fair information practices reputed to be robust.\textsuperscript{241} The principle of openness holds that the existence of any individual patient record should be known to the patient. The principle of individual participation states that any patient should have the right to see any information or data about her contained in an electronic file. The principle of collection limitation maintains that personal data should be collected only with the knowledge and consent of the patient. According to the principle of data quality, patient data should be accurate, complete, and timely.

\textsuperscript{236} Hill, Langvardt & Massey, supra note 1, at 198.
\textsuperscript{238} Hill, Langvardt & Rinehart, supra note 7, at 41. The authors liken this tension to a contrarian paradox in which the growth in consumers’ participation in their healthcare leads to a demand for higher quality care which, in turn, leads to more information exchange and greater risk of privacy breaches.
\textsuperscript{240} Electronic Frontier Foundation, About EEF, available at http://www.eff.org/about.
\textsuperscript{241} Testimony of Pam Dixon, supra note 224, at 15-17.
The principle of finality stipulates that there must be limits to the uses and disclosures of personal data, data should be used only for the purposes it was collected, and data should not be disclosed without the consent of the patient. The principle of security states that personal data must be protected by reasonable safeguards against loss unauthorized access, destruction, or use. Finally, the principle of accountability holds that those keeping patient records should be accountable for complying for fair information practices. These principles collectively form a reasonable set of standards by which to assess the adequacy of a NHIN in safeguarding PHI. In addition, since security of PHI is to some extent a matter of economics, raising the cost of undesirable behavior through sound, comprehensive, cohesive privacy laws is a principal tool for accomplishing these ends. The two main approaches are deterrence, a legal matter, and prevention, an operational one. Given the highly personal nature of PHI and the attendant costs of security breaches, prevention should be favored over deterrence. NHIN architecture informs policy development by enabling policymakers with approaches and solutions. These considerations imply that, ceteris paribus, a NHIN architecture should be favored that is structurally optimized for balancing PHI security with operational efficiency as opposed to excessive reliance upon legal redress once inappropriate disclosures occur.

B. Evolutionary Architecture Prototypes

In order to assess the difficulties in NHIN development using an evolutionary architecture, it is useful to examine prototypes of such architectures. In 2005, DHHS awarded NHIN prototype

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243 Testimony of Pam Dixon, supra note 224, at 12.
244 Rishel, et al., supra note 52, at 4.
245 The issue of the use of PHI for medical research and public health studies underscores this preference. In achieving a balance between protection of a patient’s right to privacy versus the greater good for society, design of NHIN architecture that prevents privacy breaches by simultaneously allows data anonymization while protecting patient identity becomes a necessary complement to legal deterrence.
contracts to four consortia to develop prototypes. Among various requirements, each prototype was required to maintain security and confidentiality of PHI.\textsuperscript{246}

Accenture’s architecture involves three levels: provider, HIE and NHIN. At the provider level, multiple data extraction mechanisms convert local data into standard message formats. These messages are filtered so that only messages from consenting patients are sent outside the provider’s firewall. The advantage of this approach is that it lessens the barrier of entry to healthcare organizations by reducing, but not eliminating, the need to alter systems or add infrastructure at the lower levels. At the HIE level, record-locator services (RLS), patient-matching, and information-governance capabilities translate provider data into normalized data permitting secondary uses of the data. Data stored at HIEs could be a core set, an extended clinical set, or no clinical data. At the NHIN level, data are cross-indexed for patients and providers identifying the location of a patient’s records. The architecture has the benefit of allowing multiple national health information exchanges as opposed to a single exchange.\textsuperscript{247}

In the CSC-Connecting for Health architecture, all capabilities are contained in the facilities of sub-network organizations (SNOs) wherein the NHIN is the sum of all SNOs. The NHIN is defined as a set of standards and practices by which all participating entities abide. There are no NHIN-level services or operators. Each SNO is configured differently in terms of where within it PHI resides. Although this approach supports broad heterogeneity in SNO architecture, each SNO must support a RLS for providers’ records. Thus, the SNO need only to keep track of which systems have data for a given patient, only recording demographic data and not clinical data. Once a RLS provides record locations, records can be queried directly by requesters. This makes the SNOs somewhat less vulnerable to accidental disclosures and breaches.

\textsuperscript{246} Id. at 4.
\textsuperscript{247} Id. at 13-14.
Responsibility for filtering data is part of the data transfer between holder and requester. The architecture is built upon several principles including simplicity (because “…large IT projects are difficult with many epic failures”), patient privacy must be protected at the expense of interoperability, and, based upon these two principles, data should therefore remain at the provider level. One difficulty is that this difficult to envision how this decentralized architecture will accommodate the need for large-sample medical research and public health studies using anonymized data.

IBM’s architecture relies upon three levels: a community of entities within a HIE, a community hub which provides security and identity and document locator services, and cross-community services which are interconnections among communities requiring agreed-upon standards among the communities. Community members interact with each other directly without having their interactions routed through special systems within the hub. While reducing bottlenecks, this also requires homogeneity in conformance to standards. Clinical document repositories may be deployed within the security boundaries of member organizations or maintained in community hubs. Document location is provided by a registry that tracks clinical documents and metadata making distributed queries about patient data more efficient. Unfortunately, this also increases the danger of privacy breaches within the hubs, and also suffers the aforementioned concerns about its amenability to large-sample research.

Northrop Grumman describes its architecture as based upon a “super-peer” topology wherein not all users connect to each other as peers, but where a smaller subset at the top of a hierarchy are interconnected. These super-peers provide a minimum set of core services logically aggregated into a NHIN Gateway, services similar to those provided by HIEs. There are two

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248 Id. at 16-17.
249 Id. at 17-19.
mains sets of interfaces, Gateway peer-facing and Gateway children-facing. The former are strictly controlled through standards and certifications while the latter have interfaces that do not meet NHIN standards. Core services include patient and provider identification, data location and retrieval, data anonymization, message handling, auditing, authentication, and administrative management. Also included are permissions management (providing for patient permission preferences to be stored and maintained), and directory service (a registry of entities directly connected to each gateway).250

Although all four evolutionary prototypes were determined to have met the DHHS stipulated contractual criteria,251 our examination indicates that, because they are all designed to leverage existing, middleman HIT systems, they all suffer from the developmental drawback of effectively relying upon rollup of some RHIO-like entities, whether they are called HIEs, SNOs, community hubs, or super peers. In other words, national, universal access would be dependent upon the broad and successful development of such organizations sufficient to provide coverage everywhere in the nation as well as their eventual rollup – in all likelihood distant realities, at best. In addition, their development is expected to involve a simultaneously cyclical and stepwise approach rather than a linear, more direct approach suggestive of longer development time.252 This is not to say that the prototypes are devoid of appealing attributes with respect to guarding PHI such as message filtering, RLS that avoid single, unique patient identifiers, and data repositories. However, combined with the problem that many RHIO-type HIEs as discussed in Section II are apparently failing,253 numerous problems exist in the realization of an evolutionary NHIN, ensuring the privacy of PHI within it, and its amenability to anonymized,

250 Id. at 19-20.
251 Id. at 5.
252 Id. at 5.
large-sample research.\textsuperscript{254} With HIT development lagging in the private health sector,\textsuperscript{255} this leads inexorably to the conclusion that a change in the evolutionary strategy for NHIN development is needed.\textsuperscript{256} The following subsection proposes a revolutionary, hybrid approach that simultaneously leverages the benefits of decentralized usage and centralized data storage and control, speeds NHIN development, provides a materially higher level of security for PHI, and is amenable to large-sample research.

C. A Revolutionary, Cloud-Computing Architecture

Various proponents of a NHIN have made arguments along the following lines: “Federal policies to compel the creation of a national health IT system would reduce aggregate health care costs and improve quality, goals that cannot be obtained by in the health care marketplace [only].”\textsuperscript{257} Absent considerable federal impetus, broadly networked HIT does not diffuse swiftly,\textsuperscript{258} and essential data-sharing interoperability is being neglected thereby severely limiting its benefits.\textsuperscript{259} The current evolutionary strategy of linking RHIOs together means that a NHIN is dependent upon mostly intrastate organizations to evolve and roll up, and could have a major setback if a key RHIO were to fail.\textsuperscript{260} It is also important to recognize that while the development of a NHIN will be profoundly affected by laws involving PHI, design of an optimal

\begin{itemize}
\item \textsuperscript{254} See text accompanying notes 46-67.
\item \textsuperscript{255} Colene M. Byrne, et al., The Value from Investments in Health Information Technology at the U.S. Department of Veterans Affairs, 29 HEALTH AFFAIRS (2010), 629, 620 (noting the VA’s higher levels of HIT adoption than the private sector).
\item \textsuperscript{256} The current strategy of linking various RHIOs organizations together means that a NHIN is largely dependent upon intrastate organizations to evolve. A NHIN could have a major setback if a key RHIO were to fail. Chris Rauber, CalRHIO closes, but board to help state on IT, Jan. 8, 2010, available at: http://sanfrancisco.bizjournals.com/sanfrancisco/stories/2010/01/11/story7.html.
\item \textsuperscript{257} J.D. Kleinke, Dot-Gov: Market Failure and the Creation of a National Health Information Technology System, 24(5) HEALTH AFFAIRS, 1246, 1246 (2005).
\item \textsuperscript{258} Anthony G. Bower, Federal Investment in Health Information Technology: How to Motivate It? 25(5) HEALTH AFFAIRS, 1263, 1263 (2005).
\end{itemize}
legal framework for a NHIN is dependent upon the NHIN’s architecture because different architectures have different vulnerabilities to breaches of privacy. In this subsection we argue that the current evolutionary approach should be replaced by a revolutionary approach resulting in faster NHIN development while guarding PHI at least as well if not better than the proposed evolutionary architectures outlined in the previous subsection.

We propose a cloud-computing architecture which enables on-demand network access to a shared pool of configurable computing resources and infrastructure (e.g., networks, servers, storage, applications, and services). These resources can be rapidly provisioned and released with minimal (local) management effort or service provider interaction. What distinguishes cloud computing from other proposed architectures is using HIT as a service over a network with direct access by HCPs and other users and without the necessity of RHIOs. Applications can be accessed by users from various client devices through a thin client interface such as a web browser. The user (e.g., consumer, clinician) does not need to manage or control the underlying cloud infrastructure and software and data are stored on centralized servers.

Clouds have five key traits: on-demand self-service, broad network access, resource pooling, rapid elasticity, and measured service. Services are sold on a pay-as-you-use basis such that users can use as much or little of it as desired. These services are managed by the centralized provider providing ease of scalable access. Cloud computing capitalizes on the advantages of both centralized and decentralized computing, mitigating their respective weaknesses, and

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“...changes how we invent, develop, deploy, scale, update, maintain, and pay for applications.”

Cloud computing has several beneficial attributes that would hasten NHIN development. First and foremost, it would not be necessary to wait for the development of RHIOs onto which HCPs could attach. One prerequisite for NHIN development is supporting heterogeneity across a wide variety of users, and cloud architecture is highly amenable to authorized access because users need only a personal computer to access data. HCPs and patients could communicate with one another in a reasonably secure environment. Second, cloud computing is highly efficient and has been shown to significantly reduce IT expenditures which have proven to be a material barrier to HIT adoption, an important consideration in light of rising healthcare costs. Although young and revolutionary, cloud computing is based upon established trends that drive down the cost of service delivery with rapid deployment of applications. Cloud computing requires a much lower up-front investment in HIT software and hardware for users

265 Rishel, et al., supra note 52, at 10.
266 Carolan, et al., supra note 264, at 1.
268 Carolan, et al., supra note 264, at 1.
272 Cloud Computing, supra, note 269.
273 Recognizing the enormous potential of cloud computing to improve HIT, the Federal Health Architecture Office has sponsored a software gateway that assists federal agencies, HCPs, and HIEs to better exchange health information. The idea is to manage multiple HIEs simultaneously. See Paul McCloskey, Connect HIE Gateway to Support Cloud Services, GOVERNMENT HEALTH IT (March 26, 2010), available at http://govhealthit.com/newsitem.aspx?nid=73396. Laudable as this initiative is, it would still necessitate private sector RHIOs being rolled into the cloud in order to create a true NHIN, and this rollup, though facilitated by cloud computing, would nonetheless be much slower in contrast to our proposed cloud architecture.
inasmuch as the central services provider assumes all the capital investment risk of owning infrastructure, and users do not have to engineer for peak load limits. As a developer-centric architecture, applications can be more quickly developed and deployed, are easier to maintain providing yet another cost benefit. Smaller HCPs would not be faced with the costs associated with participating in an RHIO. Third, cloud computing offers enhanced reliability through redundancy. Central servers access backup servers in the event of equipment failures thereby ensuring fast, reliable access, an important attribute in a healthcare environment. Complexity is controlled and cloud systems more manageable than their older, monolithic counterparts. Fourth, because of the use of virtualization - which abstracts hardware in such a way that software can be deployed and redeployed without being restricted to a specific server - cloud computing is highly flexible with respect to deployment and scaling of applications. Fifth, through a process known as application refactoring in which CPU-intensive tasks are farmed out to virtual machines, the speed of delivery can be adjusted to meet user demands.

Cloud architecture begs the question of what deployment model would be used in a NHIN. Various deployment models include the following: (1) *Private cloud* in which infrastructure is operated solely for an organization and may be managed by the organization or leased from a third party and may exist on premise or off premise; (2) *Community cloud* in which infrastructure is shared by several organizations and supports a specific community that has shared concerns.

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276 Our research failed to disclose any comparative cost estimates of bottom-up versus top-down cost estimates, and cost estimates for a NHIN are in flux. In 2005 it was estimated that a NHIN would cost more than $156 billion in initial capital investment and $48 billion in annual operating costs while saving $78 to $112 billion per year by reducing the numbers of medical tests and improving administrative procedures. See Testimony of Pam Dixon, *supra* note 224, at 11-12.
(e.g., mission, security requirements, policy, and compliance considerations) and may be managed by the organizations or a third party and may exist on premise or off premise; (3) Public cloud in which infrastructure is made available to the general public or a large industry group and is owned by an organization selling cloud services; and (4) Hybrid cloud in which infrastructure is a composition of two or more clouds (private, community, or public) that remain unique entities but are bound together by standardized or proprietary technology that enables data and application portability.  

Given the nature of healthcare and the already high and growing cost burden of healthcare, we propose a hybrid public/private model involving the creation of a small number of privately owned and funded, but federally chartered and regulated, for-profit cloud provider/health data repositories that exist for the sole purpose of providing EMR storage and electronic data service to patients, HCPs, and other health-related entities. Repositories should be organized and regulated similar to utilities - shareholder-owned, funded by private capital and dividend-paying. Private ownership negates the requirement for government funding in light of the impact of healthcare on the already stressed federal budget. Private cloud configurations have been criticized, however, for the amount of control that companies providing services have over the

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282 Orszag & Ellis, supra note 271, at 1875-77.
283 There is precedent for the federal creation of utilities. The Tennessee Valley Authority (TVA) provides an example of a federally created public utility created by Congressional charter in 1933. See, 16 U.S.C. §831, et seq. Today, TVA is the largest public utility in the U.S. The U.S. Supreme Court ruled TVA to be constitutional in Ashwander v. TVA, 297 U.S. 288 (1936). Other examples include the Bonneville Power Administration, Southwestern Power Administration, Alaska Power Administration, and the Western Area Power Administration. Although all of these federally chartered utilities are public, the Congressional Budget Office (CBO) has noted that their privatization could provide the greatest improvement in their efficiency and financial performance. See CBO, Should the Federal Government Sell Electricity (Nov. 1997), available at http://www.cbo.gov/doc.cfm?index=243&type=0&sequence=1.
284 See, e.g., Cloud Computing, supra note 269 (noting that the movement to cloud computing paradigm has been analogized to the displacement of electricity generators by grids in the early 20th century and that as far back as 1960 it was envisioned that computing might someday be organized as a public utility).
information they store and monitor.\textsuperscript{286} To mitigate this concern, private cloud providers should be regulated as utilities. For example, operations should be restricted to providing only services specified in their charters and would generate revenues by charging HCPs for record access rather than healthcare consumers being charged for record maintenance.\textsuperscript{287} Corporate HCPs and other health-related entities such as health insurance companies should be prohibited from owning cloud providers’ stock thereby limiting the influence of such external entities.\textsuperscript{288} In light of the oligopolistic nature of this arrangement, charges should be determined by a central board of governors appointed by Congress overseeing the cloud providers and rate set rates periodically at common levels. Records should be stored in common format, and healthcare consumers should have the right to move their record from one cloud provider to another within a reasonable period of time at no cost to the consumer. Cloud providers would thus compete based upon service quality thereby providing a strong incentive to maintain tight security and keep HCPs’ and patients’ trust.\textsuperscript{289} Numbers of records maintained would be the primary determinant of total revenues for a given cloud provider thereby providing a powerful incentive to provide excellent service in order to acquire and retain as many records as possible.

In addition to hastening movement toward a NHIN, there are numerous advantages to centralizing PHI in a small number of regulated, private cloud providers as opposed to the

\textsuperscript{287} Access charges would be offset, at least partially, by reductions in HCPs’ overhead in that current paper record maintenance and retention, software and other records-related costs would be substantially reduced. In addition, treatment efficiencies and reductions in malpractice costs due to higher quality care and improved error detection (e.g., drug interactions) would also help offset access costs. Although it is impossible to know at this stage what the net effect would be, it seems entirely possible that the cost-saving benefits would be greater than the access costs.
\textsuperscript{288} An example of limitations of public utility ownership can be found in Public Utility Holding Company Act of 1935 (P.L. 74-333) which has withstood all attempts to broaden the ownership limits it places on public utilities in the gas and electric industries. See Public Utility Holding Company Act of 1935, Answers.com, available at http://www.answers.com/topic/public-utility-holding-company-act-of-1935.
prototype architectures. First, with respect to information flow and interoperability, the problem of HIE’s being unable to communicate with one another mentioned supra in Section II would be resolved since all communication – including that among HCPs - would be handled through the cloud providers. Second, with respect to security of EMRs, having one record as opposed to the current proliferation of records stored in smaller entities with far more limited resources for security makes PHI security much tighter. Patients would also be provided with access to their PHI and a transaction record of entities accessing it. Healthcare consumers would be far better protected against unauthorized disclosure of PHI because they would control access to a significant extent. Third, with respect to patient-centric care,290 consistent with the trend toward more and more healthcare consumers taking a growing interest in partnering with HCPs in the management of their care, patients would be able to better monitor the content of their EMRs and make potentially useful inputs such as dietary and exercise habits of which only they have knowledge. Allowing patients to assume some of the responsibility for policing the accuracy and completeness of EMR content will increase the quality of information.291 Fourth, quality of care would be greatly improved in a variety of ways. Software could automatically check for drug interactions and counter-indicated treatments.292 System prompts could aid HCPs in asking


291 See generally, James B. Conway, “Update on the IHI 5M Lives Campaign,” Harvard Patient Safety Seminar (notes on file with authors), supra note 290 (noting that “there is a tidal wave across the country moving faster than the [health] industry is capable of keeping up with” with respect to healthcare consumerism and the healthcare system must be rebuilt around patients).

292 See, e.g., David W. Bates, “Technology and Safety: Transforming the Delivery of Health Care,” Harvard Patient Safety Seminar, supra note 290, (notes on file with authors) (noting that “the single leading cause of adverse drug events is the physician not having the right information at the time of prescribing even though it is usually in the record someplace”).
the right questions of patients improving diagnoses resulting in fewer medical malpractice claims with their attendant costs. The estimated two million adverse medical events annually due to inadequate communication when patients are discharged could be greatly reduced. Concentration of records would allow medical researchers to access very large, anonymized databases which would greatly facilitate medical research by increasing subject availability and statistical test power. One estimate suggests that healthcare costs could be reduced by 50 percent through improved prevention and treatment. Fifth, HCPs’ overhead would be reduced through the elimination of redundant records in a profession where HCPs are overwhelmed with requests for data.

Would such a NHIN equally or better satisfy the seven general principles of information fairness enumerated earlier in this section than other proposed architectures? A major security vulnerability of all bottom-up NHIN prototypes is the diffusion of electronic health records among various HCPs and other health-related entities, some of which may have limited resources to mitigate this vulnerability. Although some critics might argue that data security is a

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293 See, e.g., Tejal K. Ghandi, et al., Missed and Delayed Diagnoses in the Ambulatory Setting: A Study of Malpractice Claims, 154(7) ANNALS OF INTERNAL MED. (Oct. 3, 2006), 487, 491 (noting that failure to order an appropriate diagnostic test occurred in 55 percent of the malpractice cases studied).
294 See, e.g., Donald W. Moorman, “Surgery,” Harvard Patient Safety Seminar, supra note 290 (notes on file with authors) (noting that a patient-centric healthcare model would reduce the number of medical malpractice suits by improving physician-patient communication).
295 See Harvard Patient Safety Seminar, supra note 290 (notes on file with authors).
296 Currently, many medical experiments involve relatively small numbers of subjects resulting in low test power and an inability to control for extraneous factors and discover significant causal and treatment effects. See, e.g., DIGITAL CONNECTIONS COUNCIL OF THE COMMITTEE FOR ECONOMIC DEVELOPMENT, HARNESSING OPENNESS TO TRANSFORM AMERICAN HEALTH CARE 40 (2007), available at http://www.ced.org/docs/report/report_healthcare2007dcc.pdf (discussing EMRs and the nexus between EMRs and evidence-based medicine).
297 See, e.g., Lucian L. Leape, “Progress in Patient Safety,” Harvard Patient Safety Seminar, supra note 290 (notes on file with authors) (noting that the three major causes of high healthcare cost are waste, inappropriate care, and profits).
298 Conway, supra note 291 (notes on file with authors).
299 See Costin, supra note 190; Rishel, et al., supra note 52, at 10 (noting a lack of technical and organizational competencies in some health organizations). One survey has indicated that only 39% percent of HCPs believed they were fully HIPAA compliant with compliance being lower than in earlier years. Susannah Patton, The Complying Game, CIO MAGAZINE (Oct. 15, 2006), available at http://www.cio.in/features/viewArticle/ARTICLEID=2460.
concern in cloud architecture inasmuch as the data is outside of the user’s proprietary network, others counter that securing data is key to a cloud service provider’s business and that the provider has and can devote security expertise that most users do not have (e.g., physicians office).\textsuperscript{300} Further, cloud providers have a strong incentive to maintain trust and utilize a higher level of security than cloud users.\textsuperscript{301}

One obvious selling point for cloud architecture is structuring access to records in such a way as to provide improved security against unauthorized access compared to decentralized records. In the proposed architecture, a primary safeguard would be that EMRs could be accessed only by approval of the patient except in cases of emergency during which the patient is unable to provide access authorization thus satisfying the collection limitation criterion.\textsuperscript{302} In the absence of patient authorization for blanket access by a particular HCP, access to EMRs should also be layered vertically and horizontally in such as way as to allow users only that level and type of access required.\textsuperscript{303} For example, insurance companies should be allowed access only to a top layer consisting of identity, treatment codes, and other billing-related content. In contrast, depending upon the general nature of care being provided, HCPs should have deeper access to PHI. Horizontal layering could be based upon diagnosis codes such that HCPs could only access


\textsuperscript{301} Security of Virtualization, Cloud Computing Divides IT and Security Pros, \textit{supra} note 289; P. Mell & Grance, \textit{supra} note 262.

\textsuperscript{302} Such exceptional cases would be required to be documented with reason codes by the attending HCP and would also become part of an access transaction record documenting all access to the EMR.

\textsuperscript{303} Discussion with physicians suggests that access authorization might best be accomplished at the care point of contact, and that blanket approval would likely be the norm for most patients. A patient could choose to make her entire EMR - or, alternatively, only certain parts of it - available to her HCP by entering her access code into a computer at the physician’s office and clicking on the appropriate buttons. In a similar manner, the patient might authorize her primary care physician to forward certain information to specialists (or even practitioners of complementary or alternative healthcare such as acupuncturists) to which the patient is being referred. This protocol has the advantage of allowing the patient to choose what information is made available to whom. If the patient chooses so restrictively that care would be impaired, HCPs can then explain the need for more extensive access to the patient. (Interview with Dale Treash, M.D., Feb. 19, 2010 (hereinafter “Treash Interview”) (notes on file with authors).
content relevant to a particular diagnosis.\textsuperscript{304} For example, dentists might be permitted access only to identity, billing, identify, basic health history, and dental record content. If a HCP needs content beyond that \textit{ex ante} deemed required for a particular diagnosis, then patient authorization could be required. In infrequent, non-emergency cases where a patient might be deemed incompetent or incapable of providing access and no legal guardian is available, HCPs should be required to submit a request with justification to the cloud provider to be adjudicated a medical committee associated with it.\textsuperscript{305} Such procedures would serve to help satisfy the principle of finality in limiting use and disclosure of PHI.

Analogous to consumers’ rights with respect to credit reporting agencies,\textsuperscript{306} cloud providers should be required to provide patients with a history of all transactions involving EMR access upon demand within a specified period of time thus satisfying the criterion of accountability. Patients should have the right to review their EMRs, make comments in a special space provided, and submit requests and rationales for correction of erroneous content and deletion of unneeded content satisfying the principle of openness.\textsuperscript{307} Alerts regarding such requests could be forwarded to the originating HCP for attention, and HCPs would be required to provide follow-up action within a specified timeframe. Patients should not have the right to unilaterally alter or delete content entered by an HCP or other healthcare related entity. Cloud providers should also be required to maintain IT capability redundancy to minimize and temporary non-availability of records. These steps would serve to help satisfy the principles of individual participation and

\textsuperscript{304} Diagnosis codes currently exist for insurance billing purposes. \textit{See, e.g.}, Hill, Aneiros & Hogan, \textit{supra} note 12 for a discussion of healthcare billing practices and codes.

\textsuperscript{305} This access protocol is compatible with the movement toward models of care delivery such as the Medical Home that emphasize preventive care and patient–centric care as opposed to the current reactive, HCP-centric model. \textit{See, e.g.}, Hill, Aneiros & Hogan, \textit{supra} note 12, for overviews of both the rise in healthcare consumerism and evolving patient-centric care delivery models together with their implications for the future of healthcare.


\textsuperscript{307} One question that arises is whether HCPs would be required to respond to entries made by patients into their EMRs. Imposing such an onerous burden on HCPs would be both costly and impractical. The preferable alternative is to keep the burden of informing HCPs of illness-related issues where it is today -- with the patient.
data quality. Although some might argue that a number of these benefits could be obtained in evolutionary architectures, we believe that the totality of the benefits strongly argues for cloud architecture. Indeed, some proponents argue that the principle of security is actually better met in a cloud architecture that with older-generation configurations.  

In summary, the potential of a NHIN for advancing healthcare is enormous, but, despite much discussion, its architecture has yet to be defined. We have proposed a cloud architecture that holds promise of faster NHIN development, better healthcare quality, and equal to if not better PHI security than the evolutionary prototypes and satisfies the seven principles of information fairness. The following section presents the legal arguments supporting federal law necessary to create this architecture and a complementary federal preemption of state health privacy laws.

V. Legal Arguments for an Evolutionary NHIN and Federal Privacy Law Regime

The NHIN described in this article cannot be accomplished without federal legislation and regulation. Enabling legislation would be necessary to create the cloud providers and to otherwise facilitate the NHIN’s development. The same is true of the national privacy law framework that, as outlined earlier, would be a necessary complement. In previous sections, we contend that the federal government should take the necessary steps to establish the NHIN and effectuate its development with a new privacy law regime and other NHIN-complementary laws. Here, we address this key question: Can the federal government constitutionally do these things?

310 See supra text accompanying notes 18-71, 190-256, 282-309.
The answer depends upon consideration of grants of federal power contemplated by the U.S. Constitution’s Commerce and Spending Clauses. In addition, the answer requires consideration of the limits on federal power that may be imposed by the Constitution’s Tenth Amendment. We begin with the latter, and then proceed to the federal power issues that must be addressed alongside the Tenth Amendment. We conclude with an analysis that answers “yes” to the question whether it would be constitutional for the federal government to take the legislative and regulatory actions proposed earlier.

If recent experience serves as any guide, it is a near-certainty that congressional action concerning the NHIN and necessary privacy law modifications would face a constitutional challenge. That challenge would rest on the Tenth Amendment, which provides that “[t]he powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States, respectively, or to the people.” Although the Tenth Amendment has traditionally not been a large source of litigation, its public profile has been enhanced recently. Discussion of the Tenth Amendment has intensified among critics of federal policies and actions and drawn considerable media attention.

More important yet to the Tenth Amendment’s renewed prominence has been the litigation recently instituted by the attorneys general of approximately 15 states. The plaintiffs contend

311 U.S. CONST. art. I, § 8, cl. 1, cl. 3.
312 Id. amend. X.
313 Id.
that the healthcare reform bill signed into law in March 2010\textsuperscript{316} should be struck down as a violation of the Tenth Amendment.\textsuperscript{317} Given these constitutional challenges, it seems likely that NHIN-related and privacy-related laws contemplated herein would face a Tenth Amendment-based challenge.

A Tenth Amendment-based challenge rests on the notion that the federal action was not authorized by a power granted to the federal government by the Constitution, and that the state therefore held the sole constitutional authority to decide whether to regulate, or not regulate, the relevant subject matter.\textsuperscript{318} Accordingly, Tenth Amendment arguments cannot be evaluated without simultaneous consideration of what the federal government may do under its constitutional grants of power. Important Commerce Clause and Spending Power decisions will be explored in more depth later. For now, as we begin a discussion of Tenth Amendment jurisprudence, suffice it to say that Supreme Court decisions recognizing broad Commerce Clause power for the federal government have posed substantial obstacles to Tenth Amendment-based challenges\textsuperscript{319} as have decisions establishing that Congress has extensive authority under the Spending Clause.\textsuperscript{320} Yet the breadth of federal power recognized by the Supreme Court has not foreclosed the possibility that a Tenth Amendment-based challenge may succeed under the right set of circumstances.\textsuperscript{321} The Tenth Amendment, therefore, is not a dead letter, though it does not appear to be as full of promise as its current enthusiasts may wish.\textsuperscript{322}

A. The Tenth Amendment: Leading Supreme Court Decisions

\begin{itemize}
\item \textsuperscript{316} Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (2010).
\item \textsuperscript{317} Brown, \textit{supra} note 315; Sack, \textit{supra} note 315.
\item \textsuperscript{318} See U.S. CONST. amend. X.
\item \textsuperscript{319} See cases discussed at \textit{infra} text accompanying notes 323-26, 335-46, 356-59, 374-92, 433-66.
\item \textsuperscript{320} See cases discussed at \textit{infra} text accompanying notes 361-69.
\item \textsuperscript{321} See cases discussed at \textit{infra} text accompanying notes 348-55, 393-432.
\item \textsuperscript{322} See \textit{infra} text accompanying notes 348-55, 433-82.
\end{itemize}
Turning to consideration of relevant Supreme Court decisions, most Tenth Amendment-based challenges to federal action have failed. In *United States v. Darby*,\(^{323}\) for instance, the Supreme Court held that a federal law requiring employers to abide by its wage and hour requirements did not transgress the Tenth Amendment.\(^{324}\) The Court concluded that Congress had properly enacted the wage-and-hour law pursuant to its Commerce Clause power and that, accordingly, no Tenth Amendment problem existed.\(^{325}\) Commenting on how the Tenth Amendment should be interpreted and applied, the Court noted that “[f]rom the beginning and for many years the [Tenth] [A]mendment has been construed as not depriving the national government of authority to resort to all means for the exercise of a granted power which are appropriate and plainly adapted to the permitted end.”\(^{326}\) *Fry v. United States*\(^{327}\) was to a similar effect. There, the Court held that federal wage control regulations could constitutionally be applied to employees economy-wide, including those of state and local governments.\(^{328}\) The Tenth Amendment furnished no obstacle because the federal law’s effectiveness would be significantly lessened if state and local government employees were not subject to the wage controls affecting other employees.\(^{329}\) Moreover, the Court reasoned, any intrusion on state sovereignty was minimal.\(^{330}\)

The Tenth Amendment’s stock rose, however, with the Court’s 1976 decision in *National League of Cities v. Usery*.\(^{331}\) There, the Court struck down Federal Labor Standards Act (FLSA) amendments that extended the law’s wage and hour provisions to nearly all employees of states

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\(^{323}\) 312 U.S. 100 (1941).
\(^{324}\) *Id.* at 109-11, 121-25.
\(^{325}\) *Id.* at 121-24.
\(^{326}\) *Id.* at 124.
\(^{327}\) 421 U.S. 542 (1975)
\(^{328}\) *Id.* at 543-44, 547.
\(^{329}\) *Id.* at 547-48.
\(^{330}\) *Id.*
\(^{331}\) 426 U.S. 833 (1976).
and their political subdivisions.\textsuperscript{332} Distinguishing \textit{Fry} as a case dealing with a law implemented as an emergency measure because of severe inflation that threatened the U.S. economy, the Court held that the FLSA amendments went beyond the federal government’s Commerce Clause power because they usurped states’ authority to regulate relationships with their employees in areas amounting to traditional government functions.\textsuperscript{333} The Court reasoned that matters such as fire and police protection, public health, and parks and recreation had traditionally been the regulatory domains of state and local governments, and that the amendments at issue went too far in imposing the federal government’s will regarding key decisions within the purview of the states. With Congress having exceeded the power granted under the Commerce Clause, the Tenth Amendment assumed significance.\textsuperscript{334}

\textit{National League of Cities}, however, provided only a temporary profile-enhancement to the Tenth Amendment. Nine years later, the Supreme Court overruled \textit{National League of Cities} in \textit{Garcia v. San Antonio Metropolitan Transit Authority}.\textsuperscript{335} There, a federal district court had held that a municipal transit authority was a traditional government function and that the Tenth Amendment therefore prohibited application of federal wage and overtime pay rules to the transit

\textsuperscript{332} \textit{Id.} at 836-38, 840, 851-52.
\textsuperscript{333} \textit{Id.} at 845-52, 852-53.
\textsuperscript{334} \textit{See id.} at 842-43, 851-52. The Court’s express references to the Tenth Amendment were minimal, \textit{id.} at 842-43, but much of the Court’s analysis seemed Tenth Amendment-oriented. \textit{See id.} at 845-53.
\textsuperscript{335} 426 U.S. 528 (1985). Even before \textit{Garcia}, however, the Court seemed to signal that \textit{National League of Cities} had not given the Tenth Amendment significantly enhanced status. \textit{See Hodel v. Virginia Surface Mining and Reclamation Ass’n}, 452 U.S. 264 (1981) (rejecting Tenth Amendment-based challenge to federal statute that imposed performance standards on certain mines because statute was permissible exercise of Commerce Clause power and did not interfere with traditional government function even though states regulated mines); \textit{Fed. Energy Regulatory Comm’n v. Mississippi}, 456 U.S. 742 (1982) (holding that Tenth Amendment did not invalidate federal utilities regulation law even though it overrode state law on subject states had customarily regulated, because federal law came within expansive Commerce Clause power); \textit{Equal Employment Opportunity Comm’n v. Wyoming}, 460 U.S. 226 (1983) (declining to hold, in case brought by state game and fish supervisor forced to retire, that Tenth Amendment barred application of federal Age Discrimination in Employment Act (ADEA) to state and local governments, because ADEA fell within expansive Commerce Clause power and application of ADEA did not meaningfully interfere with states’ ability to manage internal operations).
authority’s employees.\textsuperscript{336} The Supreme Court held, however, that Congress had not exceeded its Commerce Clause power and that the Tenth Amendment therefore was not violated.\textsuperscript{337} State sovereignty had not been impermissibly intruded-upon, the Court reasoned.\textsuperscript{338}

Moreover, the Court concluded in \textit{Garcia} that the traditional government functions test was unworkable as a means of reliably separating what the federal government could do under its Commerce Clause power from what was reserved to the states by the Tenth Amendment. The Court scuttled the traditional government functions test,\textsuperscript{339} overruled \textit{National League of Cities},\textsuperscript{340} and rejected the notion that a list of subject-matter limitations on federal authority should control the resolution of a Commerce Clause versus Tenth Amendment issue.\textsuperscript{341} The \textit{Garcia} approach thus places primary emphasis in the Tenth Amendment analysis on what the federal government may do under the Commerce Clause. It gives the Commerce Clause preferred status in the sense that a federal action falling within the scope of the power to regulate interstate commerce will by definition not violate the Tenth Amendment.\textsuperscript{342} It is also an approach well-grounded in the text of the Tenth Amendment which contemplates a secondary role for that amendment through its language, indicating that a power is reserved for the states or the people when it is a power not granted by the Constitution to the federal government.\textsuperscript{343}

Three years after \textit{Garcia}, in \textit{South Carolina v. Baker},\textsuperscript{344} the Court rejected a Tenth Amendment-based challenge to a federal statute that eliminated the federal income tax exemption for interest earned on state governments’ publicly issued bonds unless those bonds

\begin{footnotesize}
\begin{itemize}
\item \textsuperscript{336} 426 U.S. at 530, 535.
\item \textsuperscript{337} Id. at 536-37, 549-50, 551-56.
\item \textsuperscript{338} Id. at 549-50, 553-56.
\item \textsuperscript{339} Id. at 530-31, 538-40, 546-47.
\item \textsuperscript{340} Id. at 531.
\item \textsuperscript{341} See id. at 549-50, 551-56.
\item \textsuperscript{342} See id. at 551-56.
\item \textsuperscript{343} U.S. CONST. amend. X.
\item \textsuperscript{344} 485 U.S. 505 (1988).
\end{itemize}
\end{footnotesize}
were issued in registered form.\footnote{Id. at 507-08, 511-13, 515.} Although this law effectively required states to issue their bonds in registered form, the Court saw no Tenth Amendment problem with a Commerce Clause-based federal provision setting standards that states would have to meet if they wanted to continue engaging in a given activity.\footnote{Id. at 511-14, 515.}

Next came 1992 and 1997 decisions that broke the string of losses for parties bringing Tenth Amendment-based challenges to federal action. Parties challenging the NHIN-related and privacy-related measures proposed herein would be expected to rely heavily on those two decisions. The same is likely to be true of the state attorneys general who have sued in an effort to derail the healthcare reform law that Congress enacted in 2010.\footnote{See Brown, supra note 315; Sack, supra note 315. The new federal statute is the Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (2010).}

In the first of the two cases, \textit{New York v. United States},\footnote{505 U.S. 144 (1992).} the Court struck down part of a federal statute that created obligations to dispose of radioactive waste and provided incentives for states to engage in such disposal. The Court saw no Tenth Amendment obstacle to a monetary incentive set forth in the law, but concluded that the Tenth Amendment barred an especially harsh incentive.\footnote{Id. at 152-54, 171-74, 174-75, 186.} Under the “take title” provision, a state would face severe consequences if, by a certain deadline, it did not provide for disposal of radioactive waste generated within its borders. In such a situation, the state would have to take title to, and possession of, the waste if the generator or owner of the waste so requested, and the state would be liable for damages sustained by the generator or owner if the state did not promptly do so.\footnote{Id. at 153-54, 174-75.}

The Court viewed the “take title” provision as impermissibly setting up alternatives so coercive as to be unconstitutional. One alternative--under which the states would be forced to
accept ownership of waste and potentially be liable for delay-related damages--amounted to a federal “commandeering” of the states in order to serve federal regulatory aims. The other alternative--under which the states would have to regulate according to the direction of Congress—impermissibly forced the states to implement federal law.\textsuperscript{351} New York v. United States thus indicates that if federal law goes so far as to compel states to enact or enforce a federal regulatory program, at pain of exceedingly onerous consequences if it does not do so, the federal action may violate the Tenth Amendment.\textsuperscript{352}

Printz v. United States\textsuperscript{353} was the second of the 1990s decisions in which a Tenth Amendment-based challenge to a federal law succeeded. The federal Brady Handgun Violence Prevention Act called for the Attorney General to establish a national system for instant background checks regarding handgun buyers. Printz focused on a Brady law provision stating that until the national system was in operation, the chief law enforcement officers of local jurisdictions were required to conduct background checks and perform related tasks.\textsuperscript{354} Relying on New York v. United States, the Court held that in requiring local law enforcement officers to do these things, Congress was impermissibly compelling states to administer or enforce the federal law. Accordingly, there was a Tenth Amendment violation.\textsuperscript{355}

Reno v. Condon\textsuperscript{356} rounds out this examination of the Court’s Tenth Amendment decisions. In that 2000 case, the Court upheld a federal statute that limited states’ ability to release a

\textsuperscript{351} Id. at 174-77, 186.
\textsuperscript{352} Id. at 161, 168-69, 174-77.
\textsuperscript{353} 521 U.S. 898 (1997).
\textsuperscript{354} Id. at 902-03, 904.
\textsuperscript{355} Id. at 922-23, 926-28, 930, 933, 935. Compare id. (requiring law enforcement officers to take affirmative steps described in text created Tenth Amendment problem) with Freilich v. Upper Chesapeake Health, Inc. 313 F.3d 205 (4th Cir. 2002) (federal Health Care Quality Improvement Act did not violate Tenth Amendment in requiring healthcare providers to report certain information to state medical examining board, which was then obligated to pass information along to federal data bank, because time and effort required of state officials in order to comply with federal law were minimal and reasonable and thus fell far short of affirmative enforcement measures posing Tenth Amendment problem in Printz).
\textsuperscript{356} 528 U.S. 141 (2000).
licensed driver’s personal information without the driver’s consent.\textsuperscript{357} Rejecting the Tenth Amendment-based challenge brought by South Carolina (whose law conflicted with the federal statute), the Court viewed the federal law as one regulating the states as owners of the databases containing information about licensed drivers. The Court regarded the case as similar to \textit{South Carolina v. Baker}, in which Congress permissibly regulated the states in their conduct of an activity.\textsuperscript{358} The statute at issue in \textit{Condon} neither sought to compel the states to regulate their own citizens (the problem in \textit{New York v. United States}) nor mandated that state officials take affirmative steps to enforce federal statutes (the problem in \textit{Printz}). The Tenth Amendment thus did not operate to upset an otherwise valid federal statute.\textsuperscript{359}

As the previously discussed cases indicate, proper resolution of a Tenth Amendment-based challenge to federal action depends heavily on whether the federal government acted within the scope of one of its enumerated powers when it took the challenged action.\textsuperscript{360} For purposes of this inquiry, the powers extended to the federal government by the Constitution’s Commerce and Spending Clauses serve as the critical ones. Some of the earlier discussion of Tenth Amendment cases has shed light on the scope of those powers. We now focus more closely on them, first in a subsection that addresses the Supreme Court’s view of the spending power and then in subsections dealing with the Court’s leading Commerce Clause cases.

\textsuperscript{357} \textit{Id.} at 143-44.


\textsuperscript{359} 528 U.S. at 143, 147-48, 149-50. In so ruling, the \textit{Condon} Court agreed with the government’s contention that “the personal, identifying information . . . regulate[d] [by the federal law in question] is a ‘thing in interstate commerce,’ and that the sale or release of that information in interstate commerce is therefore a proper subject of congressional regulation.” \textit{Id.} at 148 (quoting \textit{United States v. Lopez}, 514 U.S. 549, 558-59 (1995)). As will be seen, this conclusion helps to support the constitutionality of the proposals we make in this article for federal action dealing with the NHIN and privacy considerations. \textit{See infra} note 502 & accompanying text.

\textsuperscript{360} \textit{See supra} text accompanying notes 324-30, 335-46. In a later subsection in which we assess the merit (or lack of merit) of the constitutional challenge that almost certainly would be instituted if the regulatory measures proposed herein became part of federal law, we will summarize the lessons to be learned from the Supreme Court’s Tenth Amendment decisions. \textit{See infra} text accompanying notes 468-82.
B. The Spending Clause and the Scope of Federal Power

Article I, § 8 of the Constitution provides that Congress “shall have Power to lay and collect Taxes, Duties, Imposts, and Excises, to pay the debts and provide for the common Defence and general Welfare of the United States.” This language has been held to establish a broadly-ranging federal power to spend for the general welfare of the public. Hence, the provision is often referred to as the Spending Clause.

Interpretations of the Spending Clause indicate that in exercising its power, Congress may attach conditions to the receipt of federal funds if the conditions are reasonable and related to the purpose of the grant of funds. For instance, in South Dakota v. Dole, Congress conditioned states’ receipt of federal highway funds on their adoption of 21 years of age as the legal age for consuming alcoholic beverages. Although a state’s failure to adopt that drinking age would mean the state would forfeit money it otherwise would have received, the Supreme Court held that the drinking age condition was a permissible condition rather than an unwarranted penalty.

In New York v. United States, a Tenth Amendment case discussed earlier, the Court concluded that Congress permissibly exercised its Spending Clause power by providing states with monetary incentives to dispose of low-level radioactive waste. However, the Court held that the spending power did not extend so broadly as to sustain an onerous take-title-to-waste provision that Congress sought to impose on states if they did not act promptly enough to arrange

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361 U.S. CONST. art. I, § 8, cl. 1.
365 Id. at 207, 208-09.
for waste disposal. The take-title provision intruded too deeply into state sovereignty to be seen as justified by the Spending Clause.

Absent an onerous conditions problem of the sort present in New York v. United States, the Spending Clause provides a strong basis for many federal regulatory efforts. The Spending Clause also appears to have generated less controversy than the Commerce Clause, the other major enumerated power on which we will now focus.

C. The Commerce Clause: Background and Pre-1995 Supreme Court Decisions

Article I, § 8 of the Constitution contains the Commerce Clause, which empowers Congress to “regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes.” This authority to regulate interstate commerce creates two potential issues: first, whether a given federal action is permitted by the Commerce Clause; and second, whether actions taken by a state unduly burden interstate commerce and therefore violate the Commerce Clause even in the absence of federal action in the field. Our focus here will be on the first

\* Id. at 174-77. Compare id. (take-title-to-waste provision goes beyond what Spending Clause permits and violates Tenth Amendment) with West Virginia v. U.S. Dept. of Health & Human Services, 289 F.3d 281 (4th Cir. 2002) (federal Medicaid program amendments calling for participating states to adopt regulatory measures dealing with certain issues did not violate Spending Clause and thus did not violate Tenth Amendment even though federal law said failure to adopt such measures would cause states to lose all of part of their federal Medicaid reimbursements, because potential loss of funding was permissible condition rather than improper coercion).

\* E.g., South Dakota v. Dole, 483 U.S. at 206-07, 208-09.

\* Some of the controversy associated with the Commerce Clause may stem from three Supreme Court decisions regarding it during the past decade-and-a half. Each of those decisions featured a five-justice majority and strongly worded dissents. See Gonzales v. Raich, 545 U.S. 1, 16-17 (2005); United States v. Morrison, 529 U.S. 598 (200); United States v. Lopez, 514 U.S. 549, 553 (1995). For analysis of the three decisions, see infra text accompanying notes 393-466.

\* U.S. CONST. art. I, § 8, cl. 3.

issue, which more directly relates to the constitutional challenges to be expected if the NHIN-related and privacy law-related measures proposed in this article become federal law.\(^{373}\)

The modern era of Commerce Clause jurisprudence began in 1937.\(^{374}\) That year, in *NLRB v. Jones & Laughlin Steel Corp.*,\(^{375}\) the Supreme Court upheld the National Labor Relations Act as a permissible exercise of federal power under the Commerce Clause.\(^{376}\) The Court gave a broader-than-previously recognized scope to the Commerce Clause power by ruling that Congress may regulate intrastate activities if they bear a close relationship to interstate commerce.\(^{377}\) Reasoning similarly in a 1941 case, *United States v. Darby*,\(^{378}\) the Court upheld the Fair Labor Standards Act against a Commerce Clause challenge even though the statute applied in part to intrastate activities.\(^{379}\)

Then came *Wickard v. Filburn*,\(^{380}\) a still-influential\(^{381}\) 1942 decision. There, the Court upheld regulations promulgated under a federal statute that dealt with the movement of wheat in

\(^{373}\) The question whether a state law unduly burdens commerce has given rise to a body of cases known as the dormant Commerce Clause cases. *E.g.*, Dep’t of Revenue v. Davis, 553 U.S. at 336-39. Although it could be argued that certain privacy restrictions existing under state law impermissibly burden the broad-ranging interstate markets in which healthcare issues arise, it would be highly impractical to attack the numerous state law restrictions by way of multiple lawsuits raising dormant Commerce Clause issues and then proceed with federal legislative action once the state laws have been nullified. It would make more sense to enact the federal legislation, prevail on the to-be-expected constitutional challenge by demonstrating that the Commerce Clause authorizes the federal action, and rely on the preemptive effect of federal law in the event that state laws conflict with it.

\(^{374}\) United States v. Morrison, 529 U.S. 598, 607-08 (2000); *Lopez*, 514 U.S. at 55-56. Previously, many of the Supreme Court’s decisions had focused on dormant Commerce Clause issues (i.e., on whether state laws impermissibly discriminated against interstate commerce). *Id.* at 553. Some early decisions upheld federal regulatory action that clearly and directly addressed matters of interstate commerce. *E.g.*, Shreveport Rate Cases, 234 U.S. 342 (1914) (regarding railroad rates order of Interstate Commerce Commission). Other decisions, however, ascribed a narrow scope to the Commerce Clause power when Congress sought to exercise it as to intrastate matters arguably affecting interstate commerce. *E.g.*, A.L.A. Schechter Poultry Corp. v. United States, 295 U.S. 495 (1935) (holding that activities indirectly affecting interstate commerce were outside reach of Congress under Commerce Clause.

\(^{375}\) 301 U.S. 1 (1937).

\(^{376}\) *Id.* at 36-38.

\(^{377}\) *Id.* at 37.

\(^{378}\) 312 U.S. 100.

\(^{379}\) *Id.* at 118.

\(^{380}\) 317 U.S. 111 (1942).

\(^{381}\) The Court relied heavily on *Wickard* in Gonzales v. Raich, 545 U.S. 1, 17-20 (2005), a leading Commerce Clause decision that will be extensively addressed later. See *infra* text accompanying notes 433-66.
interstate commerce. To guard against the low prices that would likely result if the market included surplus amounts of wheat, the regulations allotted farmers certain numbers of acres that they could devote to wheat. The regulations allotted Filburn 11.1 acres for wheat, but he sowed 23 acres with the intent of consuming the excess on his farm rather than selling it.

Filburn challenged the federal regulations’ application to his excess wheat production, on the theory that the wheat to be consumed on his farm rather than sold was purely intrastate activity that the federal government could not reach under the Commerce Clause. The Court disagreed, holding that the federal statute and regulations were constitutional even in their application to Filburn and his excess wheat crop. The Court held that the Commerce Clause permits Congress to regulate purely intrastate activity that is not itself commercial, if the failure to regulate that activity would substantially affect the interstate market and undermine the effective regulation thereof. Although Filburn’s activity, considered by itself, would not substantially affect the interstate market, Congress could rationally believe that the impact on the interstate market would indeed be significant if all farmers’ home-consumed wheat fell outside the federal regulations.

After Wickard v. Filburn, the Court’s decisions continued to ascribe a broad scope to the federal power to regular interstate commerce. The Court consistently concluded that a rational basis existed for congressional determinations that activities warranted federal regulation because they either were part of interstate commerce or substantially affected it. For instance,

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382 317 U.S. at 115.
383 Id. at 116-18.
384 Id. at 127-28.
385 Id. at 128.
386 Id. at 127,127-28.
the Court upheld federal measures that regulated intrastate coal mining,\(^{388}\) intrastate credit transactions involving extortion,\(^{389}\) restaurants whose supplies came from out of state,\(^{390}\) and hotels whose guests came from various states.\(^{391}\) Until a key decision in 1995, limits on the breadth of the federal power to regulate interstate commerce had not disappeared but were becoming less apparent.\(^{392}\) We now turn to that decision and another that followed it five years later.

**D. The Commerce Clause: Lopez and Morrison**

*United States v. Lopez*\(^ {393}\) presented the Court with a Commerce Clause-based challenge to the Gun-Free School Zones Act, a measure that federally criminalized the knowing possession of a firearm within 1000 feet of a school. In an opinion authored by Chief Justice Rehnquist and joined by Justices O’Connor, Scalia, Kennedy, and Thomas, the Court held that the statute went beyond the expansive power extended to Congress by the Commerce Clause.\(^ {394}\)

The Chief Justice’s majority opinion characterized the *Jones & Laughlin Steel*, *Darby*, and *Wickard* decisions discussed above as having “ushered in an era of Commerce Clause jurisprudence that greatly expanded the previously defined authority of Congress under that Clause.”\(^ {395}\) In addition, the Chief Justice observed that “the doctrinal change [brought about by those decisions] reflected a view that earlier Commerce Clause cases artificially had constrained

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\(^{388}\) *Hodel*, 452 U.S. at 276-80, 281.\(^ {388}\)

\(^{389}\) *Perez*, 402 U.S. at 155-56.\(^ {389}\)

\(^{390}\) *McClung*, 379 U.S. at 299-301.\(^ {390}\)

\(^{391}\) *Heart of Atlanta*, 379 U.S. at 252-53, 258.\(^ {391}\)

\(^{392}\) See *United States v. Lopez*, 514 U.S. 549, 567 (1995) (observing that some of the Court’s Commerce Clause decisions may seem to have taken “long steps down [the] road” toward effectively establishing the Commerce Clause as a federal police power, but that the decisions had not really gone that far); *United States v. Morrison*, 529 U.S. 598, 608 (2000) (noting the “modern, expansive interpretation” of the Commerce Clause).\(^ {392}\)

\(^{393}\) 514 U.S. 549 (1995).\(^ {393}\)

\(^{394}\) *Id.* at 551.\(^ {394}\)

\(^{395}\) *Id.* at 556.\(^ {395}\)
the authority of Congress to regulate interstate commerce.”\textsuperscript{396} The Court reasoned, however, that those decisions and later ones identifying a rational basis for Commerce Clause-based regulatory action had not operated to remove all meaningful limits on how far the federal government could go under the Commerce Clause.\textsuperscript{397}

Leading up to its determination that Congress had exceeded its power to regulate interstate commerce, the Court noted that previous decisions had identified three categories that may constitutionally be subjected to federal regulation under the interstate commerce power: first, the “channels” of interstate commerce; second, the “instrumentalities” of interstate commerce and “persons or things in interstate commerce;”\textsuperscript{398} and third, activities that “substantially affect” interstate commerce even if they are intrastate in nature.\textsuperscript{399}

The \textit{Lopez} Court regarded the third category as the only one even arguably relevant to whether the Commerce Clause permitted enactment of the Gun-Free School Zones Act.\textsuperscript{400} Chief Justice Rehnquist acknowledged that under the Court’s precedents, “the pattern is clear[:] Where economic activity substantially affects interstate commerce, legislation regulating that activity will be sustained.”\textsuperscript{401} The activity causing those substantial effects may be intrastate in nature, the Court observed.\textsuperscript{402} After referring to \textit{Wickard} as “perhaps the most far reaching example of Commerce Clause authority over intrastate activity,”\textsuperscript{403} the Court added that \textit{Wickard} “involved economic activity in a way that the possession of a gun in a school zone does not.”\textsuperscript{404} The key problem with the school zone gun law was that “by its terms [it] has nothing to do with

\textsuperscript{396} \textit{Id.}
\textsuperscript{397} \textit{Id.} at 556-57.
\textsuperscript{398} \textit{Id.} at 558. This basis of regulatory activity may be employed, the Court noted, even as to intrastate activities that pose a threat to interstate commerce and give rise to a need for federal action. \textit{Id.}
\textsuperscript{399} \textit{Id.} at 558-59.
\textsuperscript{400} \textit{Id.} at 559.
\textsuperscript{401} \textit{Id.} at 560.
\textsuperscript{402} \textit{Id.} at 559-60.
\textsuperscript{403} \textit{Id.} at 560.
\textsuperscript{404} \textit{Id.}
‘commerce’ or any sort of economic enterprise, however broadly one might define those terms.” The activity the statute reached was not “an essential part of a larger regulation of economic activity, in which the regulatory scheme could be undercut unless the intrastate activity were regulated.” Therefore, the Court concluded that the statute at issue did not fall within the third category of matters or activities Congress may regulate under the Commerce Clause.

The government argued in *Lopez* that possession of a firearm in a school zone may lead to an increase in violent crime. Such an increase could affect the national economy, the government maintained, because it would produce costs that would be spread across society through insurance and other mechanisms, and because persons would become less willing to travel to areas that acquired a reputation for being unsafe. The Court noted that if such arguments were accepted, they would justify broad federal intrusions into the realms of education and family law--regulatory areas customarily left mainly to the states. Chief Justice Rehnquist concluded the majority opinion by stating that to give credence to the government’s arguments, the Court “would have to pile inference upon inference” in a manner that would “convert congressional authority under the Commerce Clause to a general police power of the sort retained by the States.” Although the Court acknowledged that “some of our prior steps have taken long steps

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405 *Id.* at 561.
406 *Id.*
407 *Id.* See *id.* at 567-68. In addition, the Court noted that the statute contained no jurisdictional element making an explicit tie to interstate commerce, such as a requirement that the possessed firearm have been transported or received in interstate commerce. *Id.* at 561-62. Moreover, the Court observed that even though congressional findings regarding a supposed connection with interstate commerce were not necessary in order for a statute to be sustained against a Commerce Clause-based attack, the absence of such findings in the statute contributed to the Court’s inability to ascertain a sufficient connection with interstate commerce. *Id.* at 562-63. The Court also noted that the states have robust bodies of criminal law applicable to the matters the federal government sought to reach in this instance, but the Court did not base its holding on that point. *See id.* at 561 n.3, 564, 567.
408 *Id.* at 563-64.
409 *Id.* at 565-66.
410 *Id.* at 567.
411 *Id.* This statement echoed an earlier observation in *Lopez* that the Constitution “withhold[s] from Congress a plenary police power that would authorize enactment of every type of legislation.” *Id.* at 566.
down that road, giving great deference to congressional action,” sustaining the Gun-Free School Zones Act would require the Court to extend that deference too far.\footnote{Id. at 567. Justice Kennedy joined the majority opinion in \textit{Lopez} but added a concurrence in which he observed that because Commerce Clause jurisprudence “counsels great restraint before the Court determines that the Clause is insufficient to support an exercise of the national power,” he experienced “some pause about today’s decision.” \textit{Id.} at 568 (Kennedy, J., concurring). He therefore wrote separately to emphasize \textit{Lopez}’s “necessary though limited holding.” \textit{Id.} Justice Kennedy observed that \textit{Jones & Laughlin Steel}, \textit{Darby}, and \textit{Wickard}, as well as the post-\textit{Wickard} decisions referred to earlier, continue to fall “within the fair ambit of the Court’s practical conception of commercial regulation and are not called in question by our decision today.” \textit{Id.} at 573-74. The problem in \textit{Lopez}, Justice Kennedy noted, was that Congress sought to regulate “an activity beyond the realm of commerce in the ordinary and usual sense of that term,” \textit{Id.} at 583, and sought to do so regarding a subject that the states seemed perfectly capable of addressing without disrupting supposed federal aims. \textit{Id.} at 581-82. As will be seen, Justice Kennedy may prove to be an especially important justice if the Court hears a challenge to the legislative and regulatory proposals set forth herein or to the 2010 healthcare reform law. \textit{See infra} note 528; \textit{infra} text accompanying notes 550-53, 564.}

After \textit{Lopez}’s reminder that there are limits to the Commerce Clause power, \textit{United States v. Morrison}\footnote{529 U.S. 598 (2000).} reinforced the message. In that 2000 decision, the Court struck down a federal Violence Against Women Act provision that provided a federal civil remedy for victims of gender-motivated violence.\footnote{Id. at 601-02, 627.} As in \textit{Lopez}, Chief Justice Rehnquist authored the majority opinion, with the same group of Justices from the \textit{Lopez} majority (Justices O’Connor, Scalia, Kennedy, and Thomas) joining him again to form the \textit{Morrison} majority.\footnote{Id. at 600.}

The Court began the analysis in \textit{Morrison} by observing that “[d]ue respect for the decisions of a coordinate branch of government demands that we invalidate a congressional enactment only upon a plain showing that Congress has exceeded its constitutional bounds.”\footnote{Id. at 607.} Such enactments may carry a “presumption of constitutionality,”\footnote{Id.} but the presumption is not irrebuttable even though decisions from 1937 on have extended Congress “considerably greater latitude in regulating conduct and transactions under the Commerce Clause than our previous case law permitted.”\footnote{Id. at 608.} The Court stressed a key message from \textit{Lopez}: that “even under our
modern, expansive interpretation of the Commerce Clause, Congress’ regulatory authority is not without bounds.”

The *Morrison* majority sought to determine whether the Violence Against Women Act provision at issue could be seen as regulating an activity that substantially affects interstate commerce.\(^{420}\) Returning to *Lopez*, the Court stated that “the noneconomic, criminal nature of the conduct at issue was central to our decision” to strike down the Gun-Free School Zones Act.\(^{421}\) The court also noted that “*Lopez*’s review of Commerce Clause case law demonstrates that . . . where we have sustained federal regulation of intrastate activity based upon the activity’s substantial effects on interstate commerce, the activity in question has been some sort of economic endeavor.”\(^{422}\) The activities targeted in the statute at issue in *Morrison*—gender-motivated crimes of violence—“are not, in any sense of the phrase, economic activity.”\(^{423}\)

Moreover, as with the statute in *Lopez*, the civil remedy provision challenged in *Morrison* contained no jurisdictional element specifically tying it to interstate commerce.\(^{424}\) The Violence Against Women Act did contain express findings regarding a supposed link with interstate commerce (unlike the statute at issue in *Lopez*).\(^{425}\) The Court, however, placed no value on the findings because they asserted a chain-of-causation theory in which gender-motivated violence would make people less willing to travel or work on an interstate basis or to engage in interstate business, would lead to economic costs, and would diminish national productivity. The Court emphasized that reasoning reflecting such an attenuated connection with interstate commerce

\(^{419}\) Id.
\(^{420}\) Id. at 609. Activities that substantially affect interstate commerce constitute the third subject matter category that Congress may regulate under the Commerce Clause. *Id.*; *Lopez*, 514 U.S. at 558-59. The other two categories were not relevant in *Morrison*. 529 U.S. at 609.
\(^{421}\) Id. at 610.
\(^{422}\) Id. at 611.
\(^{423}\) Id. at 613.
\(^{424}\) Id. See id. n.5.
\(^{425}\) Id. at 614. *See Lopez*, 514 U.S. at 562-63.
had been rejected in *Lopez*. According to the Court, giving credence to such reasoning could lead to sweeping federal regulation of crime and of such areas as family law, concerning which the states have customarily taken the lead role.

Concern about possible use of the Commerce Clause “to completely obliterate the Constitution’s distinction between national and local authority” clearly was on the mind of the *Morrison* majority, as it had been in *Lopez*. In “reject[ing] the argument that Congress may regulate noneconomic, violent criminal conduct on the basis of that conduct’s aggregate effect on interstate commerce,” the Court sought to maintain the Constitution’s “distinction between what is truly national and what is truly local.”

As noted *infra*, the brakes put on Commerce Clause jurisprudence by *Lopez* and *Morrison* make those decisions key ones on which challengers of the federal action proposed herein are likely to rely. But those challengers would have to get around the effects of the Court’s next Commerce Clause decision, which we now examine.

**E. The Commerce Clause: *Gonzales v. Raich***

*Gonzales v. Raich* presented the Court with a challenge to the federal Controlled Substances Act (CSA), which, among its many provisions, classified marijuana as an illegal drug. California, however, had enacted a statute allowing marijuana use for medicinal purposes

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427 *Morrison*, 529 U.S. at 615-16.
428 *Id.* at 615.
429 See *id.* at 615-19; *Lopez*, 514 U.S. at 563-66, 567-68.
430 *Id.* at 617.
431 *Id.* at 617-18. The Court added that “[t]he regulation and punishment of intrastate violence that is not directed at the instrumentalities, channels, or goods involved in interstate commerce has always been the province of the States.” *Id.* at 618. According to the Court, there was “no better example of the police power, which the Founders denied the National Government and reposed in the States, than the suppression of violent crime and vindication of its victims.” *Id.*
432 See *infra* text accompanying notes 496-97, 542-43. The same is true of those challenging the Patient Protection and Affordable Care Act, enacted by Congress in 2010. Pub. L. No. 111-148 (2010).
If a physician prescribed it.\textsuperscript{434} Two California residents using marijuana for medicinal purposes under the state law sought legal relief when federal drug agents confiscated and destroyed the marijuana one of the plaintiffs had been growing for her medicinal use. Because of the plaintiffs’ concern that federal authorities would not respect the California statute as an obstacle to enforcement of the federal law, the plaintiffs sought a declaration that enforcing the CSA against them would violate the Commerce Clause and the Tenth Amendment.\textsuperscript{435}

Of the five justices in the majority in both \textit{Lopez} and \textit{Morrison}, only one--Justice Kennedy--was in the \textit{Raich} majority.\textsuperscript{436} This time, Justice Kennedy joined the four justices who had dissented in \textit{Lopez} and \textit{Morrison} (Justices Stevens, Souter, Ginsburg, and Breyer) to form a majority in holding that the Commerce Clause permitted enforcement of the CSA against the plaintiffs and similarly situated California residents.\textsuperscript{437} Although five justices made up the majority, \textit{Raich} was not a 5-to-4 decision. Rather than joining Chief Justice Rehnquist and Justices O’Connor and Thomas in dissent, Justice Scalia concurred in the judgment.\textsuperscript{438}

Early in the \textit{Raich} majority opinion, Justice Stevens reminded readers that the relevant question was not whether it was wise to enforce the CSA against California users of marijuana for medicinal purposes. Rather, the question was “whether Congress’ power to regulate interstate markets for medicinal substances encompasses the portions of those markets that are supplied with drugs produced and consumed locally.”\textsuperscript{439} Answering that question affirmatively, the Court pointed to “[w]ell-settled law” as indicating that the CSA “is a valid exercise of federal power, even as applied to the troubling facts of this case.”\textsuperscript{440}

\textsuperscript{434} \textit{Id.} at 5-7.
\textsuperscript{435} \textit{Id.} at 6-8.
\textsuperscript{436} \textit{Id.} at 4.
\textsuperscript{437} \textit{Id.} See \textit{supra} text accompanying notes 394, 415.
\textsuperscript{438} 545 U.S. at 33-42 (Scalia, J., concurring in the judgment).
\textsuperscript{439} \textit{Id.} at 9 (majority opinion).
\textsuperscript{440} \textit{Id.}
The Raich majority saw “striking” similarities between the case at hand and Wickard v. Filburn. Both cases involved intrastate, home consumption of a commodity for home consumption. Both cases involved federal efforts to regulate interstate markets for that commodity, though in Wickard the federal objective was to keep wheat prices from going too low and in Raich the federal aim was to suppress the sale of prohibited drugs. In each case, the relevant intrastate activities may not have been commercial themselves, but they substantially affected interstate commerce. With Wickard having held that the Commerce Clause permitted the federal government to regulate the intrastate growth and consumption of wheat at issue there, the Raich majority had little trouble concluding that Congress had a rational basis for determining that there would be a “gaping hole” in the CSA’s regulatory scheme if the intrastate production and use of marijuana were exempted from the federal law’s operation. Accordingly, the Court reasoned, the CSA and full enforcement thereof fell comfortably within the third category of regulatory action permitted by the Commerce Clause. Reaching the intrastate activities affected in Raich was “well within [congressional] authority to ‘make all Laws which shall be necessary and proper’” to exercise its Article I, § 8 power to regulate interstate commerce.

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441 Id. at 18.
442 Id. at 18-19.
443 Id. at 19.
444 Id. at 22. See id. at 20-21. Further emphasizing the parallels, the Court noted that in Wickard, it was reasonable for Congress to conclude that rising wheat prices could draw wheat originally meant for home consumption into the market—thus potentially leading to the over-supply and lowered prices that Congress sought to avoid. Hence, such wheat needed to be covered by the federal regulatory scheme. Id. at 19-20. Similarly, the Court noted that in Raich, Congress could rationally assume that high demand for marijuana could lead to a situation in which marijuana originally meant for a medicinal use might find its way to the general market Congress wanted to suppress or eradicate. Marijuana meant for medicinal use therefore had to be included within the CSA’s sweep. Id. at 19, 21-22.
445 Id. at 22, 26-27, 32-33.
446 Id. at 22. Including the reference to the Necessary and Proper Clause may have been a way of bringing Justice Scalia on board for the case’s outcome, even though Justice Scalia did not join the majority opinion. See id. at 33 (Scalia, J., concurring in the judgment). The same might be said of the Court’s earlier statement that the question presented in Raich was “whether the power vested in Congress by Article I, § 8 . . . ‘to make all Laws which shall be necessary and proper for carrying into Execution’ its authority to ‘regulate Commerce with foreign Nations, and
Predictably, the plaintiffs in *Raich* rested their challenge primarily on *Lopez* and *Morrison*. The Court emphatically rejected this attempt, stating that “[i]n their myopic focus, [the plaintiffs] overlook the larger context of modern-era Commerce Clause jurisprudence preserved by those cases.” In addition, the Court stressed that “even in the narrow prism of [the plaintiffs’] creation, they read those cases far too broadly.” *Lopez*, the *Raich* majority noted, dealt with a short, single-subject statute that “did not regulate any economic activity” and offered no reasonable link to current or future economic activity. Similarly, the federal law at issue in *Morrison* neither dealt with an economic activity nor presented a sufficient connection with interstate commerce. The CSA, in contrast, regulated activities that are “quintessentially economic,” including the “production, distribution, and consumption of commodities for which there is an established, and lucrative, interstate market.” The regulation of marijuana produced and consumed on an intrastate basis was an integral component of the broad federal scheme. Accordingly, the Court emphasized that “*Lopez* casts no doubt on the validity” of the CSA’s provisions. Shortly after that statement, the Court used nearly identical language in stressing that “*Morrison* casts no doubt on [the CSA’s] constitutionality.”

In addition, the Court pointed out a further flaw in the plaintiff’s contention that the California law should operate to carve out an exemption from the CSA. That flaw was the
failure to appreciate the role of federal supremacy.\textsuperscript{456} The Constitution’s Supremacy Clause provides that federal law controls when federal and state law conflict.\textsuperscript{457} The Court regarded it as “beyond peradventure that federal power over commerce is superior to that of the States to provide for the welfare or necessities of their inhabitants, however legitimate or dire those necessities may be.”\textsuperscript{458}

Justice Scalia provided an interesting and potentially important concurrence in the judgment in \textit{Raich}.\textsuperscript{459} He labeled the first two in the list of categories that Congress may regulate under the Commerce Clause (the channels of interstate commerce; and the instrumentalities of, and persons or things in, interstate commerce) as “self-evident, since they are the ingredients of interstate commerce itself.”\textsuperscript{460} Justice Scalia then went on to explain his view that the third category--activities that substantially affect interstate commerce--“are not themselves part of interstate commerce, and thus the power to regulate them cannot come from the Commerce Clause alone.”\textsuperscript{461} Instead, the Necessary and Proper Clause provides Congress its “regulatory authority over intrastate activities that are not themselves part of interstate commerce (including activities that have a substantial effect on interstate commerce).”\textsuperscript{462} He went on to note that in an appropriate case, the Necessary and Proper Clause would justify federal regulation of “intrastate activities that do not themselves substantially affect interstate commerce” if such regulation were necessary to make an instance of interstate commerce regulation effective.\textsuperscript{463}

In addition, Justice Scalia explained how various Commerce Clause precedents upholding federal regulatory actions were justified from the perspective of the Necessary and Proper

\begin{footnotes}
\item[456] Id. at 29-30.
\item[457] U.S. CONST. art. VI.
\item[458] 545 U.S. at 29 (citations and internal quotation marks omitted).
\item[459] Id. at 33 (Scalia, J., concurring in the judgment).
\item[460] Id. at 34.
\item[461] Id.
\item[462] Id.
\item[463] Id. at 35.
\end{footnotes}
Clause. The activities the federal government attempted to reach in *Lopez* and *Morrison* were different, however. They could not be sustained under the Necessary and Proper Clause because they were not connected in any meaningful sense with a true interstate market that the federal government sought to regulate. No such problem existed in *Raich*, Justice Scalia noted. He regarded the intrastate activity at issue there as one that Congress, in regulating an obvious interstate commerce in a banned substance, could logically reach through the Necessary and Proper Clause.

F. Putting It Together: No Constitutional Obstacle to the Proposed Federal Actions

As noted earlier, there would almost certainly be a constitutional challenge if our proposals for NHIN-related and privacy law-related measures became federal law. To assess the merit, or lack of merit, of such a challenge, one must take proper account of the Tenth Amendment, Spending Clause, and Commerce Clause decisions discussed above. We begin that task by identifying key lessons that the previously summarized Tenth Amendment decisions collectively teach us, and by applying those lessons to the proposals advanced herein.

_Tenth Amendment Lessons and Their Application_

Six important and interrelated lessons stem from the Supreme Court’s Tenth Amendment decisions during the past 70 years. First, proper resolution of a Tenth Amendment-based challenge to a federal law depends to a great extent on whether Congress acted within the scope

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464 See *id.* at 35-39.
465 *Id.* at 38-39.
466 *Id.* at 39-42.
467 Some of our later comments will also apply to the ongoing constitutional challenge to the recently enacted Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (2010). However, we make no attempt here to provide a detailed discussion of that law’s provisions.
468 Discussion of those decisions appears at *supra* text accompanying notes 323-60.
of an enumerated power in enacting the law.  

Second, the wide berths granted to the federal government to regulate under the Commerce and Spending Clauses make it an uphill battle for those bringing Tenth Amendment-based challenges to succeed. Third, the demise of the traditional government functions approach means that there is no list of designated regulatory areas exclusively reserved for the states pursuant to the Tenth Amendment (i.e., no list of areas amounting to exceptions to the federal government’s otherwise broad-ranging ability to regulate under the Commerce and Spending Clauses).

Fourth, there is no Tenth Amendment problem when federal law resulting from a constitutionally granted power preempts state law and/or requires states to abide by the federal law (subject to the fifth and sixth lessons identified below). Tenth Amendment scrutiny is not warranted simply because federal law displaces a state law that the state likes better or because the federal law rests on policy determinations with which the state disagrees. Fifth, the federal government will not create Tenth Amendment problems by nudging the states in a direction it wants them to go, assuming the incentives offered do not involve such onerous punishments to declining states that there is obvious coercion or “commandeering” of the sort identified in the immediately following lesson.

Sixth, the Commerce Clause does not authorize--and the Tenth Amendment will not permit--federal action that commandeers the states by requiring that they enact a particular regulatory program with regard to individuals or businesses within their borders, or by mandating that state

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470 See cases cited supra note 469.


or local officials take substantial affirmative steps to enforce federal requirements. For purposes of this sixth lesson, there is a distinction between requiring the state to abide by federal law the state may not be happy about (not a Tenth Amendment problem) and requiring the state to engage in affirmative measures to bring a federal program into operation and keep it going (potentially a Tenth Amendment problem).  

How should the Tenth Amendment lessons be applied to the NHIN-related and privacy law-related measures that we have proposed for enactment by Congress? The first two lessons emphasize the critical role that proper action by Congress under an enumerated power plays in the Tenth Amendment analysis. Shortly, we will provide a more detailed application of Spending Clause and Commerce Clause principles to our proposals for federal action. For now, it should suffice to say that for purposes of the first two lessons, those bringing a Tenth Amendment-based challenge to federal law regarding our proposals would not find comfort in that amendment because the federal action would fit comfortably within what the Spending Clause and Commerce Clause allow.

The third lesson from the Tenth Amendment cases also would operate against the challengers. Although matters related to health and privacy have been the subject of much state law over the years, the federal government has also played a key role regarding such matters (as later discussion will note more fully). In any event, there is no sound legal support for the proposition that health and privacy are regulatory domains exclusively reserved for the states.

Application of the fourth lesson from the Tenth Amendment cases would also work against those challenging the federal statutes and regulations that would make our proposals a reality.

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474 See cases cited supra note 473.
475 See supra text accompanying notes 469-70.
476 See infra text accompanying notes 483-93, 494-547.
477 See infra text accompanying notes 505-08; infra note 542.
478 See infra text accompanying notes 505-08.
Fear of changing the status quo might make such challenges more likely to be filed, even though such fear of course is not a valid basis for a meritorious challenge. An example may lie in the Tenth Amendment-based challenge recently instituted by state attorneys general to the broad-ranging healthcare reform law enacted by Congress in 2010. It does not seem unreasonable to suspect that dislike of the new federal law--and perhaps political preferences as well--may have influenced the decisions to file the case or join it as an additional plaintiff. But the fundamental doctrine of federal supremacy means that properly enacted federal law becomes the law of the land regardless of whether a state would prefer a different set of rules, and may preempt state law when the two conflict.

Finally, the fifth and sixth lessons from the Tenth Amendment cases should not pose obstacles to federal statutes and regulations necessary to effectuate our proposals. To the extent that federal inducements to state actions might be seen as desirable portions of a new federal regulatory scheme, such inducements presumably would fall within the broad federal latitude to attach conditions to federal funding and would not amount to improper coercion or to commandeering the states. Requiring the states and their citizens to abide by federal law--which is all that would be done by the federal action we contemplate--is not improperly coercive. Instead, it is a necessary corollary of the constitutional principle of federal supremacy. Nor does it amount to commandeering of the sort about which the Court expressed concern in the New York v. United States and Printz decisions discussed earlier. Our proposals for federal legislative and regulatory action would neither compel the states to enact a particular regulatory regime (the problem in New York v. United States) nor mandate that state or local government

479 See Brown, supra note 315; Sack, supra note 315.
480 U.S. CONST. art. VI. See, e.g., Gonzales v. Raich, 545 U.S. 1, 29-30 (2005).
481 E.g., Raich, 545 U.S. at 29-30; Reno v. Condon, 528 U.S. 141, 147-50 (2000).
officials assume critical enforcement roles regarding the federal scheme (the problem in
\textit{Printz}).\footnote{For discussion of those cases, see \textit{supra} text accompanying notes 348-55.}

\textbf{The Spending Clause’s Role}

With a key Tenth Amendment question being whether the challenged congressional action was a valid exercise of an enumerated power granted by the Constitution,\footnote{E.g., \textit{Condon}, 528 U.S. at 148-49.} we now consider the role that the Spending Clause may play as to the federal action contemplated by our proposals. The cases discussed earlier establish that Congress has broad power under the Spending Clause to use federal funds in order to advance the general welfare. Congressional action remains permissible even if the federal government attaches conditions to the federal funding. Those conditions cannot go so far as to compel a particular action by a state government or raise the commandeering problem noted above.\footnote{E.g., \textit{New York v. United States}, 505 U.S. 144, 167, 174-77 (1992); \textit{South Dakota v. Dole}, 483 U.S. 203, 206-09 (1987).} But as \textit{South Dakota v. Dole}\footnote{483 U.S. 203 (1987).} indicates, the federal government is given a long leash in nudging desired behavior through attaching conditions to funding.\footnote{Id. at 206-09.} Accordingly, courts are unlikely to conclude that there was outright coercion by the federal government in exercising its Spending Clause power.\footnote{See id. at 206-09.} Such should be the case concerning the federal action contemplated by our proposals.\footnote{The same presumably would be true of the Patient Protection and Affordable Care Act, which Congress enacted in 2010. Pub. L. No. 111-148 (2010). However, one of the provisions to the state attorneys general challenging that law have objected is the requirement that all individuals have health insurance in force or pay a penalty for the failure to have it. Those objecting to this provision have characterized it as an unprecedented mandate that individuals make a purchase from a private party (an insurance company). \textit{See Room for Debate: Is the Health Care Law Unconstitutional?}, N.Y. TIMES, March 28, 2010, http://roomfordebate.blogs.nytimes.com/2010/03/28/is-the-health-law-unconstitutional/? The penalty provision, however, may make the supposed mandate effectively a tax imposed on those who do not have health insurance in force. To the extent that the provision amounts to the imposition of a tax, Congress could be acting within its Article I, \S 8 authority to “lay and collect Taxes . . . and provide for the General Welfare of the United States.” U.S. CONST. art. I, \S 8, cl. 1. (This is the same provision referred to as the “Spending Clause” in this article and in cases construing that constitutional provision.) \textit{See Room}}
What about the Spending Clause provision requiring that congressional allocations of federal funds must be for the “general Welfare of the United States”? It is hard to imagine a more appropriate general welfare concern than healthcare, the subject of our proposals and the federal action that would effectuate them. If the general welfare test is applied in regard to effects on society and on our economy, the test is easily passed. Healthcare and its many tentacles occupy a very substantial segment of our economy. Appropriately managing that multi-faceted segment, from not only a cost standpoint but also other standpoints such as quality, is of considerable importance to society and to the government itself. If the general welfare test is applied in regard to effects on individual persons, it again is easily passed. Access to high-quality healthcare at, one hopes, a reasonable cost is a vital concern for huge numbers of persons.

We therefore conclude that the Spending Clause furnishes ample authority for the federal action that would be necessary to bring our proposals into being, insofar as that federal action directly contemplates expenditures of federal funds. The same is true for much of the broader Patient Protection and Affordable Care Act, enacted by Congress in 2010 (and undergoing a constitutional challenge from a minority of state attorneys general). Although the Commerce Clause seems to have a higher profile than the Spending Clause—perhaps because of widely publicized Commerce Clause decisions of the Supreme Court—the Spending Clause should not go underappreciated as a key source of power relevant to healthcare-related legislation.

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489 U.S. CONST. art. I, § 8, cl. 1.
490 See supra text accompanying notes 2-3, 18-36.
492 We refer here to the Lopez, Morrison, and Raich decisions, which are extensively discussed and analyzed herein at supra text accompanying notes 393-466 and infra text accompanying notes 510-47.
extent that components of the relevant legislation do not directly contemplate federal funding, however, an enumerated power other than the Spending Clause must be tapped to support those other components. We therefore must consider what role the Commerce Clause would play.

The Commerce Clause’s Role

Those who would bring a constitutional challenge to the federal legislative and regulatory action we call for herein would of course accompany their Tenth Amendment arguments with an argument that Congress had exceeded its Commerce Clause power. Given the first one of the Tenth Amendment lessons examined earlier, the two arguments would have to go hand-in-hand.494 The same is to be expected in the constitutional challenge that a minority of state attorneys general have brought regarding the Patient Protection and Affordable Care Act.495

In both challenges--the expected one concerning our proposals for federal action and the one launched concerning the recently enacted federal law--the challenging parties will no doubt rely heavily on United States v. Lopez and United States v. Morrison, because in both cases the Supreme Court held that Congress had exceeded its Commerce Clause power.496 One assumes, too, that the challenging parties would attempt to soft-pedal Gonzales v. Raich, in which the Court cautioned that Lopez and Morrison should not be read too broadly.497 As we shall show, Raich offers more useful guidance for the resolution of the issues surrounding our proposals (and for the issues surrounding the broader 2010 law) than do Lopez and Morrison.498 Before we examine the issues just suggested, however, there is an important set of Commerce Clause issues whose proper resolution could control the constitutional challenges on an alternative basis (i.e.,

494 See supra text accompanying note 469.
497 Gonzales v. Raich, 545 U.S. 1, 23 (2000).
498 See infra text accompanying notes 543-47.
without the courts becoming mired in working through whether Raich controls or whether, instead, Lopez and Morrison do).

Recall that the Court’s Commerce Clause decisions have consistently recited the list of three categories of permissible regulation by Congress under its power to regulate interstate commerce. First, there are channels of interstate commerce. Second, there are instrumentalities of interstate commerce and persons or things in interstate commerce. Third, there are activities that substantially affect interstate commerce, even if they are intrastate activities.\textsuperscript{499} Lopez, Morrison, and Raich recited the list, but each of those cases involved only the third category.\textsuperscript{500} The federal action contemplated by our proposals, however, implicates not only the third category but also the second. The same would be true of the healthcare law enacted by Congress in 2010. We therefore turn to the second-category issues before returning to those surrounding the third category.

Our proposals contemplate federal action involving instrumentalities of, and persons or things in, interstate commerce. The information technology components of the NHIN architecture discussed have an unmistakable interstate, as well as economic, character. Moreover, the cloud providers whose creation we propose would be interstate instrumentalities or things. They would exist in different states. Their operations would be multistate, and they would employ persons from various states. The economic character of these cloud providers’ operations would be clear.\textsuperscript{501} Moreover, the data they would acquire and disseminate on an interstate basis would be “things” in interstate commerce. Precedent establishes that information

\begin{itemize}
\item \textsuperscript{499} E.g., Lopez, 514 U.S. at 558-59.
\item \textsuperscript{500} Id. at 559; Morrison, 529 U.S. at 609; Raich, 545 U.S. at 16-17.
\item \textsuperscript{501} See supra text accompanying notes 282-309.
\end{itemize}
is a “thing” for purposes of federal regulation under the Commerce Clause. Thus, the second category of permissible Commerce Clause-based action should serve to justify the federal regulatory activity contemplated by our proposals.

Further support for the above conclusion comes from consideration of the other interstate commerce connections associated with matters our proposals would affect. Consider, for instance, the interstate distribution of pharmaceuticals and medical devices, the interstate nature of many medical consultations, and the interstate nature of many insurance claims processing and payments (even if insurance companies are regulated by state law). The exchange of medical information, of course, relates directly to these matters, each of which has an economic character. For the same reasons just noted, the constitutional authority to enact the 2010 healthcare reform law should stem in large part from the law’s connections with the second category of permissible Commerce Clause-based enactments.

Moreover, consideration of Commerce Clause issues suggested by new or proposed federal actions dealing with healthcare should take place against the backdrop of what the federal government has long been doing in the healthcare realm. For instance, there are the Medicare, Medicaid, and Social Security programs. There are the federal laws dealing with the

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502 Reno v. Condon, 528 U.S. 141 (2000) is especially useful here. In Condon, the Court unanimously upheld, as a valid exercise of its power under the Commerce Clause, a federal law that limited the ability of states to release personal information regarding drivers licensed by the states. Id. at 143-44, 147-51. In so ruling, the Court expressed its agreement with the government’s contention that “the personal, identifying information . . . regulate[d] [by the federal law in question] is a ‘thing in interstate commerce,’ and that the sale or release of that information in interstate commerce is therefore a proper subject of congressional regulation.” Id. at 148 (quoting United States v. Lopez, 514 U.S. 549, 558-59 (1995)). The Court went on to say that the identifying information is “used in the stream of interstate commerce by various public and private entities” in connection with interstate matters. Id. This meant that the relevant information “is, in this context, an article of commerce, [and that] its sale or release into the interstate stream of business is sufficient to support congressional regulation.” Id.

503 The same rationale underlying the Condon conclusion regarding drivers’ personal information should apply to patients’ medical information. See id.

504 See Raich, 545 U.S. at 16-17; Condon, 528 U.S. at 148; Morrison, 529 U.S. at 609; Lopez, 514 U.S. at 558-59 (all noting well-established nature of second category that Congress may regulate under Commerce Clause).

505 42 U.S.C. §§ 1395 et seq. (Medicare); 42 U.S.C. §§ 1396 et seq. (Medicaid); 42 U.S.C. §§ 901 et seq. (Social Security).
prescribing of narcotic drugs. What about the requirements that pharmaceuticals and certain medical devices receive Food & Drug Administration approval before they can be sold? Consider HIPAA and its regulation of medical information privacy (even though in its current form, HIPAA does not preempt more restrictive state laws). All of these federal laws have clear interstate commerce connections. Drawing a principled distinction for Commerce Clause purposes between those longstanding laws and new or proposed federal action in the healthcare field is difficult. Of course, a valid constitutional challenge to healthcare-related federal action cannot be based on the objecting parties’ view that the measures are a bad idea. Such opposition is relevant to the political arena, but not in the realm of constitutional challenges. In addition, validly enacted federal law can and does preempt what otherwise had been valid state laws in the relevant field.

We next consider the third category of matters that Congress may constitutionally regulate under the Commerce Clause - activities substantially affecting interstate commerce, even if they are intrastate in nature. Were it not for Lopez and Morrison, it would not be difficult to conclude that the Commerce Clause permits the federal action we propose herein as well as the 2010 healthcare reform enactment. As the earlier discussion reveals, matters relating to healthcare and medical information privacy have significant interstate aspects in addition to whatever intrastate character they may have. But even if such matters were exclusively intrastate in nature, pre-Lopez and pre-Morrison Commerce Clause decisions would seem to give the green light to the measures we propose herein and those Congress enacted in 2010. Cases such as United States v. Darby and Wickard v. Filburn provide strong support for the argument that the

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508 See supra text accompanying notes 77-94.
509 U.S. CONST. art. VI; Raich, 545 U.S. at 29-30.
510 Raich, 545 U.S. at 16-17; Morrison, 529 U.S. at 609; Lopez, 514 U.S. at 558-59.
proposed and actual statutes reach intrastate activities substantially affecting interstate commerce.\footnote{For discussion of these cases and other pre-1995 Commerce Clause decisions, see \textit{supra} text accompanying notes 374-92.}

The Supreme Court complicated the third-category analysis when it decided \textit{Lopez} and \textit{Morrison}, but analysis of those two decisions, especially in light of \textit{Gonzales v. Raich}, reveals that the \textit{Lopez-Morrison} duo does not provide a winning argument to those who would challenge the federal action we propose, or to the attorneys general who are challenging the 2010 healthcare reform law.\footnote{See infra text accompanying notes 515-47.} \textit{Lopez} and \textit{Morrison} can fairly be characterized as decisions in which the same five-justice majority sought to, and did, signal that there are limits to how far Congress can go under the Commerce Clause power. Those justices presumably regarded prior decisions as having given Congress the idea that the Commerce Clause was effectively a federal police power that could displace state police power regulation in any and all instances.\footnote{See \textit{Lopez}, 514 U.S. at 556-57, 566-67; \textit{Morrison}, 529 U.S. at 609, 615-18.} Hence, \textit{Lopez} and \textit{Morrison} contain statements about preserving a meaningful distinction between what is truly national and what is local in nature.\footnote{\textit{Lopez}, 514 U.S. at 567-68; \textit{Morrison}, 529 U.S. at 617-18.}

The particular laws at issue in \textit{Lopez} and \textit{Morrison} provided the justices in the majority a convenient context in which to send the message that the Commerce Clause power is not unlimited. The statutes addressed in those decisions dealt with criminal conduct of a violent or potentially violent nature, and were thus easily susceptible to the Court’s characterizations of them as laws regarding noneconomic activities. In each case, the Court also had no difficulty concluding that these noneconomic activities were intrastate in nature.\footnote{\textit{Lopez}, 514 U.S. at 561; \textit{Morrison}, 529 U.S. at 611, 613.} The statute at issue in \textit{Lopez} contained no findings or other provisions expressly connecting the relevant activities with
interstate commerce. The government sought to argue about how those activities could be connected with interstate commerce, but the Court, not liking the implications of the reasoning, dismissed it as too attenuated and as calling for piling “inference upon inference.”\textsuperscript{516} In \textit{Morrison}, an interstate commerce connection was not obvious from the text of the civil remedy provision at issue. Even though the statute did contain findings regarding an interstate commerce connection, the majority was able to discount the findings because they seemed to employ the attenuated, inference-upon-inference reasoning condemned in \textit{Lopez}.\textsuperscript{517}

Moreover, the subject-matter differences between the statutes challenged in \textit{Lopez} and \textit{Morrison} and those examined in earlier Commerce Clause cases made it easy for the Court to assert that when Congress has been permitted to regulate intrastate activity under the Commerce Clause, the activity has had an economic character to it.\textsuperscript{518} This was a basically accurate characterization of the earlier cases, even if it would not be accurate to assert that intrastate activity must always be obviously commercial in order to substantially affect interstate commerce and thus be something Congress can regulate.\textsuperscript{519}

Without question, the five justices in the majority in both \textit{Lopez} and \textit{Morrison} successfully signaled that the federal power to regulate interstate commerce is not unlimited.\textsuperscript{520} If, however, those justices hoped to accomplish a complete turnaround in Commerce Clause jurisprudence, they failed. Their own language in \textit{Lopez} and \textit{Morrison} prevents the conclusion that those decisions accomplished such a turnaround. In addition, as will be seen, \textit{Gonzales v. Raich} drives home that very point.\textsuperscript{521}

\textsuperscript{516} \textit{Lopez}, 514 U.S. at 567. \textit{See id.} at 561-63, 563-64, 565-66.
\textsuperscript{517} \textit{Morrison}, 529 U.S. at 613-16.
\textsuperscript{518} \textit{Lopez}, 514 U.S. at 560; \textit{Morrison}, 529 U.S. at 611.
\textsuperscript{519} \textit{Gonzales v. Raich}, 545 U.S. 1, 18 (2005). \textit{See id.} at 36 (Scalia, J., concurring in the judgment).
\textsuperscript{520} \textit{See Lopez}, 514 U.S. at 556-57, 566-67; \textit{Morrison}, 529 U.S. at 609, 615-18.
\textsuperscript{521} 545 U.S. 1, 16-27 (2005). \textit{See infra} text accompanying notes 534-43.
Chief Justice Rehnquist’s majority opinion in *Lopez* noted that earlier decisions such as *Wickard v. Filburn* helped to “usher[] in an era of Commerce Clause jurisprudence that greatly expanded the previously defined authority” Congress had under the clause. The Chief Justice referred to *Wickard* as “perhaps the most far reaching example of Commerce Clause authority over intrastate authority,” but his opinion neither disavowed *Wickard* nor discredited other cases that had led to the era he had noted. Instead, the Chief Justice sought to show why the statute at issue in *Lopez* did not involve economic activity in the way the statute in *Wickard* had. It may have been a backhanded re-affirmation of *Wickard*, but it was a reaffirmation. Throughout the decision in *Lopez*, the Court continued to emphasize the noneconomic nature of the intrastate actions regulated by the statute. Those references, plus the Court’s reiterations that the actions were connected with violent or potentially violent crime, also serve to limit the ability to argue credibly that *Lopez* effectively nullified the previous line of Commerce Clause cases extending Congress broad authority to regulate.

Language in *Morrison* is of similar effect. Chief Justice Rehnquist’s majority opinion stated that the Court’s decisions from 1937 on have given Congress “considerably greater latitude” to regulate under the Commerce Clause. The Chief Justice later noted *Lopez*’s message that “even under our modern, expansive interpretation of the Commerce Clause, Congress’ regulatory

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522 514 U.S. at 556.
523  Id. at 560.
524  See id. at 556-57, 559-60.
525  See id. at 560-61.
526  See id. at 560-61, 562-63, 567-68.
527  See id. at 563-64, 567-68.
528  It may be that Chief Justice Rehnquist did not include language that would have undermined the earlier precedents because if he had done so, he might have lost the vote of Justice Kennedy. Had that happened, the Chief Justice would not have had a majority. See id. at 568, 573-74 (Kennedy, J., concurring) (observing that the holding in *Lopez* was “limited” and that the Court’s earlier Commerce Clause decisions remained alive and well). For further discussion of Justice Kennedy’s concurrence, see supra note 412.
529  529 U.S. at 608.
authority is not without bounds.”\textsuperscript{530} This is language reaffirming the “modern, expansive application,”\textsuperscript{531} even though the Court would go on to invalidate the law at issue in \textit{Morrison}.\textsuperscript{532} The Court also noted the “noneconomic, violent criminal conduct” that the statute at issue sought to reach, as well as the failure of Congress to connect the “regulation and punishment of intrastate violence” to interstate commerce. As with similar statements in \textit{Lopez}, these statements in \textit{Morrison} should limit the ability to argue that the decision seriously undermines the Court’s earlier Commerce Clause decisions.\textsuperscript{533}

Justice Stevens’s majority opinion in \textit{Gonzales v. Raich}\textsuperscript{534} leaves little doubt about whether \textit{Lopez} and \textit{Morrison} fundamentally altered Commerce Clause jurisprudence. \textit{Raich} clearly indicates that the pre-\textit{Lopez} decisions remain alive and well, and that \textit{Lopez} and \textit{Morrison} must be interpreted with proper perspective.\textsuperscript{535} Earlier, we examined the \textit{Raich} majority opinion’s heavy reliance on \textit{Wickard v. Filburn}, which the Court regarded as strikingly similar to the case at hand.\textsuperscript{536} We will not reiterate that discussion here, except to note that \textit{Raich}’s emphasis on \textit{Wickard} demonstrates how extensively current Commerce Clause analysis continues to rely on the line of cases preceding \textit{Lopez} and \textit{Morrison}.\textsuperscript{537}

After reaffirming \textit{Wickard}, the Court went on in \textit{Raich} to emphasize that \textit{Lopez} and \textit{Morrison} would not control the analysis. The Court criticized the plaintiffs for having a “myopic focus” in their reliance on the \textit{Lopez-Morrison} tandem—a reliance that caused the plaintiffs to “read those cases far too broadly.”\textsuperscript{538} In a further attempt to show why \textit{Lopez} and \textit{Morrison} did not

\textsuperscript{530} Id.
\textsuperscript{531} Id.
\textsuperscript{532} Id. at 613, 616-19.
\textsuperscript{533} See \textit{id.} at 608, 610-11, 613.
\textsuperscript{534} 545 U.S. 1 (2005).
\textsuperscript{535} Id. at 16-27.
\textsuperscript{536} See supra text accompanying notes 441-46.
\textsuperscript{537} See \textit{Raich}, 545 U.S. at 16-22, 25-33.
\textsuperscript{538} Id. at 23.
meaningfully speak to the issues in *Raich*, Justice Stevens highlighted the *Lopez* and *Morrison* references to the noneconomic, violent criminal nature of the activities the statutes examined in those cases sought to address.\(^{539}\) Although the Controlled Substances Act (CSA) provision at issue in *Raich* involved matters of criminal behavior, it was not directed at criminal violence per se and, in any event, the likely effects on the interstate market for marijuana were abundantly clear.\(^{540}\) Therefore, the Court stressed that *Lopez* and *Morrison* “cast[] no doubt” on the validity of the CSA and its application to intrastate use of marijuana for medicinal purposes.\(^{541}\)

Parties relying on *Lopez* and *Morrison* in challenging either our proposed federal action or the 2010 healthcare reform enactment may wish that those cases had revamped Commerce Clause jurisprudence in a sweeping manner. As demonstrated above, however, *Lopez* and *Morrison* themselves undermine such an argument, and *Raich* forecloses it.

*Raich* offers other support for the argument that the Commerce Clause permits the federal action we propose. The Court’s extensive examination of the economic and interstate commerce aspects of the broad-ranging CSA relates directly to the federal regulation discussed herein and to the healthcare reform law Congress enacted in 2010.\(^{542}\) In addition, *Raich* helpfully emphasizes that in deciding Commerce Clause-based challenges, courts are normally loath to excise parts of extensive regulatory measures and label those parts as not permitted by the Commerce Clause even though the rest of the regulatory measure is.\(^{543}\) As indicated elsewhere

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\(^{539}\) See id. at 23-24, 25.

\(^{540}\) See id. at 24-25, 26-27, 28-29. The Court also noted that statutes at issue in *Lopez* and *Morrison* were narrow, single-subject enactments, whereas the drug regulation law at issue in *Raich* was very wide-ranging. Id. at 23-24, 26-27.

\(^{541}\) Id. at 25, 26.

\(^{542}\) See id. at 23-24, 26-28. *Raich* also cites ways in which the federal government regulates medical matters, especially those involving the prescribing of narcotics and the need for Food & Drug Administration approval for new pharmaceutical products. See id. at 27-28.

\(^{543}\) Id. at 23.
herein and as noted earlier in this section, the federal legislation we see as necessary would be extensive. So are the interstate commerce connections present in our proposals.544

The economic nature of the uses made of the health information affected by our proposals is also substantial. Uses by physicians and other medical personnel, uses by hospitals, clinics, and other healthcare-related organizations, uses by insurance companies, uses by patients in making decisions regarding their healthcare, uses by researchers—all these uses have economic aspects of either a direct or indirect nature. Therefore, the approach taken in Raich lends further support to the notion that our proposals for federal regulatory action would be constitutional, as would the even more broad-ranging Patient Protection and Affordable Care Act, which tackles many healthcare-related issues and their economic and interstate aspects.545

In addition, Raich furnishes a clear reminder of the role of federal supremacy. Properly enacted federal law overrides conflicting state law,546 leaving those who regard the federal law as a bad idea to turn to Congress—but not the courts—for relief.547 This reminder is of obvious relevance not only to the challenge we would expect if the federal action we propose becomes a reality, but also to the pending challenge being made by a minority of state attorneys general to the 2010 healthcare reform law.

Comments on Changes in the Supreme Court’s Composition

     Above, we considered how Lopez, Morrison, and Raich affect, or do not affect, the resolution of the Commerce Clause issues in the constitutional challenges on which we are focusing. Because changes in the composition of the Supreme Court have occurred since those

544 See supra text accompanying notes 501-08.
545 See Pub. L. No. 111-148 (2010). As noted earlier, however, we are not attempting a detailed analysis of individual provisions in the new law. See supra note 467. Neither are we taking a firm position on the constitutionality of the have-insurance-in-force-or-pay-a-penalty provision in the recently enacted law. See supra note 488.
546 U.S. CONST. art. VI; Raich, 545 U.S. at 29-30.
547 See Raich, 545 U.S. at 9, 33.
decisions were handed down, because another change is in the offing, and because a constitutional challenge to the Patient Protection and Affordable Care Act (and perhaps to our proposed federal action) seems likely to make it to the Supreme Court, we conclude this section by commenting on whether the changes in the Court’s composition are likely to make a difference in how the Commerce Clause issues play out.

Chief Justice Rehnquist, the author of the five-justice majority opinions in *Lopez* and *Morrison,* died in 2005. It seems reasonable to assume that his replacement, Chief Justice Roberts would have voted as Chief Justice Rehnquist did in *Lopez, Morrison,* and *Raich* (where Chief Justice Rehnquist was in the minority), if Chief Justice Roberts had then been on the Court. It also seems reasonable to assume that if a Commerce Clause-based challenge were to come to the Court soon, the current Chief Justice would take positions similar to those of his predecessor.

One might argue that Chief Justice Roberts could be inclined to take an even harder line against sweeping federal authority under the Commerce Clause than his predecessor did, given that the Rehnquist opinions in *Lopez* and *Morrison* contained language preserving the earlier decisions that contemplated an expansive federal power even though the statutes in *Lopez* and *Morrison* were being invalidated. The language preserving the earlier decisions may have been inserted to keep Chief Justice Rehnquist from losing Justice Kennedy and therefore losing his majority. If so, and if Chief Justice Roberts were to write an opinion taking too strong a stand against an expansive Commerce Clause power, he might have trouble keeping Justice

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548 *Lopez,* 514 U.S. at 550; *Morrison,* 529 U.S. at 600.
549 *Raich,* 545 U.S. at 4.
550 See *Lopez,* 514 U.S. at 556-57, 559-60; *Morrison,* 529 U.S. at 608, 610-11, 613.
551 See supra note 528.
Kennedy in the fold and might not be able to muster a majority for a hard-line approach. Accordingly, Chief Justice Roberts would seem likely to end up about where Chief Justice Rehnquist was on the Commerce Clause. In any event, *Lopez* and *Morrison* contain language that limits the sweep of those decisions—and that language would pose a difficult obstacle around which to maneuver.

Justice O’Connor, who was in the majority in *Lopez* and *Morrison* but in the minority in *Raich*, retired from the Court in 2005. One assumes that her replacement, Justice Alito, would now take positions very similar to hers in Commerce Clause cases. Justice Souter retired from the Court in 2009 and was replaced by Justice Sotomayor. It seems reasonable to think that her view of Commerce Clause issues would be largely the same as that of Justice Souter, who dissented in *Lopez* and *Morrison* but was part of the *Raich* majority.

Justice Stevens recently announced his retirement. At this writing, his replacement had neither been named nor confirmed. One assumes that the new justice would likely take Commerce Clause positions consistent with how Justice Stevens voted in *Lopez* (in the minority), *Morrison* (in the minority), and *Raich* (in the majority). Importantly, the guidance Justice Stevens provided in his *Raich* majority opinion would be very difficult to cast aside. After *Raich*, an attempt by a group of justices to disavow or limit that decision, or to take too narrow a view of congressional authority under the Commerce Clause, could leave those justices unable to persuade Justice Kennedy to join them. Recall that he joined the majority in *Raich* and

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552 See id.
553 See *Lopez*, 514 U.S. at 556-57, 559-60; *Morrison*, 529 U.S. at 608, 610-11, 613.
554 See *Lopez*, 514 U.S. at 550; *Morrison*, 529 U.S. at 600; *Raich*, 545 U.S. at 4.
555 See *Lopez*, 514 U.S. at 550; *Morrison*, 529 U.S. at 600; *Raich*, 545 U.S. at 4.
557 See *Lopez*, 514 U.S. at 550; *Morrison*, 529 U.S. at 600; *Raich*, 545 U.S. at 4.
558 See *Raich*, 545 U.S. at 16-33; supra text accompanying notes 439-66, 543-47.
was the only one of the justices who had been in the *Lopez* and *Morrison* majorities to do so. As for the holdover justices other than Justice Kennedy, we would expect them to continue taking the same Commerce Clause positions they have taken.

What is therefore likely to happen if the Supreme Court hears the challenge being pursued by a minority of state attorneys general to the 2010 healthcare reform law and the challenge we anticipate if our proposed federal action becomes law? We predict that unless the Court ignores the applicable Commerce Clause precedents, fundamentally recasts them, or overrules them outright, the laws are likely to be upheld. In the probable majority would be Justices Kennedy, Ginsburg, Breyer, and Sotomayor, as well as the new justice who replaces Justice Stevens. Chief Justice Roberts and Justices Thomas and Alito would likely be in the minority. Justice Scalia is a potential wildcard. His decision to concur in the judgment in *Raich* (rather than joining the dissenters) suggests that he could do a similar thing in the constitutional challenges being addressed. In the end, given the swing position he held in *Lopez*, *Morrison*, and *Raich*, Justice Kennedy would probably again be the key.

We believe the foregoing analysis strongly suggests that legislation authorizing the creation of a revolutionary NHIN centered on the creation of federally chartered and regulated but

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559 *Lopez*, 514 U.S. at 550; *Morrison*, 529 U.S. at 600; *Raich*, 545 U.S. at 4. See *supra* note 528.
560 As noted earlier, however, we are not taking a firm position on the constitutionality of an especially contentious provision in the new law: the provision contemplating that all individuals must have health insurance or pay a penalty. See *supra* notes 488, 545.
561 This seems very likely if the cases are seen as third-category cases for purposes of the congressional authority to regulate under the Commerce Clause. If they are seen as second-category cases, one or more of those the justices just noted might be peeled off to join the majority. For discussion of the difference between second-category and third-category cases, see *supra* text accompanying notes 499-511. See also *Reno v. Condon*, 528 U.S. 141, 148-49 (2000) (unanimous decision in which Court concluded personal information of license drivers was “thing in interstate commerce,” for purposes of regulation under Commerce Clause). Further discussion of the relevance of *Condon* appears at *supra* notes 502-03.
562 545 U.S. at 4, 33.
563 This is a possibility if the cases are treated as third-category cases. If they are treated as second category cases, he may be somewhat more likely to go with the majority. See *Condon*, 528 U.S. at 148-49. See also *supra* notes 502-03 (discussing *Condon’s* relevance).
564 See *Lopez*, 514 U.S. at 550; *Morrison*, 529 U.S. at 600; *Raich*, 545 U.S. at 4.
privately funded cloud providers, as well as the legislation of federal privacy law preempting the patchwork of disparate state privacy laws that would impede the NHIN, would stand an excellent chance of surviving Constitutional challenges. The following section summarizes our thoughts.

VI. Conclusion

The U.S. is currently experiencing a healthcare crisis involving problems of quality and affordability. A NHIN holds great potential for reducing these problems by linking various healthcare-related entities and patients to provide real-time flow of medical information. The current federal evolutionary strategy involves developing the NHIN by the rollup and eventual consolidation of RHIOs. RHIOs, however, are fraught with difficulties, have been slow to develop, and many are not financially viable. Consequently, NHIN development is too slow, and the realization of a true, seamless, nationwide health information exchange may be many years away. Given the healthcare cost and quality issues at stake, the nation can ill afford this delay.

NHIN architecture and patient privacy laws are interdependent because security of PHI is, in part, a function of the manner in which a NHIN is structured, and laws need to be written keeping that structure in mind. The electronic flow of PHI across state lines in currently impeded by disparate state privacy laws layered on top of federal privacy law. This problem will only grow worse as the nation moves toward more and more interstate transmission of PHI under a NHIN. Consequently, addressing the privacy law problem is an important complement to both the development of a NHIN and its architecture.

We have proposed a revolutionary NHIN architecture and a complementary framework for preemptive federal law that will allow a NHIN to develop much faster that with the current evolutionary strategy. This architecture is based upon cloud computing, a cutting-edge concept that has many benefits over evolutionary architecture approaches including lower cost, easier
access, and enhanced reliability. In addition, a cloud-based architecture can afford at least as good, if not better, security of PHI. We have proposed implementation of this architecture through the creation of a small number of federally regulated but privately owned and funded utility-like entities that would act as both cloud providers and data repositories for PHI. This architecture and implementation strategy would permit facilitate reasonably tight control over access to PHI meeting the seven principles of information fairness while allowing for competition based upon service quality and secure use of selected data for purposes of public health administration and medical research, thereby greatly enhancing the NHIN’s social utility.

We have also proposed a preemption of state privacy laws to remove the serious impediment they represent to a smooth functioning NHIN. Such laws should be designed not only to remove state law impediments to transmission of PHI across state lines but also to complement the cloud-based, utility-like architecture by permitting the use of PHI contained in cloud providers’ health data repositories for medical research and public health purposes while adequately controlling these uses. Although we anticipate objections to both the NHIN and to state privacy law preemption based upon Tenth Amendment concerns, we have shown that key judicial precedents dealing with the Commerce Clause and with the Tenth Amendment should ultimately render these objections fruitless.

In summary, the vast potential of a true, seamless, universal NHIN to improve the quality of healthcare while reducing its cost will likely go unrealized for many years to come unless the federal government adopts a new strategic vision and direction for its development. Given the unaffordable cost of healthcare as well as its substantial quality problems, the nation simply cannot continue on the current path.