PATIENT CONSENT TO HEALTH INFORMATION TECHNOLOGY: SAFEGUARDING PATIENTS’ RECORDS AND CONFIDENCES

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As the health care reform encourages more hospitals and physician networks to adopt electronic health record systems and more regional networks to develop, the federal and state governments will have the difficult task of safeguarding patients’ records and confidences. While the public health benefits of electronic health record systems are plentiful, concerns of privacy and consent permeate patients’ minds. North Carolina has made great strides in laying the groundwork for creating these networks; however, more regulations are necessary to advocate measures for obtaining consent from patients and to facilitate patient confidence in these networks. In order to encourage participation in the network, North Carolina should incorporate an opt-in, provider by provider consent process and should consider expanded recourse rights for patients.

I. INTRODUCTION

Patrick is fifty-six years old and suffers from diabetes, high cholesterol, and heart disease. He has different specialists for each condition and was recently referred to a new specialist, Dr. Rodriguez, for his heart disease. At Patrick’s first appointment, Dr. Rodriguez changed his medication to a newer, more effective medication and scheduled a follow-up appointment with Patrick to monitor his progress. Patrick incorporated this new medication into his regimen. Four nights later, soon after going to sleep, he awoke with an uneasy feeling. Patrick was sweating and felt dizzy. His wife immediately took him to the emergency room. The emergency room physicians, upon soliciting his medication information, realized that his new medication was adversely interacting with his cholesterol medication. They were able to

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stabilize him, and fortunately, Patrick suffered no long-term health consequences.

Patrick’s problem arose primarily because Dr. Rodriguez was unaware of the other medications he was taking. Prior to his appointment with her, Patrick completed the preliminary paperwork but had inadvertently left off one of the medications he was taking to control his cholesterol. Had Dr. Rodriguez been aware that Patrick was taking this medication, she would have known not to prescribe the new heart disease medication. Unfortunately, she had incomplete information.

If there had been a system in place that allowed Dr. Rodriguez to view Patrick’s medical history, including diagnoses and treatment plans from other physicians, adverse health consequences such as the one that Patrick suffered could be avoided. This is precisely what the Health Information Technology for Economic and Clinical Health (“HITECH”) Act, which was enacted as part of the American Recovery and Reinvestment Act of 2009, aims to do. The Act seeks to encourage the adoption of electronic health records (“EHRs”) by providing Medicare incentives. While the public health benefits are potentially plentiful, there are a myriad of concerns that arise from the creation of a nationwide health information network (“NHIN”) as it raises questions about whether patients have control over how their health records are shared. These concerns


2 See American Recovery and Reinvestment Act § 3001.

3 Sharona Hoffman & Andy Podgurski, Finding a Cure: The Case for Regulation and Oversight of Electronic Health Record Systems, 22 HARV. J.L. & TECH. 103, 112–26 (2008) (discussing EHR system benefits, such as facilitating access to patients’ medical records, improving quality of care, and reducing poor treatment decisions). A Nationwide Health Information Network (“NHIN”) refers to “a national effort to establish a network to improve the quality and safety of care, reduce errors, increase the speed and accuracy of treatment,
include determining what organizations will have access to a patient’s medical records, what these organizations’ motives are for obtaining access, how patients can control which organizations may have access to the records, and whether a patient may choose which records are shared and which remain private. This Recent Development focuses on two preliminary concerns: the ideal methods of patient consent regarding the sharing of patient health information through regional health information organizations (“RHIOs”) and how to encourage patient participation in RHIOs.

Specifically, this Recent Development will explore the background of the HITECH Act, the public health benefits that are likely to result from the widespread adoption of EHRs and coordination through RHIOs, and North Carolina’s efforts to create RHIOs. Further, it will explore the Tiger Team’s recent recommendations for ensuring privacy. Finally, this Recent Development will advocate measures for obtaining consent from patients and for facilitating patient confidence in the network.

II. BACKGROUND

A. The HITECH Act

improve efficiency, and reduce healthcare costs.” N.C. Dep’t of Health and Human Servs. Health IT, supra note 1 at 80.


5 A Health Information Organization (“HIO”) is “[a]n organization that oversees and governs the exchange of health-related information among organizations according to nationally recognized standards.” N.C. Dep’t of Health and Human Servs. Health IT, supra note 1, at 80.

6 The Office of the National Coordinator for Health Information Technology organized a tiger team (“the Tiger Team”) to research and address privacy and security concerns inherent in the adoption of health information technology. See Privacy and Security Tiger Team, The Office of the Nat’l Coordinator for Health Info. Tech., http://healthit.hhs.gov/portal/server.pt?open=512&mode=2&objID=2833&PageID=19421 (last visited Sept. 27, 2010); See also infra Part III.
The HITECH Act was passed as a part of the American Recovery and Reinvestment Act of 2009 ("ARRA"). The Statement of Purpose includes, as the third of five purposes, the intent to "provide investments needed to increase economic efficiency by spurring technological advances in science and health." As a result, $25.8 billion of recovery funding was devoted to health information technology. The overall goal of this funding is to create a nationwide health information infrastructure by encouraging the adoption of health information technology to create health information organizations.

B. Public Health Benefits

President Obama illustrated the need for EHRs and the benefits of a NHIN when he addressed the American Medical Association on June 15, 2009. President Obama said:

We need to upgrade our medical records by switching from a paper to an electronic system of record keeping. And we have already begun to do this with an investment we made as part of our Recovery Act. It simply doesn't make sense that patients in the 21st century are still filling out forms with pens on papers that have to be stored away somewhere . . . . You shouldn't have to tell every new doctor you see about your medical history, or what prescriptions you're taking. You should not have to repeat costly tests. All of that information should be stored securely in a private medical record so that your information can

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7 The HITECH Act consists of Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 ("ARRA"). American Recovery and Reinvestment Act of 2009, § 13001(a), 123 Stat. at 226. ARRA was passed in an effort to stimulate the economy:

ARRA is a $787.2 billion stimulus measure, signed by President Obama on February 17, 2009, that provides aid to states and cities, funding for transportation and infrastructure projects, expansion of the Medicaid program to cover more unemployed workers, health [information technology] funding, and personal and business tax breaks, among other provisions designed to “stimulate” the economy.

N.C. Dep’t of Health and Human Servs. Health IT, supra note 1, at 78.


10 Jared Rhoads & Greg DeBor, HIEs Create Privacy Issues for Providers, 32 HEALTHCARE RISK MGMT. 68, 69 (2010).
be tracked from one doctor to another—even if you change jobs, even if you move, and even if you have to see a number of different specialists. That will not only mean less paper pushing and lower administrative costs, saving taxpayers billions of dollars. It will also make it easier for physicians to do their jobs. It will tell you, the doctors, what drugs a patient is taking so you can avoid prescribing a medication that could cause a harmful interaction. It will help prevent the wrong dosages from going to a patient. And it will reduce medical errors that lead to 100,000 lives lost unnecessarily in our hospitals every year.\footnote{Barack Obama, President, U.S., Address at the 2009 Annual Meeting of the Amer. Med. Ass’n. House of Delegates (June 15, 2009) (transcript available at http://www.ama-assn.org/ama/pub/about-ama/our-people/house-delegates/2009-annual-meeting/speeches/president-obama-speech.shtml) (last visited Sept. 26, 2010).}

As President Obama highlighted, Patrick’s unforeseen health consequence could have been avoided if Dr. Rodriguez had access to his medical records from his other physicians to determine what other health problems he had as well as how his other physicians were treating him. Indeed, these types of errors are common; as the Institute of Medicine’s notable \textit{To Err is Human} indicates, more Americans die annually from preventable medical errors than from AIDS or breast cancer.\footnote{COMM. ON QUALITY OF HEALTH CARE IN AM., INST. OF MED. \textit{TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM I} (Linda T. Kohn et al. eds. 1999) (citing Centers for Disease Control and Prevention preliminary data on birth and deaths in 1998).}

\textbf{C. North Carolina’s Efforts}

Prior to the adoption of the HITECH Act, various RHIOs had already developed in North Carolina.\footnote{RHIOs in North Carolina include the Southern Piedmont Health Information Exchange which was established in 2008; and newer networks, established in 2010, such as the Coastal Connect Health Information Exchange by the Coastal Carolinas Health Alliance and the North Carolina Healthcare Exchange by the North Carolina Hospital Association. N.C. Dep’t of Health and Human Servs. Health IT, \textit{supra} note 1, at 17–18.} The most developed of these is the Western North Carolina Health Network, which was established in 2006 and includes sixteen hospitals.\footnote{\textit{Id.}}
Since the passage of the HITECH Act, North Carolina has taken additional steps to stimulate the development of a more extensive and coordinated RHIO. Pursuant to the funding provisions of the HITECH Act, North Carolina Governor Beverly Perdue signed Executive Order 19 on July 16, 2009, which designated the North Carolina Health and Wellness Trust Fund as the State Designated Entity (“SDE”). As the SDE, it applied to the Office of the National Coordinator for Health Information Technology (“ONC”) for funding of a statewide health information exchange (“HIE”). North Carolina subsequently received $12.9 million in funding from the ONC with the intent of using the funds to create a public-private partnership model for its not-for-profit network, the NC HIE.

To further guide the adoption of health information technology, on August 31, 2010, the state released the update to the North Carolina Statewide HIE Strategic Plan, recognizing that while there are various statutes related to the requirements of confidentiality and privacy as well as disclosure of medical

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15 The HITECH Act requires the Governor to name a SDE to apply for funding. Id. at 1.
17 The ONC guides implementation of health IT:

The Office of the National Coordinator serves as principal advisor to the Secretary of [Health and Human Services (“HHS”)] on the development, application, and use of health information technology; coordinates HHS’s [sic] health information technology policies and programs internally and with other relevant executive branch agencies; develops, maintains, and directs the implementation of HHS’ strategic plan to guide the nationwide implementation of interoperable health information technology in both the public and private health care sectors, to the extent permitted by law; and provides comments and advice at the request of [the Office of Management and Budget] regarding specific Federal health information technology programs. ONC was established within the Office of the Secretary of HHS in 2004 by Executive Order 13335.

18 Id. at 2–3.
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records, the state has none geared towards the sharing of EHRs. Additionally, the state has not yet determined a model for consent although it has established guiding principles to help with this determination.

III. TIGER TEAM PRIVACY RECOMMENDATIONS

Although North Carolina’s guidance for creating networks is limited, the ONC created the Privacy & Security Tiger Team under the Health IT Policy Committee, which should provide guidance to North Carolina as well as other states that apply for funding from the ONC. The Tiger Team was tasked with researching privacy and security issues arising under the HITECH Act and making recommendations to address these issues. On August 19, 2010, the Tiger Team released consent suggestions for directed exchange for treatment and for RHIOs.

A directed exchange for treatment occurs when a physician exchanges a patient’s health records with another physician for the purpose of treating that patient. A RHIO refers to a collaboration of health care organizations in a specified geographic area that share health information electronically for the purpose of improving health care in the community. Because of the differences in purposes of these two types of exchanges, the Tiger Team has created different standards for each.

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19 See e.g., N.C. GEN. STAT. ANN. §§ 8-53, 90-21.20, 130A-12, 130A-143 (West 2010).
20 See N.C. Dep’t of Health and Human Servs. Health IT, supra note 1.
21 Id. at 69–70.
23 Privacy and Security Tiger Team, supra note 6.
24 See Memorandum from the Privacy & Security Tiger Team, supra note 22.
25 Id. at 5.
26 N.C. Dep’t of Health and Human Servs. Health IT, supra note 1, at 81.
27 See Memorandum from the Privacy & Security Tiger Team, supra note 22, at 5.
The Tiger Team maintains that patient consent is not required for directed exchange for treatment, which corresponds to the guidelines of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). Prior to the HITECH Act, HIPAA was the primary source of guidelines for safeguarding privacy in the context of health information exchanges. With the adoption of EHRs, the HITECH Act maintains HIPAA’s guidelines for directed exchange and allows the exchange of a patient’s health records for the purpose of treating that patient without the consent of the patient. Directed exchange of medical records is limited in scope because only providers that require a patient’s medical records for treatment of that specific patient receive the records. Additionally, the provider who is sending the records should only send the medical records pertaining to the condition for which the patient requires treatment. Therefore, with a directed exchange, only necessary records should be sent to the treating physician, which is analogous to the way patient records are currently

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28 45 C.F.R. §§ 164.502, 165.506 (2009). HIPAA focuses on both health insurance portability and health information privacy:

HIPAA was enacted by Congress in 1996. Title I of HIPAA protects health insurance coverage for workers and their families when they change or lose their jobs. Title II of HIPAA, known as the Administrative Simplification (AS) provisions, requires the establishment of national standards for electronic health care transactions and national identifiers for providers, health insurance plans, and employers. The Administration Simplification provisions also address the security and privacy of health data. The standards are meant to improve the efficiency and effectiveness of the nation’s health care system by encouraging the widespread use of electronic data interchange in the U.S. health care system.

N.C. Dep’t of Health and Human Servs. Health IT, supra note 1, at 79; see Memorandum from the Privacy & Security Tiger Team, supra note 22, at 9.


32 Memorandum from the Privacy & Security Tiger Team, supra note 22, at 3, 9–10.
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exchanged for the purposes of treating the patient.\textsuperscript{33} The difference exists in the format; instead of paper records being mailed or faxed, the records are sent electronically.\textsuperscript{34}

While HIPAA regulations suggest a standard for the directed exchange of medical records, they do not indicate a standard for creating a network of health records, such as a RHIO.\textsuperscript{35} However, the Tiger Team determined that “meaningful consent” would be required to release a patient’s health records on a RHIO.\textsuperscript{36} The Tiger Team indicated that consent must be “meaningful” in that it must allow the individual advanced knowledge, education, and time to make a decision; it must not be compelled or used for discriminatory purposes; it must be revocable; it must be consistent with reasonable patient expectations for privacy, health, and safety; and it must be commensurate with the circumstances.\textsuperscript{37} The “meaningful consent” recommendation promotes individual choice and autonomy when deciding whether to participate in a RHIO.

\textbf{IV. CONSENT ISSUES}

The Tiger Team’s “meaningful consent” recommendation highlights the importance of patient choice. The method by which a physician obtains consent from a patient can also affect patient control and thereby help to ensure that the consent is indeed meaningful. For instance, when obtaining health care services, patients already have to complete medical histories and undergo insurance verifications, so the addition of a RHIO consent form may merely be glanced at. As a result, the patient may sign it without understanding the full consequences of consent. To avoid unintended consent to the release of medical records on the RHIO,

\textsuperscript{33} \textit{Id.} at 10.
\textsuperscript{34} \textit{Id.}
\textsuperscript{35} A RHIO is “[a] health information organization that brings together healthcare stakeholders within a defined geographic area and governs health information exchange among them for the purpose of improving health and care in that community.” N.C. Dep’t of Health and Human Servs. Health IT, \textit{supra} note 1, at 81.
\textsuperscript{36} Memorandum from the Privacy & Security Tiger Team, \textit{supra} note 22, at 10.
\textsuperscript{37} \textit{Id.} at 12.
there should be greater emphasis placed on this form, and it should be separated from the numerous other forms that a patient must sign prior to his or her appointment. Furthermore, the type of consent model that a state chooses to adopt can also contribute to patients’ control and choice over their participation.

A. Universal Versus Provider by Provider

After a hospital or physician group decides to adopt this sort of health information technology and participate in a local RHIO, it has a number of options regarding how it may obtain consent from the patient. One patient consent option involves having the patient consent to disclosure on a RHIO for all of his or her physicians and procedures; this type of consent is referred to as universal consent. A patient may get the initial consent form at his or her primary care provider and decide to consent to the release of all of his or her medical records on a RHIO. While the Tiger Team maintains that revocability is a key feature of “meaningful consent,” a patient may nonetheless fail to reconsider this initial choice to consent. This is because this initial consent form relates to all of the patient’s medical procedures and includes information about all previous physicians, so the choice to participate is not one that is re-evaluated from one doctor visit to the next. Under a universal consent model, this patient may in the future have a more private medical matter, and he or she may not realize the implications of the consent form that was signed years ago. Sensitive information may consequently be released without the patient’s consideration of the specific medical matter.

A better consent system involves “provider by provider” consent, which is the approach supported by the state of New York. This approach allows patients to choose which providers


39 Memorandum from the Privacy & Security Tiger Team, supra note 22, at 12.

40 Goldstein, supra note 38, at 20, A-5.
can access their records. The “provider by provider” consent approach can be accomplished by allowing patients the ability to decide which providers can access their records through their preferences on the RHIO website. Alternatively, patients can complete a consent form each time they visit a new provider. Either way, the “provider by provider” method provides more flexibility than a blanket consent system. It supports a patient-centered approach to health care because the patient is making decisions with each new provider. Thus, it ensures more “meaningful consent” since that patient is not simply making one absolute decision. The “provider by provider” method provides more patient control than the universal consent method and thus is the more ideal method for obtaining consent.

B. Opt-in Versus Opt-out

There are a number of options available for models for patient consent to RHIOs. The main ones are no consent, opting in, and opting out. Because the Tiger Team determined that meaningful consent should be required, the possibility of using a no consent model is essentially nonexistent. With an opt-in system, the default is that no health information is shared on a RHIO unless a patient “opts in.” With an opt-out system, on the other hand, the default is that all health information is shared through the RHIO unless the patient “opts out.”

At first glance, the opt-out model may seem incompatible with the meaningful consent requirement. Indeed, in the United Kingdom, the opt-out model of its NHS database essentially

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41 Id.
42 Id.
43 See id. at 5–7.
44 Memorandum from the Privacy & Security Tiger Team, supra note 22, at 10.
46 Id.
became an implied consent model where patients’ abilities to opt-out was reduced to a façade because of the speed at which the government was trying to implement the project. However, the Tiger Team’s guidelines for providing patients time and transparency in the decision-making process are aimed at strengthening the opt-out model so that it is a workable option. While Tiger Team member Wes Rishel conceded that “[o]pt-out has been used historically sometimes to avoid consent,” Tiger Team chair Deven McGraw insists that “[o]pt-out is acceptable if it meets all the criteria of meaningful choice.” Therefore, an opt-out model in which the provider offers clear disclosure statements and adequate notice so that patients are able to make an informed decision and have the opportunity to opt-out before making the patient’s data available on a RHIO would be acceptable.

Additionally, with both the opt-in and opt-out models, granular consent may be a possibility so long as the network technology allows for it. The best consent model, regardless of whether it is opt-in or opt-out, would allow for granular consent. Similar to the reasons for the preference of a provider by provider model over a universal consent model, granular consent would allow the patients to have more control over which records are shared and which are not.

Due to the “meaningful consent” requirement, the difference in “opting-in” and “opting-out” is minor. However, if granular consent is available, this distinction may be relevant. If the RHIO allows for the option for sensitive information to be disclosed, then

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47 Kate Devlin, Patients’ Medical Records Go Online Without Consent, TELEGRAPH (Mar. 9, 2010, 10:20 PM), http://www.telegraph.co.uk/health/heathnews/7408379/Patients-medical-records-go-online-without-consent.html.
49 Id.
50 Id.
51 Granular patient consent refers to a patient’s ability to authorize the exchange of certain pieces of information while excluding other pieces. Memorandum from the Privacy & Security Tiger Team, supra note 22, at 4.
52 Id.
the opt-in system would be the only system that would allow a
patient to affirmatively consent to the release of this information.53
Thus, the opt-in system would allow for maximum sharing if
patients are able to consent to the disclosure of sensitive
information.

Furthermore, while there is an argument that the opt-out model
can guarantee meaningful consent if patients are given adequate
notice and information so that they have the opportunity to deny
consent prior to the time when their records are to be shared,
patients whose information is shared may nevertheless claim that
their records were shared without their consent or knowledge.54
Because of the potential claims of lack of meaningful consent55
that may accompany an opt-out model, the opt-in system is the more
ideal system.

The NC HIE should implement an opt-in, provider by provider
system because it allows for more patient control, more
affirmative, meaningful consent, and potentially more sharing of
health information. However, it is important that North Carolina
allow a no consent policy for emergency situations and public
health purposes as California has.56 This would allow a hospital or
physician to access a patient’s records in an emergency situation
even if the patient has not authorized that particular hospital or
physician to access his or her records on a RHIO.57 The
implication of a no consent policy for these reasons should
improve public health outcomes.58

Regardless of the consent model used, the Tiger Team states
that in order for this consent to be “meaningful,” patients must

the disclosure of drug abuse records).
54 Devlin, supra note 47.
55 See infra Part V.A.2.
56 Privacy and Security, NAT’L ACAD. FOR STATE HEALTH POL’Y,
57 Goldstein, supra note 38, at 5–6.
58 Sharona Hoffman & Andy Podgurski, Finding a Cure: The Case for
Regulation and Oversight of Electronic Health Record Systems, 22 HARV. J.
LAW & TECH. 103, 117 (2008) (indicating that access to EHRs could prevent
medical errors in the emergency room).
have time to be educated and to reflect prior to making their decisions about whether to consent to the release of their records. However, the Tiger Team provides very little guidance as to how much education and time are satisfactory. The standards regarding what constitutes “meaningful” will likely expand as more organizations adopt health information technology and more RHIOs develop, creating a demand for more defined standards. At this time, it is unclear whether a conspicuous poster or brochures in the waiting room explaining the health information technology initiative would be sufficient. However, it is likely that as more RHIOs are established, the state will develop, through collaborative efforts with other organizations, educational materials about EHRs and RHIOs, such as the efforts by the state of New York with its website, ehealth4ny.org.

C. Treatment After Denying Consent to Participation

Patients who wish to decline RHIO participation may be concerned about the possibility of discrimination in non-emergency situations. In its recommendation, the Tiger Team maintained that consent to participate in a RHIO cannot be a condition for receiving necessary medical services, but it remained silent on how this would affect services not deemed “necessary.” Presumably, any non-life threatening service or procedure is not “necessary.” Because there is no unqualified duty to treat outside of emergency situations, primary care providers and non-emergency care providers may be able to discriminate against patients who decline to participate in a RHIO.

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59 Memorandum from the Privacy & Security Tiger Team, supra note 22, at 10.
60 Id.
61 Id. (providing only a suggestion that consumer-friendly language be used and be conspicuous at the time of decision making).
63 Memorandum from the Privacy & Security Tiger Team, supra note 22.
Once an organization has invested time and money in implementing and training staff on an EHR system as part of a RHIO, it is unlikely that the organization will want to maintain both a paper system and an electronic system. For instance, if a small physician group adopts this type of health information technology, updates its whole business office protocol, and subsequently finds that for an insignificant percentage of patients it must maintain a separate system, the physician group may find it more efficient and less costly to only accept patients who have consented to participation in the RHIO.

Over time, the benefits of EHRs and RHIOs will likely become evident, and the use of EHRs and participation in RHIOs will become more customary, thus encouraging greater adoption. If widespread adoption occurs, patients who refuse to consent may find themselves in a predicament when no physicians within their managed care networks will accept patients who do not consent to participation in a RHIO. Alternatively, physicians may charge an additional fee to cover administrative and processing costs associated with the maintenance of a separate system for storage, exchange, and insurance reimbursement. The government may later choose to extend protection to unnecessary services, but until then, these results are possibilities.

V. RE COURSE RIGHTS

A. Recourse after Unauthorized Access

1. Private Right of Action to Encourage Participation


66 See Alison Young, Doctors Tack on Fees for Patients, USA TODAY, http://www.usatoday.com/news/health/2010-06-06-doctorsfees N.htm (last updated June 7, 2010) (indicating that doctors are charging additional fees for administrative costs that insurance companies do not cover including charges for filling out health forms for school and athletic teams).
Although the HITECH Act creates new federal breach notification requirements,\textsuperscript{67} it fails to address a significant patient concern. Patients have long been troubled by HIPAA’s failure to provide a private right of action, which is a concern that remains even after the passage of the HITECH Act.\textsuperscript{68} Patients have tried to personally recover after their health information has been exposed, citing HIPAA as the basis of their claims, but have failed because HIPAA does not allow individual recovery.\textsuperscript{69} Some argue that the increased adoption of health information technology for the purpose of creating a NHIN will increase unnecessary exposure of patient health information.\textsuperscript{70} If this contention proves to be correct, patients may become even more interested in having a private right of action.

While a NHIN may increase efficiency and improve health outcomes, the potential increase of unauthorized access to medical records may be of greater concern to patients.\textsuperscript{71} Patients may not prioritize the broader public health advantages when making their decisions to participate. Thus, patients may be less willing to participate if they feel that their protected health information (“PHI”) would be unnecessarily exposed and that they would be without recourse if this occurs.\textsuperscript{72}

In order to encourage participation, it may be necessary to allow a private right of action.\textsuperscript{73} Under the Clinton administration,
Congress considered and rejected a proposal by the Secretary of Health and Human Services to include a private right of action. Moreover, North Carolina does not provide for a private right of action for the inappropriate release of medical records. In the most egregious cases, however, patients in North Carolina may be able to recover damages for the tort of negligent infliction of emotional distress.

In order to encourage patients to participate in RHIOs, North Carolina should consider creating a private right of action in cases of exposed PHI. Such recourse rights may create increased incentives for stringent security measures and prevention of breaches of information in health care organizations and RHIOs. This increased security may assuage the concerns of patients and make way for them to join their local RHIO. Conversely, a private right of action may discourage physicians from adopting EHR systems due to the possibility of increased liability, which would consequently frustrate the efforts to create a NHIN.

2. Tort Claim of Lack of “Meaningful Consent”

Another option for patients who seek damages when their PHI has been accessed by an unauthorized party is to use informed consent theory to pursue a claim of lack of “meaningful consent.” Meaningful consent to participation in a RHIO can be viewed as being almost identical to informed consent to medical treatment. Both are premised on patient autonomy and self-determination.

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76 Id.

77 See Michael D. Greenberg & M. Susan Ridgely, Patient Identifiers and the National Health Information Network: Debunking a False Front in the Privacy Wars, 4 J. HEALTH & BIOMEDICAL L. 31, 60 (2008) (arguing that creating new civil claims for privacy violations would impede the development of a national network).

The threat of a suit encourages doctors to educate and inform their patients of the advantages and disadvantages of a certain course of action.\textsuperscript{79}

A prima facie case of informed consent for medical treatment involves a doctor-patient relationship giving rise to the duty to disclose risks of a certain treatment, the doctor’s breach of the duty to disclose, causation, and damages.\textsuperscript{80} Causation is found in an informed consent case if a reasonable patient would not have consented had he or she known of the risks.\textsuperscript{81} The prima facie case for a meaningful consent claim would mirror that of an informed consent claim. First, the doctor-patient relationship would give rise to the doctor’s duty to educate the patient about the RHIO.\textsuperscript{82} The failure to educate would constitute the breach, and unauthorized access of the information would constitute the injury.

The difference between an informed consent case for treatment and a meaningful consent case for participation in a RHIO would hinge on the type and uniformity of education required. From an informed consent perspective, the plethora of medical conditions and treatment options creates a great risk to the doctor of insufficient disclosure of risks to the patient.\textsuperscript{83} However, there is greater uniformity in information required for disclosure in a case involving meaningful consent to participation in a RHIO. For instance, in one day, a doctor may see numerous medical conditions, all with various treatment options, thus requiring varied

\begin{footnotes}
\footnotetext{80}{N.C. GEN. STAT. § 90-21.13 (2003).}
\footnotetext{81}{Id.}
\footnotetext{82}{See id.}
\footnotetext{83}{Shugrue, supra note 79, at 927 (indicating that a significant number of informed consent suits stem from the lack of disclosure of risks and alternatives to treatment).}
\end{footnotes}
disclosures. However, in that same day, the education required for meaningful consent to a RHIO would be more standardized. This is because the doctor would only be participating in the RHIO in his or her area; thus, the education required for the RHIO would not vary from patient to patient.

Even after taking into account the jurisdiction—professional standard or Canterbury’s patient-centered standard—there would be essentially no variation in education required. In a professional standard jurisdiction, once a RHIO is established, there will likely be consensus among the providers in the community of the standard of disclosure. Again, because the RHIO does not change from patient to patient, as the ailment and treatment options would in an informed consent case, there would essentially be one set of disclosures that would be consistently recited from patient to patient. The same would hold true in a Canterbury jurisdiction. Once a RHIO develops in an area, a standard of what the reasonable patient considers to be material will develop. This standard of disclosure would be used from one patient to the next.

The one caveat may be that for providers of sensitive treatments, like substance abuse for example, the standard may be different from that of general practitioners. However, within the

84 Shugrue, supra note 79, at 894 (indicating that “the central information needed in making an informed consent was a disclosure of the material risks involved in a medical procedure”).
85 See, e.g., EHEALTH4NY, supra note 62.
87 In Texas, medical disclosure panels determine what disclosures a physician should make for various procedures, and if these disclosures are made, the physician benefits from a rebuttable presumption that the informed consent obligations have been met. TEX. CIV. PRAC. & REM. CODE ANN. § 74.106 (West 2005). Similarly, a customary standard would probably arise for the disclosure requirements of the local RHIO.
88 Sensitive treatments often require heightened consent procedures even for directed exchange, so it is likely in order for providers of these treatments to
substance abuse professional community, a standard would eventually develop as well.

B. Future Areas of Medical Malpractice Claims

Another cause of action could arise if the use of EHRs and participation in RHIOs become the standard of care in the medical profession. Liability could arise if a patient who otherwise participates in the local RHIO sees a physician who does not participate. If this patient’s story mirrors Patrick’s visit to Dr. Rodriguez, where the doctor’s lack of knowledge regarding the patient’s other treatments causes the patient to suffer an adverse reaction, the patient could potentially sue the doctor under a medical malpractice claim, alleging that the physician had a duty to access the patient’s medical records through the RHIO to prevent such an error. Of course, as with any other malpractice claim, the patient would have to prove that EHR use and RHIO participation are the standards of care to which the physician failed to conform. Currently, the standard of care does not require physicians to consult a patient’s prior medical records. However, because one of the main justifications for the creation of a NHIN is to reduce medical error, it is foreseeable that consultation of a patient’s prior medical records would become a part of the standard of care, especially if adoption of health information technology and participation in RHIOs increase. The risk of medical malpractice claims based on the doctor’s refusal to participate in the local RHIO is currently minimal but could be an eventual result as more providers choose to adopt EHRs and participate in RHIOs.

obtain meaningful consent to RHIOs, they will have a heightened disclosure requirement when educating their patients about the RHIO. See supra note 53.

90 Id.
92 Id.
93 Helen Oscislawski, HIE Standard of Care—What You Don’t Join Can’t Hurt You. or Could it?, LEGAL HEALTH INFO. EXCHANGE (July 19, 2010),
It is difficult to understand the full extent of concerns and consequences of the adoption of EHRs and the creation of RHIOs and a NHIN until more adoption takes place. Additionally, because there is no one RHIO infrastructure program that is widely used, options and abilities of each vary, which makes it difficult for the ONC, the Tiger Team, and state governments to determine more standard requirements and recommendations for maintaining privacy and assuring meaningful consent. Until a standard program is advocated or certain functions are required of these programs, there will remain numerous concerns about patient privacy, which will likely thwart patient support of the initiative.

Therefore, in order to encourage patient support, North Carolina must advocate a consent model. Adoption of a consent model that offers provider by provider, opt-in, granular consent would encourage patient participation due to the degree of patient control that it allows. Additionally, this type of consent model would help ensure that patient consent is “meaningful” and thus help insulate providers from liability.

Finally, it is important to recognize the expansion of recourse rights that comes with the adoption of health information technology. While the creation of a private right of action in cases of unauthorized access is a policy decision for the state, other areas of recourse are probable. These areas include lack of meaningful consent claims and medical malpractice claims arising from the failure to access patient records on a RHIO.

Health Information Technology