State Law Governance Of Health Information Technology

Cason Schmit*

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Abstract

Howdy! So I am new to Texas A&M and that is the official Texas A&M greeting. It is a little awkward for a former California boy to say. Thank you very much to NSU for welcoming me. Thank you to the faculty and staff. It is really an honor to be here.

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Howdy! So I am new to Texas A&M and that is the official Texas A&M greeting. It is a little awkward for a former California boy to say. Thank you very much to NSU for welcoming me. Thank you to the faculty and staff. It is really an honor to be here.

So I am a recent transplant from the U.S. Centers for Disease Control and Prevention, and I have to acknowledge that a lot of what I am going to be talking about today is work that I did while I was there. I worked with a truly fantastic team of attorneys, including Gregory Sunshine, Dawn Pepin, Tara Ramanathan, Akshara Menon, and, of course, our director Matthew Penn, and they put a lot of work into what I am going to be presenting today.

Of course, as a former government attorney, we have to have our disclaimer. Believe me, these are not CDC official determinations or policies. This is [for] educational purposes only. I am an attorney, but I am not your attorney—[this is] not legal advice. So, let's dive into this here.

[The] US Health system is in the middle of a digital revolution. It has already transformed the health systems efficiency, capacity, and function. Health information, in all shapes and sizes in all sectors of healthcare and public health systems, is being created and shared electronically. Electronic health information is incredibly diverse: it includes electronic medical records, laboratory reports, syndromic surveillance data, electronic prescriptions, vital records, and epidemiological reports. Digitization of health information allows for a single piece of health information to be used for multiple purposes simultaneously, and law plays a critical roll in this health information technology revolution. Every data type, every data use is governed by law. Consequently, the future of health information technology is heavily dependent on this legal framework. While some of the laws have changed to adapt to this new technology, in many cases, it is the technology that has been forced to adapt to the law.

Thirty years ago, the Office of Technology Assessment made the claim that "technological change is now outpacing the legal structure that governs the system, and [it] is creating pressures on Congress to adjust the

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law to accommodate these changes."[1] Now, given the pace of technological change, the age of this statement should be really alarming. Since then, the pace of information technology development has only increased, and I thought it would be interesting to put things in perspective for you. If we were to assume that the speed of legal adaptation has not changed—and knowing our current Congress, that is probably a little generous—if we assume that information technology remains consistent with Moore's law by doubling about every two years, and if we assume that 1986 was the first time that the pace of technology passes or sped past the pace of legal adaptation, then we find a staggering difference in the rates of that change for technology and law. Under this methodology, legal adaptation is estimated to have changed by a factor of eleven, whereas pace of technology is estimated to have changed by a factor of 32,768. Obviously, this is a pretty crude estimation, but it is helpful to put things into perspective, the relative change between law and technology. These significant technological advances are not taking place in a regulatory vacuum. There are many preexisting laws that might apply to these new technologies; however, these existing laws are designed to handle the technology that was in place when those laws were enacted, and they often do not account for future technology developments. Thus, these laws can become quickly outdated, and this puts an incredible amount of stress on existing laws to compensate.[2]

As technology advances, both the benefits and risks of technology are apparent. Society places rules on technology to attempt to balance the potential benefits with the potential risks. These rules come in many forms: They can be laws, they can be policies, they can be industry standards, but all of these rules collectively form the governance framework for that technology.   Ideally, we would hope that a governance framework maximizes the potential benefits [and] minimizes the potential risks.

When I was with the CDC Public Health Law Program, we conducted a study of state laws on electronic health information. This study provides evidence that the current state law component of health information technology might be poorly suited to appropriately balance the risks and benefits of this rapidly evolving technology.   Now, if true, the current governance framework for health information technology could leave us vulnerable to consequences of mismatches between technology and the law. Commentators note two significant consequences for these types of

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1. U.S. CONG., OFFICE OF TECH. ASSESSMENT, OTA-CIT-302, INTELLECTUAL PROPERTY RIGHTS IN AN AGE OF ELECTRONICS AND INFORMATION 3 (1986).
2. Gregory N. Mandel, *Regulating Emerging Technologies*, 1 L. INNOVATION & TECH. 75, 75 (2009).

mismatches. [3]   On one hand, outpaced laws could impede and stall technological development, and this would ultimately delay the potential benefits of that technology. On the other hand, outpaced laws might leave regulatory gaps that allow technology to develop unchecked, ultimately exposing society to the potential risks of the technology, potential and preventable in many cases.

Given this staggering estimated difference in health information technology that we just went through, health information technology is probably vulnerable to these two consequences. It is possible that state law frameworks are contributing to a stalled health information technology sector, delaying the true potential benefits of health information technology, and, conversely, there are probably some applications of health information technology that are not being regulated and that are exposing society to some potential risks.

Now, understanding the legal framework is critical to identifying strategies to improve health information technology governance. Commentators note that the dynamics between law and technology are similar to the tortoise and the hare allegory. So, in this allegory, the hare outpaces the tortoise, but then stops and rests while the tortoise eventually catches up. Once caught up, the hare eventually wakes up and continues the race. Technology, like the hare, moves very swiftly, but it can only progress so far before the laws become mismatched.

We see those mismatches, and users of health information technology start to experience more uncertainty, risk, or experience laws that are otherwise impeding the development of the technology. The law must catch up to technology to provide innovators with clarity to move forward. Health information technology is really a story of two hares. The first hare is information technology more generally, and this hare has taken off and introduced society to radical new applications and uses for health information generally. The second hare is health information technology specifically. This hare has been remarkably slow. In 2005, the chairman of the Center for Information Technology Leadership noticed the slow rate, and noted that the "healthcare information technology market [was] broken."[4] Since then, the tortoise has made some progress. In 2009, the HITECH Act was passed, which is a federal law that incentivized the adoption and meaningful use of electronic health records, so this incentivized widespread

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3.   Jennifer Kozma, *Properly Paced or Problematic? Examining the Past and Present Governance of GMO's in the United States*, *in* INNOVATIVE GOVERNANCE MODELS FOR EMERGING TECHNOLOGIES 3 (2014).

4.   Blackford Middleton, *Achieving U.S. Health Information Technology Adoption: The Need for A Third Hand*, 24 HEALTH AFFAIRS 1269, 1269–72 (2005).

advances in health information technology. At CDC, we are interested in incentives that HITECH provided to health public health uses of health information technology, including case reporting, syndromic surveillance, and many new public health registries.

However, these new improvements to the health information technology infrastructure supported by HITECH enabled more uses of health information technology, including bidirectional communication between providers and public health, including the ability to have increased situational awareness tools in emergencies. In some cases, it has revolutionized the way that we investigate disease outbreaks. Many of these new health information technologies were initiated by state governments under new statutes and new regulations.

At the CDC Public Health Law Program, we investigated these laws to better understand this state legal landscape.[5] So here is what we did: We used Westlaw to identify relevant laws using standardized search streams and systematic searches. Our search scope was limited to laws that related to electronic health information, and that is an incredibly broad net. We included only those laws that were in effect January 2014. We used two or three legal researchers to categorize each legal provision on the nature of the described use of the prescribed use within the law, and we did this blind to each other. We independently coded each legal provision, and then held meetings to discuss any inconsistencies to determine final consensus codes. Our coding scheme involved two types of codes—main-codes [and] cross-reference codes. We assigned every single law a main-code relating to the general purpose of health information within the law, or the general activity that comprised the focus of the law.

Now, some laws related to more than one use of health information technology or health information, so we assigned those laws cross-reference codes for whenever the law related primarily to one use but also referenced other uses in health information technology. Consequently, every law contained a main-code, but not every law had a cross-reference. This study identified 2364 state statutes and regulations relating to health information technology. State law frameworks varied qualitatively and quantitatively. Jurisdictions averaged just over forty-three laws. Texas, Oregon, and California were the states with the most laws—Texas had 145, Oregon had 104, [and] California had 103. We only found three territories with laws with health information technology—Guam, Virgin Islands, [and] Puerto

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5.   Cason Schmit et al., Assessing the Impact of State Laws Related to Electronic Health Information in the Centers for Medicare & Medicaid Services State Innovation Models Initiative, Presentation at the National Association of County and City Health Officials Annual Conference (Jul. 8, 2015).

Rico. Each of those had fewer than ten laws. Hawaii, South Carolina, Delaware, and South Dakota were the states with the fewest health information technology laws, and each of them had fewer than twenty laws. We identified three primary use categories relating to patient treatment: This is treatment in traditional settings, treatment in correctional settings, and treatment in educational settings. We also identified forty-six use categories that relate to other uses of health information apart from patient treatment. These secondary use categories are incredibly diverse, covering traditional public health functions, such as case reporting [and] vital records, to new public health registries, voter registration, and medical marijuana among many, many others. In total, we found 228 different main-code/cross-reference code combinations, suggesting that the landscape is not only big, it is incredibly complex, and states are approaching health information technology governance in very different ways.

It follows then that the race between law and technology does not involve one tortoise and a hare, it involves fifty tortoises running fifty very different races. This then begs the question: Is it good to have more laws? A number of scholars that have examined other emerging technology, such as bio-technology, nanotechnology, and genomics, have placed some pretty hard criticism on complex governance frameworks. Some have suggested the quality oversight can suffer without sufficient coordination,[6] or that the multiplicity of statutes and agencies involved could create confusion among the regulated industry, reduce the clarity, or otherwise slow technological development.[7] Others have argued that when there are multiple entities managing the risks, there is a chance they might neglect some risks by relying on other risk managers, or they can make decisions that have unintended consequences without sufficient coordination, or otherwise slow technological development here.[8] [The] International Risk Governance Council has warned that whenever a governance system involves multiple entities [or] multiple responsibilities, there is a real danger that the risk response is not going to be coordinated.[9] This can be duplicated efforts. We see this in HIT with health information exchanges and wasted resources, reinventing the wheel over and over again.

All these critiques aside, it might be the case this complex health information technology governance framework is inevitable. Many health

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6.   GARY E. MARCHANT ET AL., INNOVATIVE GOVERNANCE MODELS FOR EMERGING TECHNOLOGIES 11 (2013).
7.   Mandel, *supra* note 2, at 82.
8.   INT'L RISK GOVERNANCE COUNCIL, RISK GOVERNANCE DEFICITS: ANALYSIS, ILLUSTRATION AND RECOMMENDATIONS 11 (2010), http://www.irgc.org/IMG/pdf/IRGC_RiskGovernanceDeficits_PolicyBrief2010.pdf.
9.   *Id.* at 16.

information technology applications are undertaken or at least supported by government entities. These government entities need legal authority to do these things. In many cases, this means new statutes and new regulations to authorize these new technological applications. Now, fortunately, this study does not conclude that more health information technology laws are necessarily bad for health information technology.[10] It is undeniable that the federal HITECH incentives have been a driving force in health information technology adoption.   Moreover, at the 2015 National Association for County and City Health Officials Annual Meeting, we reported that there are some important healthcare and public health objectives that are associated with jurisdictions with more health information technology laws.   For example, using data from this assessment, we found that the number of laws relating to health information exchange among those states that are innovating—the state innovation model states—were positively correlated and significantly correlated with the percentage change and information sharing among federal acute care hospitals.[11]

Similarly, we found that the number of laws relating to health information technology oversight was positively and significantly correlated with the percentage of non-federal acute care hospitals that are sharing public health data with local and state health authorities. Consequently, we have evidence that some types of laws could be enabling health information technology uses rather than stifling the development.

To kind of wrap things up with some key points here: This Public Health Law Program state law study revealed the governance framework for health information technology is incredibly complex and could pose a significant risk to health information technology development. However, given that many health information technology uses involve state actors, some of this complexity might be inevitable. Additionally, we do have evidence that at least some laws could be authorizing governments and enabling entities to engage in new and innovative health information technology uses.

So, moving forward, experience from other emerging technologies, such as biotechnology, genomics, [and] information technology more generally, these different approaches and different thoughts about governance with relation to these technologies might point to different innovative governance models for health information technology.   Some people argue for the use and increase in soft law mechanisms. We have seen some industries rely on leveraging legal requirements for contracts between entities to impose a governance framework.   We have also seen some

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10.   Schmit, *supra* note 5.
11.   *See id.*

proposals for adding and coordinating a governing entity among the different industries. We hope that this public health law program study can provide a strong foundation to analyze new approaches if people are so interested. With that, there is my contact information. Thank you very much. [applause]