

2012

Making Room for Patient Autonomy in Health Information Exchange: The Role of Informed Consent

Sarah R. Rupp
srupp2@slu.edu

Follow this and additional works at: <https://scholarship.law.slu.edu/lj>



Part of the [Law Commons](#)

Recommended Citation

Sarah R. Rupp, *Making Room for Patient Autonomy in Health Information Exchange: The Role of Informed Consent*, 56 St. Louis U. L.J. (2012).

Available at: <https://scholarship.law.slu.edu/lj/vol56/iss3/18>

This Comment is brought to you for free and open access by Scholarship Commons. It has been accepted for inclusion in Saint Louis University Law Journal by an authorized editor of Scholarship Commons. For more information, please contact [Susie Lee](#).

MAKING ROOM FOR PATIENT AUTONOMY IN HEALTH INFORMATION EXCHANGE: THE ROLE OF INFORMED CONSENT

INTRODUCTION

Over the past fifty years, the doctrine of informed consent has played an important role in changing the dynamics of the doctor-patient relationship.¹ In the past decade, health information technology (“HIT”) has played an increasingly important role in changing the dynamics of the health care industry.² Years from now, will onlookers note that the doctrine of informed consent has played an important role in HIT? This Comment examines the extension of informed consent from the treatment context to the context of health information sharing, focusing on the distinct roles of providers and payers therein.

Health information sharing across industry stakeholders represents a growing aspect of HIT development—one positioned to bring advances in both clinical and non-clinical areas of the health care industry.³ This sharing, facilitated through health information exchange (“HIE”), will give a physician immediate and timely access to a patient’s health information and amplify the patient information to which a physician has access during a clinical encounter. Until recently, physicians have been restricted to patient information from paper or electronic medical records stored in their offices.⁴ Through HIE,

1. See JESSICA W. BERG ET AL., *INFORMED CONSENT: LEGAL THEORY AND CLINICAL PRACTICE* 44 (2d ed. 2001) (describing the onset of contemporary informed consent litigation in the mid-1950s and the consequent requirements imposed upon the physician in the physician-patient relationship).

2. See DELOITTE & TOUCHE USA LLP, *HEALTH INFORMATION EXCHANGE (HIE) BUSINESS MODELS: THE PATH TO SUSTAINABLE FINANCIAL SUCCESS* 4 (2006), available at http://www.providersedge.com/ehdocs/ehr_articles/Health_Info_Exchange_Business_Models.pdf (noting that although HIE has its origin in the early 1990s, notable developments commenced with health information sharing within communities at the start of the twenty-first century); Joshua R. Vest & Larry D. Gamm, *Health Information Exchange: Persistent Challenges and New Strategies*, 17 J. AM. MED. INFORMATICS ASS’N 288, 289 (2010) (describing efforts to exchange health information electronically from the early 1990s to present).

3. See generally Leslie Pickering Francis, *The Physician-Patient Relationship and a National Health Information Network*, 38 J.L. MED. & ETHICS 36 (2010) (describing clinical benefits such as automatic data entry, reduced error risks, reduced costs, and increased transparency in physician-patient relationships, with non-clinical benefits including improved external evaluation of physician performance, quality improvement, and expanded research).

4. OFFICE OF THE NAT’L COORDINATOR FOR HEALTH INFO. TECH., *GET THE FACTS ABOUT ELECTRONIC HEALTH RECORDS: ADVANCING AMERICA’S HEALTH CARE* (2011),

physicians will treat their patients based upon a more complete patient health record that combines information such as recent lab tests, diagnoses, and medical history recorded by other treating physicians as well. This electronic health record (“EHR”) is marked by its interoperability; that is, an EHR is “created, managed, and consulted by authorized clinicians and staff across more than one health care organization.”⁵ Thus a primary care physician, dermatologist, cardiologist, and maybe even dentist are able to upload directly to their common patient’s EHR and then treat the patient based upon this more complete patient health picture. Among potential benefits of HIE, patients become drivers of HIT. Among potential risks, patients are left in the backseats listening to loud music.

If patients are to be autonomous stakeholders in HIE, this Comment argues that informed consent must have an integral role in HIE development and implementation. Part I describes the HIE framework, stakeholders, and patient consent models on the table. Part II introduces informed consent as one means with which to safeguard patient autonomy as the health care industry moves into the future. Applying this doctrine, part III proposes that patient autonomy is best reflected in a consent model that calls for affirmative patient participation when providers will exchange EHRs. Finally, part IV examines the implications of participation in HIE by those outside of the treatment context, and specifically by third-party payers (“payers”), ultimately proposing that a role for payers necessarily entails a special role for informed consent.

I. BIG PICTURE

HIT has assumed a leading role in the future of health care in the United States. Even cautious accounts recognize the vast benefits promised by a technologically-integrated health care system.⁶ To name a few, the implementation of HIE is projected to improve quality of care, reduce health care costs, and expand medical research.⁷ Indeed, HIT development has been

available at http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_0_7461_2996_20385_43/http/wci-pubcontent/publish/onc/common_content/alt_spot_light/files/hitech_overview_consumer_fact_sheet_v5.pdf.

5. THE NAT’L ALLIANCE FOR HEALTH INFO. TECH., REPORT TO THE OFFICE OF THE NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY ON DEFINING KEY HEALTH INFORMATION TECHNOLOGY TERMS 15 (2008) [hereinafter NATIONAL ALLIANCE].

6. See Richard J. Baron et al., *Electronic Health Records: Just around the Corner? Or over the Cliff?*, 143 ANNALS INTERNAL MED. 222, 223–24 (2005) (describing multiple benefits of EHR use, but also describing first-hand the financial and practical difficulties of implementing EHR use in a primary care practice).

7. DELOITTE & TOUCHE USA LLP, *supra* note 2, at 7; MELISSA M. GOLDSTEIN, CONSUMER CONSENT OPTIONS FOR ELECTRONIC HEALTH INFORMATION EXCHANGE: POLICY CONSIDERATIONS AND ANALYSIS 57 (2010), available at healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_11673_911197_0_0_18/ChoiceModelFinal032610.pdf.

identified as not only beneficial, but indispensable: “[t]he fragmentation of health care delivery without the parallel distribution of critical health care information lays the groundwork for an error-prone and inefficient health care delivery system.”⁸ Developing an integrated system has been a major focus of health reform in the United States.⁹ In 2004, former President George W. Bush created the Office of the National Coordinator for Health Information Technology (“ONC”), predicting that Americans would have interoperable EHRs by 2014.¹⁰ As part of the American Recovery and Reinvestment Act (“ARRA”) of 2009, President Obama directed approximately twenty billion dollars to the Health Information Technology (“HITECH”) Act, which mandates the ONC to adopt HIT standards and create incentives for the adoption of EHR technology.¹¹

This section briefly addresses the HIE framework. It describes the steps being taken to realize the revolutionary potential of HIT, the stakeholders involved in HIE, and HIE patient consent models currently under consideration and/or use. Yet “[t]hat confidence does not conflict with caution,” reminds Epictetus.¹² The implementation of HIE has potentially negative ramifications, not the least of which being its effect on patients’ control of personal health information.¹³ Accordingly, this section presents the HIE framework as a foundation for considering the integral role of informed consent therein.

A. *HIE Framework*

HIE is a process,¹⁴ defined by the Department of Health and Human Services (“HHS”) as “[t]he electronic movement of health-related information among organizations according to nationally recognized standards.”¹⁵ To present, there are 234 public or private HIE initiatives working on intrastate

8. Gregory W. Daniel et al., *Efficiency and Economic Benefits of a Payer-Based Electronic Health Record in an Emergency Department*, 17 ACAD. EMERGENCY MED. 824, 824 (2010).

9. Vest & Gamm, *supra* note 2, at 288–89.

10. Mike Allen, *Bush Touts Plan for Electronic Medicine: Campaign Aimed at ‘Wired’ Voters*, WASH. POST, May 28, 2004, at A8; *About ONC*, OFF. NAT’L COORDINATOR FOR HEALTH INFO. TECH., http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__onc/1200 (last visited Mar. 15, 2012).

11. Daniel J. Gilman & James C. Cooper, *There Is a Time to Keep Silent and a Time to Speak, the Hard Part Is Knowing Which Is Which: Striking the Balance Between Privacy Protection and the Flow of Health Care Information*, 16 MICH. TELECOMM. & TECH. L. REV. 279, 280 nn.2 & 4 (2010).

12. EPICETUS, THE DISCOURSES AS REPORTED BY ARRIAN, THE MANUAL, AND FRAGMENTS bk. II, at 213 (E. Capps et al. eds., W. A. Oldfather trans., Loeb Classical Library 1926) (c. 108 A.D.).

13. Deborah C. Peel, Op-Ed., *Your Medical Records Aren’t Secure*, WALL ST. J., Mar. 24, 2010, at A17.

14. NATIONAL ALLIANCE, *supra* note 5, at 23.

15. *Id.*

and interstate levels to achieve interoperability in the exchange of health information.¹⁶ Seventy-three initiatives are now operational; that is, they transmit data used by healthcare stakeholders.¹⁷ By far, the majority of HIE initiatives are being driven by statewide leadership—whether in planning or implementation phases.¹⁸ Collaborative efforts on the intrastate and interstate levels have been implemented in the form of Regional Health Information Organizations (“RHIOs”).¹⁹ Where health information organizations (“HIOs”) organize and oversee the exchange of health information, RHIOs do so within defined geographic regions in order to improve the health of the populations therein.²⁰

As advancements in HIE continue on intrastate and interstate levels, the ultimate goal remains to transition HIE initiatives into a Nationwide Health Information Network (“NHIN”).²¹ Through the NHIN Exchange, federal and private initiatives are working to establish nationwide standards, services, and policies to facilitate the exchange of information on a national level.²² To this end, the ONC Health IT Policy Committee is making recommendations regarding the achievement of secure and viable HIE on a national scale.²³

B. Stakeholders in HIE

The success of HIE requires a host of stakeholders. Providers, ranging from physicians, physician assistants, nurses, hospitals, clinics, outpatient centers, and many more, create the front line of patient care. Currently, hospitals and primary care physicians are the largest stakeholders, among both

16. EHEALTH INITIATIVE, THE STATE OF HEALTH INFORMATION EXCHANGE IN 2010: CONNECTING THE NATION TO ACHIEVE MEANINGFUL USE 5, 30 (2010), available at http://www.thcc2.org/PDFs/ehealth_meaningfull_use.pdf.

17. *Id.* at 8 (noting that this number is up from nine in 2004, thirty-two in 2007, and fifty-seven in 2009).

18. *Id.* at 16 (showing that of 133 responding initiatives, 107 initiatives are working with at least “formal state leadership” as compared to twenty-six operating on more local levels).

19. DELOITTE & TOUCHE USA LLP, *supra* note 2, at 4; Vest & Gamm, *supra* note 2, at 290.

20. NATIONAL ALLIANCE, *supra* note 5, at 25.

21. See OFFICE OF THE NAT’L COORDINATOR FOR HEALTH INFO. TECH., GET THE FACTS ABOUT THE NATIONWIDE HEALTH INFORMATION NETWORK, DIRECT PROJECT, AND CONNECT SOFTWARE (2010), available at http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_12811_953714_0_0_18/HITECH_FS_HIN_Facts_V1.pdf (discussing efforts to expand HIE through NHIN standards).

22. *Id.*

23. For access to the Committee’s recommendations through Dec. 7, 2011, see *National IT Policy Committee: Recommendations to the National Coordinator for Health IT*, OFF. NAT’L COORDINATOR FOR HEALTH INFO. TECH., http://healthit.hhs.gov/portal/server.pt?open=512&objID=1815&parentname=CommunityPage&parentid=7&mode=2&in_hi_userid=11113&cached=true (last visited Feb. 1, 2012).

providers and HIE stakeholders generally.²⁴ The federal government, through the Veterans Health Administration, is the largest provider in the United States.²⁵ HIE vendors are also necessary participants. Vendors put the “Exchange” in “Health Information Exchange,” providing the technology to replace paper and non-interoperable electronic medical records with interoperable EHR databases.²⁶ A recent study has identified five vendors as market dominators—out of thirty-eight potential vendors, the only five to be considered by more than ten percent of buyers.²⁷ Patients are the very source of health information. Having one’s health information entered into an exchange means better communication between treating physicians, but it also allows for the aggregation of health information into databases that will become invaluable to providers, researchers, public health analysts, payers, and beyond.²⁸ Finally, federal and state agencies have been very instrumental in the early stages of HIE development.²⁹ Federal ARRA funding has been crucial to HIE start-up, although in 2010, 107 of 199 responding HIE initiatives reported no dependence upon federal funding for sustainability.³⁰ As ARRA funds continue to diminish, it will be crucial for all initiatives to rely upon alternate funding.³¹ Aside from funding, government agencies will have a continuing role in standard-setting and the development of HIE across states and ultimately on a national level.³² Stakeholders who operate outside of the treatment context, including payers, researchers, and public health analysts, are addressed in part IV.

24. EHEALTH INITIATIVE, *supra* note 16, at 15.

25. *About VHA*, DEP’T VETERANS AFF., <http://www.va.gov/health/aboutVHA.asp> (last updated Oct. 5, 2011). *See generally* Colene M. Byrne et al., *The Value from Investments in Health Information Technology at the U.S. Department of Veterans Affairs*, 29 HEALTH AFF. 629 (2010) (providing a detailed update on the status of HIT developments in the Department of Veterans Affairs).

26. The current meaningful use capability requirements for vendors’ EHR systems are set out in 45 C.F.R. §§ 170.205–.306. For a vendor comparison tool, see Margaret Steen, *17 Leading EHR Vendors*, INFO. WEEK: HEALTHCARE (Dec. 18, 2010), <http://www.informationweek.com/news/galleries/healthcare/EMR/228800771>.

27. Anthony Guerra, *Five Vendors Dominate HIE Market*, INFO. WEEK: HEALTHCARE (July 8, 2010), http://www.informationweek.com/news/healthcare/clinical_systems/showArticle.jhtml?articleID=225702631 (reporting on KLAS, HEALTH INFORMATION EXCHANGES: PERCEPTION IN AN EXPANDING FRONTIER (2010)).

28. *See generally* Francis, *supra* note 3 (describing in detail the clinical and non-clinical benefits of EHRs).

29. *See supra* notes 18–20 and accompanying text.

30. EHEALTH INITIATIVE, *supra* note 16, at 11. The number of HIE initiatives no longer reliant upon federal funding has increased from 2009, when only seventy-one reported not being dependent. *Id.* at 2.

31. DELOITTE & TOUCHE USA LLP, *supra* note 2, at 9.

32. EHEALTH INITIATIVE, *supra* note 16, at 2 (noting that HIE initiatives cite federal policy and governance as a major challenge).

Notwithstanding the importance of providers, vendors, and patients to HIE, consideration of each highlights important barriers to a truly integrated health care system. Providers face substantial up-front financial and administrative burdens in the decision to invest in a system of EHRs.³³ The technology required to support the envisioned HIE is vast, and it remains unclear whether vendors' technological capacities will be able to keep up with policy.³⁴ An optimal HIE database will include EHRs compiled from all patients, but patients may not wish to participate.³⁵ Finally, state and federal agencies face significant challenges in setting standards for HIE on intrastate, interstate, and federal levels, garnering the trust of participants, and maintaining a balance between the benefits to be reaped from HIE and the risks inherent to an ever-increasing aggregation of EHRs.

C. Patient Consent Models

“The issue of whether, to what extent, and how individuals should have the ability to exercise control over their health information represents one of the foremost policy challenges related to the electronic exchange of health information.”³⁶ There are currently five models for patient participation in HIE either under consideration or in use among HIE initiatives, providing patients with varying levels of participation choice.³⁷ In a “No Consent” model, patient health information is automatically exchanged and patients do not have the option to forgo participation.³⁸ This model comports with the federal floor for privacy protection established by HIPAA but does not accommodate individual choice.³⁹ Some states that began exchanging health information without first obtaining consent have, as the exchanges developed, adopted models incorporating choice.⁴⁰ A global “Opt-Out” participation model maintains inclusion of a pre-defined set of health information as the

33. Gilman & Cooper, *supra* note 11, at 295.

34. Neil Versel, *Privacy, Security 'Tiger Team' Told Granular Consent Technology is Flawed*, FIERCEHEALTHIT (Aug. 9, 2010), <http://www.fiercehealthit.com/story/privacy-security-tiger-team-told-granular-consent-technology-flawed/2010-08-09>.

35. Micky Tripathi et al., *Engaging Patients for Health Information Exchange*, 28 HEALTH AFF. 435, 435 (2009).

36. GOLDSTEIN, *supra* note 7, at ES-1.

37. *Id.* at 5–7.

38. *Id.* at 5. For example, state laws in Indiana, Virginia, and Tennessee do not require patient consent for EHR creation. *Id.* at 15.

39. *Id.* at 5–6.

40. Kathleen Delaney Greenbaum et al., Health Information Security and Privacy Collaboration, Intrastate and Interstate Consent Policy Options—Final Report 2-2 (Mar. 31, 2009) (unpublished report prepared for the Office of the National Coordinator for Health Information Technology), available at healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_10741_872327_0_0_18/C2_1_1_Final_Rpt.pdf.

exchange default, but also allows the patient to fully opt-out of participation.⁴¹ This model has been widely adopted and is considered to be both easiest and most adept for creating a robust pool of EHRs while still giving patients the choice of whether to participate.⁴² Less pursued has been the global “Opt-In” model,⁴³ whereby patients must actively manifest their consent to participation before the pre-defined set of information is entered into the exchange.⁴⁴ While this model calls for a higher degree of patient initiative before information is exchanged,⁴⁵ it also carries the risk of low participation levels and thus could vitiate the benefits of an exchange.⁴⁶ The fourth and fifth consent models replace the global consent approach with granular participation choices: the “Opt-Out with Exceptions” approach has the participation default of the opt-out model but allows patients to granularly withhold information from the exchange, and the “Opt-In with Restrictions” model provides a basis for a patients to consent to the inclusion of some, but not necessarily all, of their health information into the exchange.⁴⁷

Granular approaches under consideration provide patients the choice whether to participate in exchange based upon (1) data type; (2) provider; (3) time range; or (4) purpose, or some combination therein.⁴⁸ Granularity by data type allows a patient to withhold a specific data set from the exchange.⁴⁹ The data blocked could range from a patient’s reproductive health records, to all medication records, to mental health records.⁵⁰ Exchange models that have adopted this type of granularity have done so largely based upon what they classify as “sensitive health information,” which is then as a data set

41. GOLDSTEIN, *supra* note 7, at 6. For example, the Delaware HIE uses an opt-out consent mechanism for provider access (but requires no consent for EHR creation), and Maryland, Kentucky, and Nebraska all use an opt-out approach. *Id.* at A-1, A-3; MO. OFFICE OF HEALTH INFO. TECH., HEALTH INFORMATION EXCHANGE OPERATIONAL PLAN L-1 (June 30, 2010), available at http://www.dss.mo.gov/hie/action/pdf2010/operationalplan_draft.pdf.

42. See Howard Anderson, *Survey: ‘Opt-In’ for HIE Consent is Rare*, HEALTHCARE INFO. SECURITY (July 23, 2010), http://www.healthcareinfosecurity.com/articles.php?art_id=2779 (explaining that an “Opt-In” model would create an administrative burden by requiring every patient to sign a consent form).

43. See EHEALTH INITIATIVE, *supra* note 16, at 24 (finding that of 199 responding HIE initiatives, only 36 reported using an “opt-in” model to include patient information in HIE).

44. GOLDSTEIN, *supra* note 7, at 7. States taking an opt-in approach include Massachusetts, New York, Rhode Island, and Washington. *Id.* at A-4 to -7.

45. *Id.* at 51.

46. See Anderson, *supra* note 42.

47. GOLDSTEIN, *supra* note 7, at 6-7.

48. *Id.* at 7-12.

49. *Id.* at 8.

50. *Id.*

summarily withheld.⁵¹ The National Center for Vital and Health Statistics (“NCVHS”) has recommended that the future NHIN adopt a consent model that allows a patient to control the disclosure of nationally predetermined “sensitive” categories of health information.⁵² Sequestered information would be marked by a notation in the patient’s record indicating that certain information has been blocked from access.⁵³ Where an exchange adopts a model with granularity by provider, the patient may have the choice to disclose her EHR to either specific providers (Dr. Jones and Dr. Smith only) or to specific provider types (all MDs but no RNs), or to restrict access within the provider type (OB/GYN but not dentist).⁵⁴ While this type of granularity threatens efficient and effective coordination of care across providers,⁵⁵ it may serve as an effective model for patients wishing to restrict access by non-providers (e.g. payers or researchers).⁵⁶ Granularity by time range gives a patient control of information according to its time and date.⁵⁷ Among uses for such a model is emergency room treatment, in which emergency providers could “break the glass” of the protected information and access it only for the time period in which the patient is treated for her emergency.⁵⁸ Finally, where a patient has granular control according to purpose of access, she may choose the ways in which her EHR will be put to use (e.g. for clinical purposes but not for research).⁵⁹

There is notable confusion for a HIE initiative regarding the degree of consent required within each state, the consent requirements for a multi-state approach, and the best approach in anticipation of the developing NHIN. The HIPAA Privacy Rule does not require patient consent for covered entities (including providers and payers) to use identifiable health information for

51. *Id.* at 9. For example, federal law affords extra protection to drug and substance abuse information. 42 C.F.R. § 2.31(a)(1) (2010).

52. Letter from Simon P. Cohn, Chairman, Nat’l Comm. on Vital and Health Statistics, to Michael O. Leavitt, Sec’y, Dep’t of Health and Human Servs., Individual Control of Sensitive Health Information Accessible via the Nationwide Health Information Network for Purposes of Treatment 3–4 (Feb. 20, 2008), available at www.ncvhs.hhs.gov/080220lt.pdf [hereinafter Letter from Simon P. Cohn].

53. *Id.* at 7.

54. GOLDSTEIN, *supra* note 7, at 9.

55. *See id.* (noting that granularity by provider could compromise coordination of care because a physician may not be able to get “the full picture” of the patient); Letter from Simon P. Cohn, *supra* note 52, at 5–6 (explaining that granularity by provider may burden the efficiency by creating the need to question patients about every category to insure no relevant information is missing).

56. *See infra* Part IV for consideration of granularity to the exchange in which payers participate.

57. GOLDSTEIN, *supra* note 7, at 10.

58. *Id.*; MO. OFFICE OF HEALTH INFO. TECH., *supra* note 41, at 46.

59. GOLDSTEIN, *supra* note 7, at 10.

clinical, payment, or health care operations purposes.⁶⁰ It does, however, allow states to require consent for these purposes, and some states have done so through statutes and/or case law.⁶¹ The Health Information Security and Privacy Collaboration (“HISPC”), a national initiative developed by contract with HHS, has been instrumental in addressing privacy and security challenges inherent in multi-state collaborative approaches to HIE.⁶² HISPC conducted a study of statutory options with which an interstate (and eventually national) exchange could implement uniform consent procedures.⁶³ Comparing statutory provisions of model act, choice of law, uniform code, and interstate compact, the study ultimately recommended that an interstate compact would best resolve conflicts among states, legally bind participating states, and quickly adjust to fit ever-growing exchange.⁶⁴ An outstanding issue is whether—in light of the constitutional requirement that states enter into contracts with each other only after obtaining the consent of Congress—an interstate compact would require congressional approval.⁶⁵

The ONC Health IT Committee’s Privacy and Security Tiger Team has grappled with the appropriate role of patient consent in exchanging health information. In August 2010 it released its recommendation that patients have the opportunity to consent to participation before any personal health information is exchanged with a third party, i.e. beyond the direct treatment context.⁶⁶ Notwithstanding the Tiger Team’s recommendation, however, some highly successful HIE initiatives do exchange certain personal health information without first obtaining consent.⁶⁷ In the wake of potentially nationalized exchange, the viability of such a no-consent framework is

60. Greenbaum et al., *supra* note 40, at 2-1.

61. GOLDSTEIN, *supra* note 7, at 48; Greenbaum et al., *supra* note 40, at 2-1.

62. *The Health Information Privacy and Security Collaboration*, OFF. NAT’L COORDINATOR FOR HEALTH INFO. TECH., <http://healthit.hhs.gov/portal/server.pt?open=512&mode=2&cached=true&objID=1240> (last updated April 9, 2010).

63. Greenbaum et al., *supra* note 40, at 1-1 to -2.

64. *Id.* at 5-6 to -7.

65. *Id.* at 5-7 to -8.

66. Letter from Paul Tang, Vice Chair, HIT Policy Comm., to David Blumenthal, Nat’l Coordinator for Health Info. Tech., Dep’t of Health and Human Services 10 (Sept. 1, 2010), available at http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_11673_949147_0_0_18/Transmit-Priv-SecTigerTeam-Nov-19-10.pdf [hereinafter Letter from Paul Tang] (“When the decision to disclose or exchange the patient’s identifiable health information from the provider’s record is not in the control of the provider or that provider’s organized health care arrangement (‘OHCA’), patients should be able to exercise *meaningful consent* to their participation.”) (emphasis in original).

67. For example, the Indiana HIE takes a “no consent” approach, but has established trust through enhanced privacy protections such as withholding behavioral and mental health information from exchange. Lisa A. Eramo, *Permission Predicament*, FOR THE REC., Sept. 13, 2010, at 24.

questionable; as exchanges grow and consolidate geographically, more stakeholders will necessarily become involved and consequently, there will be increased hands in the exchange and more opportunities for threats to security and privacy.⁶⁸ Beyond increased risks, the no consent model is troublesome as it fails to recognize the fundamental, per se importance of patient autonomy and accordingly, the role of patients as equal partners in HIE.

In order to underscore why the implementation of particular consent models is so important, Part II considers the theory of informed consent and examines the relationship between the patient and the option of consent in HIE.

II. INFORMED CONSENT—THEORETICAL FRAMEWORK

A. *History and Purpose of Informed Consent*

Informed consent, as a concept, evades uniform definition. In the health care context, descriptions include “process of communication,”⁶⁹ “written permission,”⁷⁰ and “the giving of information to the patient as to just what would be done and as to its consequences,”⁷¹ and as described below, it is approached from both moral and legal perspectives. Considering the purpose of informed consent—and what it really means to give informed consent—is helpful in determining just what role informed consent should have in the electronic exchange of patients’ health information. This section considers informed consent primarily in terms of individual autonomy. It lays out a framework with which to consider informed consent in health care and specifically, the autonomous patient and the creation and use of EHRs.

Professors Faden and Beauchamp describe two distinct but corresponding doctrines of informed consent: 1) a moral doctrine structured by principles and 2) a legal doctrine focused on procedural rules and requirements.⁷² Faden and Beauchamp devote a great deal of attention to informed consent, from a moral perspective, as “autonomous authorization by a patient or subject.”⁷³

68. Nicholas P. Terry & Leslie P. Francis, *Ensuring the Privacy and Confidentiality of Electronic Health Records*, 2 U. ILL. L. REV. 681, 725 (2007) (“[A] national, fully interoperable architecture poses the greatest privacy, confidentiality, and security risks and suggests that the protection of personal health information will depend on patient choice and legal protections.”).

69. *Patient Physician Relationships Topics: Informed Consent*, AM. MED. ASS’N, <http://www.ama-assn.org/ama/pub/physician-resources/legal-topics/patient-physician-relationship-topics/informed-consent.shtml> (last visited Mar. 15, 2012).

70. OFFICE FOR CIVIL RIGHTS, SUMMARY OF THE HIPAA PRIVACY RULE 5 (2003), available at <http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/privacysummary.pdf>.

71. RUTH R. FADEN & TOM L. BEAUCHAMP, A HISTORY AND THEORY OF INFORMED CONSENT 275 (1986) (quoting *Planned Parenthood of Cent. Mo. v. Danforth*, 428 U.S. 52, 67 n.8 (1976)).

72. *Id.* at 24–25.

73. *Id.* at 3.

Alternatively, the legal doctrine of informed consent is focused less on patient autonomy and more on a physician's duties and liabilities—the duty to inform and to obtain consent before treating along with the legal mechanisms by which a physician avoids liability.⁷⁴ The moral and legal doctrines of informed consent correspond, with the moral providing a foundation for the creation and promulgation of legal requirements.⁷⁵ This Comment will argue that the strongest justification for informed consent in the context of HIT is necessarily a moral justification; patient autonomy, but not rules and requirements, justify upholding patient choice despite increased costs, administrative burdens, and even relaxed security or privacy concerns.

The concept of autonomy has a vibrant history beginning well before 1957—the date cited as the birth of autonomy-based informed consent in the United States⁷⁶—and extending well beyond the bounds of the bioethical considerations in which the concept is so often framed:⁷⁷

[Enlightenment] philosophy reinforced emphasis on the sanctity of the individual conscience, which was central to beliefs of the Puritans and other radical Protestant groups who came to the New World from Europe . . . [I]ndividualistic values were reinforced by the 'frontier mentality' of self-reliance that emerged with the settlement of the new continent, that remains highly prized in American culture today, and that further reinforces individualistic values.⁷⁸

Thus underlying the concept of autonomy across fields from moral philosophy to politics to bioethics are notions of liberty, self-rule, and individualism.⁷⁹ In bioethics, this translates as a patient's responsibility and control over a treatment plan in the face of an expert physician's divergent but beneficent opinion.⁸⁰

74. *Id.*

75. *Id.* at 24.

76. FADEN & BEAUCHAMP, *supra* note 71, at 59 (describing the views of leading authorities Martin Pernick and Jay Katz).

77. Autonomy holds a central role in Kant's moral philosophy, namely his "categorical imperative" that one should "[a]ct only on that maxim by which you can at the same time will that it should become a universal law." IMMANUEL KANT, *GROUNDWORK FOR THE METAPHYSICS OF MORALS* ¶ 25 (Thomas E. Hill and Arnulf Zweig eds., Arnulf Zweig trans., Oxford Univ. Press 2002). This famous tenet exemplifies Kant's reverence for rationality, manifested in the autonomous will—the categorical imperative is the foundational principle according to which the truly autonomous will conforms. *Id.* As explained by John Stuart Mill, "[e]ach is the proper guardian of his own health, whether bodily or mental and spiritual." BERG ET AL., *supra* note 1, at 23 (quoting JOHN STUART MILL, *ON LIBERTY* 12 (Elizabeth Rapaport ed. 1978)).

78. BERG ET AL., *supra* note 1, at 21.

79. GERALD DWORKIN, *THE THEORY AND PRACTICE OF AUTONOMY* 6 (1991).

80. BERG ET AL., *supra* note 1, at 18–19; DWORKIN, *supra* note 79, at 112–13.

B. Autonomy Defended and Privacy Distinguished

As legal scholar Melissa Goldstein describes the role of autonomy in HIT, “[i]t is this idea—that policies governing rule-based consent should be based on autonomous decision making—that must remain central to our policy making during this nascent stage of HIT development if we are to create a framework for health care information sharing that facilitates patient choice.”⁸¹ This postulation presupposes that health information sharing *should* facilitate patient choice. Legal scholar Carl Schneider points out, however, that due to complexities inherent in the medical context, choice may not actually be a keystone to patient satisfaction.⁸² Schneider characterizes the focus on patient autonomy as an “autonomy paradigm” in which “hyper-rationalist assumptions” lead decisionmakers to overlook the reality of patients’ fears,⁸³ lack of knowledge,⁸⁴ and pain⁸⁵ and categorize all patients as “autonomy-maximizers.”⁸⁶ “The paradigm calls for patients to make medical decisions. The evidence suggests that some significant number of patients are loath to assume that authority.”⁸⁷ A response to the recent emphasis on patient autonomy, Schneider’s approach contends that pushing patients as decisionmakers may run contrary to the reality of patients’ desires: “many patients reject the full burden of decision autonomists would wish upon them.”⁸⁸ However, in the context of HIT and consent to having one’s health information exchanged, the autonomy principle may not be so “hyper-rational.” Arguably, the factors that allegedly overwhelm patients in the treatment context will factor less strongly in decision making regarding participation in HIE. Schneider points out that desire for autonomy is inversely correlated to the seriousness of the condition.⁸⁹ Following this line of reasoning, it seems that when participation in HIE rather than treatment—whether minor or serious—is at issue, there will be more room for the autonomous patient.

Shifting the focus to the HIT context, it is important to distinguish informed consent from privacy and security. While informed consent has an important role in protecting patient privacy, its function is not so restricted.⁹⁰

81. Melissa M. Goldstein, *Health Information Technology and the Idea of Informed Consent*, 38 J.L. MED. & ETHICS 27, 29 (2010).

82. CARL E. SCHNEIDER, *THE PRACTICE OF AUTONOMY: PATIENTS, DOCTORS, AND MEDICAL DECISIONS* 32–33 (1998).

83. *Id.* at 35, 56.

84. *Id.* at 50.

85. *Id.* at 75.

86. *Id.* at 35.

87. SCHNEIDER, *supra* note 82, at 47.

88. *Id.* at xii.

89. *Id.* at 36.

90. Goldstein, *supra* note 81, at 30.

As described above, informed consent serves an independent purpose in reflecting and facilitating the patient's independence and self-decision;⁹¹ that is, the patient's ability to provide "autonomous authorization."⁹² Much of the discussion surrounding patient HIE consent models has focused on the ways in which increased patient control relates to the privacy, security, and confidentiality risks of storing and exchanging aggregated EHRs. The Center for Democracy and Technology, for example, frames the issue of consent in terms of its relation to privacy protection: "Patient consent should be viewed as one element of a comprehensive framework of privacy protections for personal health information, and any requirement for patient consent or authorization should be an adjunct to clear rules that limit how the information can be accessed, used and disclosed and that are adequately enforced."⁹³ There is no doubt that consent alone cannot ensure patient privacy,⁹⁴ but it is misleading to address consent only insofar as it furthers this end. An example borrowed from the context of human subjects research, the Institute of Medicine ("IOM") recently recommended relieving information-based research on human subjects from compliance with the Common Rule,⁹⁵ which requires informed consent.⁹⁶ As Professor Mark Rothstein pointed out, however, the IOM's justifications for this recommendation—including the allegedly minimal privacy risks involved—overlook the role of informed consent outside of privacy protection: "The IOM Report's central proposal demonstrates a lack of respect for individuals as autonomous agents and assumes that all individuals have the same values and interests with regard to research."⁹⁷

C. *Theory of Informed Consent in the HIT/HIE Context*

One might argue that because the choice whether to participate in HIE does not entail complex treatment decisions, the choice does not need to be

91. For further discussion of the relation between autonomy and informed consent, see DWORKIN, *supra* note 79, at 100–03.

92. See Goldstein, *supra* note 81, at 27–30 (discussing Faden and Beauchamp's formulation of informed consent as, in one sense, "autonomous authorization" and distinguishing informed consent from privacy and security protection); *supra* notes 72–75 and accompanying text.

93. CTR. FOR DEMOCRACY & TECH., RETHINKING THE ROLE OF CONSENT IN PROTECTING HEALTH INFORMATION TECHNOLOGY 10–11 (2009), available at <http://www.cdt.org/health/privacy/20090126Consent.pdf>.

94. See Deven McGraw et al., *Privacy as an Enabler, Not an Impediment: Building Trust into Health Information Exchange*, 28 HEALTH AFF. 416, 418 (2009) (explaining that a heavy focus on the role of consent in privacy protection may serve to weaken patient privacy).

95. 45 C.F.R. § 46 (2010).

96. INST. OF MED., BEYOND THE HIPAA PRIVACY RULE: ENHANCING PRIVACY, IMPROVING HEALTH THROUGH RESEARCH 30–34 (2009).

97. Mark A. Rothstein, *Currents in Contemporary Ethics: Improve Privacy in Research by Eliminating Informed Consent? IOM Report Misses the Mark*, 37 J.L. MED. & ETHICS 507, 509 (2009).

aggressively protected; that is, consent to participate in HIE is distinguished from consent to treatment not only in the type of choice at issue, but in what is at stake. In one sense, participation in HIE does not bring to mind the immediate questions of bodily rights, integrity, and personal health that are implicit in treatment decisions. However, in an important sense physical integrity is very much related to the decision whether to participate in HIE: the choice of whether to participate is a choice whether to grant access to *personal health* information. EHRs are an area in which patients may feel empowered to make informed choices and accordingly, the choice may be that much more important—as Schneider argues, competent patients forgo decision making because the decisions are too complex.⁹⁸

HIT highlights the relationship between consent and privacy and the foundational importance of patient autonomy therein. Professors Nicholas Terry and Leslie Francis describe an “instrumental approach” similar to Faden and Beauchamp’s legal doctrine of informed consent, whereby “institutions and compliance” rather than patient control and choice are placed at the forefront of privacy concerns.⁹⁹ HIE presents a pivotal context for the future of autonomy. Healthcare technology, itself “process-driven,” runs the risk of undermining an autonomy justification, but as Terry and Francis explain, EHRs could also become a catalyst for the role of autonomy in upholding consent, privacy, and confidentiality:

Process-driven, technologically enabled healthcare delivery, of which the EHR is a core component, seeks to minimize the role of the individual autonomous physician (and the correlative autonomous patient). . . . [T]he adoption of EHR technologies should be used as an opportunity to reverse this [instrumental] trend and adopt an approach to patient privacy and confidentiality that recognizes an autonomy-based, default position of full patient control over personal information.¹⁰⁰

Recognition of patient autonomy in the HIT movement is a means by which to gain patient trust in electronic record-keeping.¹⁰¹ Trust is crucial in a regime vulnerable to security and privacy breaches,¹⁰² but autonomy is about much more than assuaging security and privacy concerns.¹⁰³ Indeed, advances in HIT are positioned to reduce security concerns, thereby mitigating the need for consent as a tool against breach.¹⁰⁴ To highlight the per se importance of

98. See *supra* notes 82–89 and accompanying text.

99. Terry & Francis, *supra* note 68, at 699–700.

100. *Id.* at 700 (internal citation omitted).

101. See Gilman & Cooper, *supra* note 11, at 315–16; Terry & Francis, *supra* note 68, at 700.

102. Francis, *supra* note 3, at 37.

103. See *supra* notes 81–87 and accompanying text.

104. For example, the ONC has charged the Health IT Policy Committee, through its Privacy and Security Tiger Team, to make recommendations regarding privacy and security in a NHIN. *Supra* note 23 and accompanying text.

patient autonomy, this Comment presupposes a possible world devoid of hackers, of breach. Even in such a utopia, “informed consent” should be part of basic HIE vocabulary. Put another way, the issue of patient control should be approached not from the perspective of defense against illicit access, but rather in recognition of the patient’s autonomous nature.

III. INFORMED CONSENT TO CLINICAL USE OF EHRs

The preceding section proposed that the concept of informed consent is important—important in relation to privacy rights and more to the point here, as a safeguard of autonomy. This section focuses on the application of informed consent. Granted a role for informed consent in patients becoming HIE stakeholders, what consent model best facilitates patients as autonomous agents? Taking up this question, this section proposes that the consent model most closely aligned with “autonomous authorization” is one in which patients affirmatively opt-in to HIE participation.

A. *In or Out?*

Why “opt-in” rather than “opt-out?”¹⁰⁵ Both models give the patient a choice in whether to participate and further, the opt-out model would more likely ensure higher numbers of EHRs and ease administrative burdens.¹⁰⁶ However, there are benefits to utilizing an opt-in participation model, a model requiring affirmative patient action. First, the risk of breach is pressing in both the nascent stages of HIE and as HIE grows nationally.¹⁰⁷ “Breach,” defined by HHS as “an impermissible use or disclosure under the Privacy Rule [of HIPAA] that compromises the security or privacy of the protected health information such that the use or disclosure poses a significant risk of financial, reputational, or other harm to the affected individual,”¹⁰⁸ has become an important buzzword in the HIE movement, especially among privacy watchdogs. Consent requirements are unlikely to have much effect on the occurrence of breach,¹⁰⁹ but the requirements will help to ensure that patients are aware of the way(s) in which their information is being used.¹¹⁰ In addition, while evidence suggests that the risks of actual harm from breach are

105. For a detailed consideration of the two options, see MO. OFFICE OF HEALTH INFO. TECH., *supra* note 41, at 42–46.

106. See Anderson, *supra* note 42.

107. Terry & Francis, *supra* note 68, at 724–25.

108. *Health Information Privacy: Breach Notification Rule*, U.S. DEP’T HEALTH & HUMAN SERVS. OFF. FOR CIVIL RTS., <http://www.hhs.gov/ocr/privacy/hipaa/administrative/breachnotificationrule/index.html> (follow “Definition of Breach” hyperlink) (last visited Mar. 15, 2012).

109. Gilman & Cooper, *supra* note 11, at 327.

110. See *id.* at 284 (explaining that consent and breach notification requirements are unlikely to affect incidences of breach, but that most benefits will arise from “the utility that patients derive from the fact that they have dominion over their personal medical information”).

relatively low,¹¹¹ the risks will likely increase as information is aggregated to a greater degree.¹¹² One response to the problem of breach has been to require notification; HITECH mandates that parties affected by breach, including patients, be notified of any unauthorized disclosure of protected health information.¹¹³ However, this response may do more harm than good. While knowing that they will be alerted if their records are illicitly accessed would seem to bolster patients' comfort with HIE, actually receiving notifications may undermine patients' trust in the exchange: "[I]f notifications become commonplace, consumers may begin to develop unfounded fears of HIT."¹¹⁴

Apart from privacy and security concerns, an opt-in model better facilitates and reflects the goal of having autonomous patients as participants in HIE. The consent model in place should promote patients' understanding of (rather than mere acquiescence to) the uses of and potential risks to their personal health information.¹¹⁵ If a patient must affirmatively manifest her consent to being part of HIE, it is more likely that her consent is genuine.¹¹⁶ Thus the opt-in model, as opposed to the opt-out, better reflects the goal of the patient as an integral stakeholder in HIE. On a practical note, the opt-in model may ease some administrative burdens when sensitive health information is being exchanged. Sensitive health information generally commands additional patient privacy and confidentiality protections,¹¹⁷ and an exchange-wide opt-in model relieves providers from distinguishing consent models based upon the data-type eligible for exchange or the providers slated to access the information.¹¹⁸

111. *Id.* at 323–24.

112. *Id.* at 321–22 (describing the way in which the aggregation of EHRs may “facilitate misuse by reducing the cost of theft” through illicit remote access and easy storage).

113. 42 U.S.C. § 17932 (Supp. III 2010).

114. Gilman & Cooper, *supra* note 11, at 331.

115. See Tripathi et al., *supra* note 35, at 438–39.

116. MO. OFFICE OF HEALTH INFO. TECH., *supra* note 41, at 44–45.

117. Stephen J. Weiser, *Breaking Down the Federal and State Barriers Preventing the Implementation of Accurate, Reliable and Cost Effective Electronic Health Records*, 19 ANNALS HEALTH L. 205, 207–08 (2010); see 42 C.F.R. § 2.31(a)(1) (2010) (describing federal requirement of written consent to disclosure of drug and substance abuse information); 45 C.F.R. § 164.508 (2010) (describing federal requirement of authorization for disclosure of psychotherapy notes); MO. OFFICE OF HEALTH INFO. TECH., *supra* note 41, at 44 (chart listing protections required for sensitive information by Missouri state law).

118. See, e.g., MO. OFFICE OF HEALTH INFO. TECH., *supra* note 41, at 45 (describing inability to exchange sensitive health information in Missouri using an opt-out model); N.Y. EHEALTH COLLABORATIVE, PRIVACY AND SECURITY POLICIES AND PROCEDURES FOR RHIOS AND THEIR PARTICIPANTS IN NEW YORK STATE – V2.2, at 12 (2011), available at http://nyhealth.org/images/files/File_Repository16/pdf/final%20pps%20v2.2%204.1.11.pdf (outlining New York's affirmative consent approach and explaining that through affirmative consent, authorized parties can access all protected health information, including sensitive health information).

B. All or Nothing?

Having granular choices in a consent model will allow patients who might not participate under an all-or-nothing approach to consent to some degree of participation. As described in Part I, granular approaches will allow patients to opt in or out of participation based upon factors such as data-type, provider, data age, or purpose of access.¹¹⁹ This granular approach places the burden of communication on the various stakeholders to educate patients on the stakeholders' legitimate purposes for accessing EHRs.¹²⁰ In this way, the granular approach becomes an important mechanism with which other stakeholders can garner patient trust and willingness to participate.

As states consider and implement HIE consent models, granular opting has remained at the foot of the table while decisions regarding whether and how to gain patient consent (that is, "no consent" versus "opt-in" versus "opt-out") are resolved.¹²¹ Rhode Island is one of the few states to have implemented (provider-based) granular opting in its consent model.¹²² In the Rhode Island HIE, *currentcare*, a patient must explicitly opt in to the exchange and then must grant authorization before a stakeholder may access the patient's information through the exchange.¹²³ Further, the information that may be accessed by an authorized stakeholder is limited according to the stakeholder's role: for example, a primary care physician has "system permission" to access the patient demographics, but may not access the data quality function in the exchange, whereas authorized data management specialists may access the data quality function.¹²⁴ The Rhode Island model does not, however, have options for patients to limit provider access to patient health information according to health information type; that is, a provider may not access system management functions, but it has full access to patient health records.¹²⁵ It

119. See *supra* note 48 and accompanying text.

120. See Tripathi et al., *supra* note 35, at 439 (describing this burden in the context of an opt-in approach).

121. See GOLDSTEIN, *supra* note 7, at 6. However, the ONC has recently announced a grant opportunity for states to focus on and pursue granular consent options. OFFICE OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., HEALTH INFORMATION EXCHANGE CHALLENGE PROGRAM: FUNDING OPPORTUNITY ANNOUNCEMENT 4-5 (2010).

122. GOLDSTEIN, *supra* note 7, at 15-16.

123. R.I. HEALTH INFO. EXCHANGE, RI HIE ENROLLMENT POLICY 1 (2008), available at http://www.currentcareri.org/matriarch/documents/Enrollment_Policy_And_Procedure_2008_Apr%2024_FNL_Approved.pdf.

124. R.I. HEALTH INFO. EXCH., RI HIE ROLE-BASED PERMISSIONS POLICY 2 (2008), available at http://www.currentcareri.org/matriarch/documents/Role-based%20Permissions-2008_Mar_27-FNL.pdf.

125. *Id.* at 3. The Rhode Island HIE has attracted attention recently; the American Civil Liberties Union filed suit against the Exchange for failing to explicitly address patient privacy, confidentiality, and informed consent protections. Mike Miliard, *ACLU Brings Suit Against Rhode Island HIE*, HEALTHCARE IT NEWS (Sept. 8, 2010), <http://www.healthcareitnews.com/>

remains unclear whether a granular framework could be viable on a national level. The granular approach highlights the challenges facing those charged with the task of standardization: restrictions on data access and transparency vary state to state, but if a multi-state or national approach to HIE is to be achieved, there must be some standardization of the protection of sensitive health information.¹²⁶ Section C below considers challenges to implementing opt-in and/or granularity in the patient participation model.

C. *Challenges of Implementing Robust Consent*

“All too often, considerations of ethical nicety founder on the rocks of pragmatic reality.”¹²⁷ This statement concisely identifies one of the biggest problems facing the realization of a robust consent model: is it merely an “ethical nicety” to be dispensed of when financial cuts loom? Is it a platform for philosophers and ethicists, but a moot point for patients? This section weighs the costs of a robust HIE patient consent model.

1. Challenges to “Opt-in”

The practicalities of implementing an opt-in consent model may be the biggest challenge to its adoption.¹²⁸ During a clinical encounter, a provider would furnish a form explaining the uses of EHRs, the stakeholders who would access the EHRs, benefits of having an EHR, risks pursuant to the exchange, and the ways in which the EHRs would be protected.¹²⁹ An agreeing patient would then affirmatively give her consent to the creation of an EHR.¹³⁰ Theoretically, this could be a once-and-done authorization, adjusted only if the patient changed her mind (or, in a granular model, her particular preferences)

news/aclu-brings-suit-against-rhode-island-hie. While the exchange allows patients to consent to access based upon provider, it does not create exceptions based upon sensitive health information. *Id.*

126. Terry & Francis, *supra* note 68, at 728.

127. Eike-Henner W. Kluge, *Informed Consent to the Secondary Use of EHRs: Informatic Rights and Their Limitations*, in MEDINFO 2004: PROCEEDINGS OF THE 11TH WORLD CONFERENCE ON MEDICAL INFORMATICS 635, 637 (Marius Fieschi et al. eds., 2004).

128. See Kristen Rosati, *Consumer Consent for Health Information Exchange: An Exploration of Options for Arizona’s HIEs*, ARIZ. HEALTH-E CONNECTION 5–6, <http://www.azgita.gov/ehealth/hispc/ConsumerConsent.pdf> (last visited Mar. 15, 2012) (describing administrative burdens of an opt-in approach).

129. N.Y. EHEALTH COLLABORATIVE, MODEL LEVEL 1 MULTI-PROVIDER CONSENT FORM 1 (2011), available at http://www.nyehealth.org/images/files/Policies/level_1_multi-provider_consent_form%20v%202.1.doc [hereinafter MULTI-PROVIDER CONSENT FORM]; see Terry & Francis, *supra* note 68, at 726.

130. MULTI-PROVIDER CONSENT FORM 1, *supra* note 129.

about participating.¹³¹ Consent during an office or hospital visit could encompass consent for the laboratory as well, just as consent for one's primary care physician could encompass consent for referred specialists.

Despite the sufficiency of a once-and-done authorization, providers may decide to seek patients' consent upon each visit. First, obtaining HIE consent with each visit may be administratively easier because providers could just include the opt-in form as a routine aspect of patient treatment. Second, by obtaining consent with each visit, the provider has more assurance that the patient still wants to have an EHR. This is especially relevant in light of the legal uncertainty regarding consent and disclosure requirements, which has prompted participating providers to over-comply in order to avoid liability.¹³² However, if having a patient opt-in involves excessive instances of obtaining consent and if there is variation across providers regarding the consent forms used, the benefits of the opt-in model may be outweighed by onerous implementation challenges: "Rapid and low-cost exchange of health information" becomes difficult when consent requirements stand as a barrier to information exchange.¹³³

Further, with a great deal of variation across providers added to an already uncertain legal environment, providers may be hesitant or unwilling to share information.¹³⁴ Another problem with defensively giving patients the consent form is that a patient might unwittingly decline to consent, perhaps forgetting that during the previous visit she had consented. Of course, if the patient is truly giving autonomous authorization rather than just signing her name, she will not randomly change her mind about participation. However, autonomous authorization is only a goal and by no means a current reality for all instances of informed consent. The HIE consent process must facilitate autonomous authorization while at the same time balancing the importance of generating a robust pool of EHRs.

With the opt-in model, some research shows a potential cost of insufficient patient participation,¹³⁵ stripping from an optimal HIE the benefits of the aggregation effect. Applying a network effect model, the benefits of HIE materialize only as more providers (and accordingly more patients)

131. N.Y. EHEALTH COLLABORATIVE, *supra* note 118, at 6, 14–15 (describing the durable effect of affirmative consent in New York for Level 1 Use—treatment, quality improvement, care management, and insurance coverage review); *see also* GOLDSTEIN, *supra* note 7, at 20.

132. *See* Tripathi et al., *supra* note 35, at 438 (describing "[u]ncertainty among legal experts about what constitutes consent in an electronic environment" as one reason that the Massachusetts eHealth Collaborative ("MAeHC") implemented the protective opt-in consent model rather than an opt-out model).

133. Gilman & Cooper, *supra* note 11, at 327–28.

134. *Id.* at 328.

135. GOLDSTEIN, *supra* note 7, at 52–53.

participate.¹³⁶ However, stringent privacy protections—including robust consent models—have been shown to reduce network effects in HIT, with states in which robust consent is required showing up to twenty-five percent lower HIT adoption rates.¹³⁷ Still, robust consent—including the opt-in and granular models—could also serve to encourage patient participation, engaging patients as equal stakeholders in exchange.¹³⁸ While adoption rates may be slower, HIE will be more viable in the long run if patients are truly engaged.¹³⁹ In the wise words of the tortoise, “slow and steady wins the race.” In addition, some initiatives project that both opt-in and opt-out consent models would garner high participation rates.¹⁴⁰

2. Challenges to Granularity

Technological barriers are chief among challenges associated with an opt-in with exceptions consent model. While a granular approach gives patients increased control over their EHRs, it also requires complex software from vendors.¹⁴¹ The complex technology required is a major reason why granular opting has not been widely adopted or even seriously considered by HIOs, intrastate and interstate initiatives, and the ONC.¹⁴² Still, stakeholders should vigorously encourage vendors in this area so that demand for granularity in turn prompts technological developments.¹⁴³ A concept from the pollution context illustrates this point and may serve as a model for developments in HIT. Environmentalist Bruce La Pierre identified three ways in which “technology-forcing” may prompt improvements in pollution control: “the implementation of an existing technology on a wider basis within an industry, the development of a theoretical technology or the transfer of control technology between industries, and the development of an entirely new, innovative technology or process.”¹⁴⁴ As technology develops, the current

136. Gilman & Cooper, *supra* note 11, at 310–11.

137. *Id.* at 312.

138. Tripathi et al., *supra* note 35, at 438 (explaining that for the MAeHC, consumer councils and advocacy organizations called for patients to be custodians of their medical information).

139. *Id.* at 442.

140. MO. OFFICE OF HEALTH INFO. TECH., *supra* note 41, at 46; Tripathi et al., *supra* note 35, at 441 (showing a ninety percent opt-in rate for the MAeHC).

141. See Eramo, *supra* note 67, at 24, 26 (describing the view of an industry practitioner that achievement of granular opting is not viable); Versel, *supra* note 34.

142. See *supra* note 121 and accompanying text.

143. INST. OF MED., CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY 5 (2001), available at <http://www.iom.edu/~media/Files/Report%20Files/2001/Crossing-the-Quality-Chasm/Quality%20Chasm%202001%20%20report%20brief.pdf>.

144. D. Bruce La Pierre, *Technology-Forcing and Federal Environmental Protection Statutes*, 62 IOWA L. REV. 771, 773 (1977).

challenges presented by granularity weigh in favor of implementing robust consent on a macro level; that is, implementing global opt-in consent.¹⁴⁵

As mentioned in Part I, funding is also a major concern for HIE initiatives,¹⁴⁶ and a granular approach to patient consent is expensive, requiring more complex hardware and software.¹⁴⁷ A related issue is that while providers bear the brunt of the costs of implementation,¹⁴⁸ the benefits are predicted to flow equally if not in greater degrees to patients, payers, and researchers.¹⁴⁹ For providers hesitant to adopt expensive EHR technology,¹⁵⁰ their willingness to adopt granular technology—technology that, as described next, has detrimental potential for care—may be slight at best.¹⁵¹

Cost concerns aside, providers may feel that they have much to lose from a granular consent model. From a provider's perspective, certain types of granular opting may create incomplete patient EHRs or prevent some providers from having a full and clear record of a patient's health.¹⁵² This could negatively impact quality of care,¹⁵³ not to mention expose the provider to increased risks of liability and difficulties in coordinating care.¹⁵⁴ However, the trust engendered by robust consent—including granular opting—may mitigate the risk of incomplete medical records and low participation; a

145. Bob Brown, Column, *Protecting the Confidentiality of Medical Records in an Interconnected Environment*, J. HEALTH CARE COMPLIANCE, Nov.–Dec. 2010, at 35, 38.

146. See *supra* notes 30–31 and accompanying text.

147. See Joseph Conn, *Patient Consent and 'Granular' Privacy Control Ties*, MODERNHEALTHCARE.COM (Dec. 14, 2010, 11:00 AM), <http://www.modernhealthcare.com/article/20091214/REG/312149987> (describing stakeholder complaints that granular opting is, among other things, expensive, but calling for the health care industry to nonetheless pursue the technology).

148. Gilman & Cooper, *supra* note 11, at 299.

149. *Id.* at 281–82.

150. See Adam Wright et al., *Physician Attitudes Toward Health Information Exchange: Results of a Statewide Survey*, 17 J. AM. MED. INFORMATICS ASS'N 66, 66 (2010) (reporting the results of a 2007 survey where, although a high percentage of responding physicians felt that HIE would result in overall benefits to quality of care, costs, and time, only thirty-seven percent would be willing to pay \$150 or more per month to participate).

151. See GOLDSTEIN, *supra* note 7, at 26–27 (describing the position of the American Medical Association and the American College of Physicians—that with the exception of sensitive health information, physicians should have “unencumbered” access to all patient medical data).

152. *Id.* at 8.

153. See Eramo, *supra* note 67, at 26; *Letter from Simon P. Cohn, supra* note 52, at 5.

154. See Shana Campbell Jones et al., *The Interoperable Health Record: Preserving its Promise by Recognizing and Limiting Physician Liability*, 63 FOOD & DRUG L.J. 75, 82–83 (2008) (discussing implications of interoperable EHRs on physician liability, including problems grounded in a physician's inability to access a complete EHR). For a general illustration of the potential negative consequences of HIT for patient care, see James McCormack et al., *H.I.T. or Miss*, in TRANSFORMING HEALTH CARE THROUGH INFORMATION: CASE STUDIES 97 (Laura Einbinder et al. eds., 3d ed. 2010).

patient's willingness to participate fully may correspond to the degree to which the patient is able to exercise her autonomy in doing so.¹⁵⁵ In addition, studies show that patients who do not trust their providers are more likely to engage in risky and evasive behavior that taints medical records.¹⁵⁶ As privacy advocate Deborah C. Peel explains, "[w]hen patients realize they can't control who sees their electronic health records, they will be far less likely to tell their doctors about drinking problems, feelings of depression, sexual problems, or exposure to sexually transmitted diseases."¹⁵⁷

The preceding paragraphs lay out the (at times high) costs of welding together HIE and robust patient consent. These costs may be overwhelming if the benefits of robust consent are diminished; that is, if by opting in, a patient exercises no more than her ability to sign her name. This Comment recognizes the inherent limitations to the legalized and defensive context in which consent is gained by the checking of boxes and initialing what can be highly legalistic and complex risk disclosures.¹⁵⁸ To be sure, the health care industry has yet to fully embrace the late Dr. Jay Katz's call to escape "the silent world" in which doctors and patients too often coexist.¹⁵⁹ However, HIT developments are happening now. While implementing a consent model (whether opt-in or opt-out) is not sufficient for the achievement of patient autonomy in HIE, it is certainly necessary.¹⁶⁰ It is equally important that implementing an opt-in consent model not be the end of the informed consent discussion. Initiatives to educate patients on HIE and patients' roles through EHRs, along with continued conversations between provider and patient, are some of the ways in

155. See Francis, *supra* note 3, at 40 (discussing how patients' trust in their providers may be undermined when providers have access the patient did not expect the provider to have).

156. McGraw et al., *supra* note 94, at 417 (explaining that one in six adults report withholding information from providers due to fear of inadequate privacy protections).

157. Peel, *supra* note 13, at A17.

158. Alan Meisel, *From Tragedy to Catastrophe: Lawyers and the Bureaucratization of Informed Consent*, 6 YALE J. HEALTH POL'Y L. & ETHICS 479, 481 (2006).

159. See *id.* at 481–82 (citing JAY KATZ, *THE SILENT WORLD OF DOCTOR AND PATIENT* (1984)).

160. In a recent article addressing patient consent and autonomy generally, philosopher Natalie Stoljar points out the insufficiency of informed consent, an "opportunity" concept, to secure patient autonomy, an "exercise" concept. Natalie Stoljar, *Informed Consent and Relational Conceptions of Autonomy*, 36 J. MED. & PHIL. 375, 381 (2011). Merely presenting an opportunity for a patient to consent does not ensure that the patient will exercise her choice in accordance with conditions of an autonomous choice—what Stoljar describes as "self-referring attitudes" such as self-esteem and self-trust. *Id.* at 378–79, 381–82. Further, informed consent does not normally require the patient to be what the Stoljar calls a "strong evaluator"—an individual who makes qualitative assessments of the values inherent to the choice at hand. *Id.* at 382. Despite its insufficiency, informed consent should not be whole cloth "jettisoned." *Id.* Stoljar calls for providers to "encourage imaginative reflection on different options and create the conditions in which patients truly feel authorized to speak for themselves." *Id.* at 383.

which the consent options exercised by patients may become more meaningful.¹⁶¹ Placing the burden of communication on the stakeholder by implementing an opt-in model is a good start.

IV. CONSENT TO NON-CLINICAL USES OF EHRs

In the preceding sections, this Comment has explained the goal of establishing EHRs for all patients by 2014. It has also highlighted the concept of informed consent as a dynamic feature of patient autonomy and specifically, as an important topic for consideration as states and the nation as a whole work toward the goal of improving health care through HIE. This section takes up briefly the issue of secondary, non-clinical uses of EHRs. There are various and notable non-clinical purposes that may be served with aggregated health information.

A common feature to all these purposes is that patients derive only indirect benefits.¹⁶² Those outside the treatment context—including payers, researchers, and public health analysts—are focused on benefits that extend beyond the well-being of the individual patient, whether it be the insurance pool, the bottom line, the future of medicine, or community health.¹⁶³ Focusing here on the non-clinical uses of this information by payers, this Comment argues that secondary use of EHRs is a game-changer and thus requires fresh consideration of patient informed consent. Section A considers the role of payers in HIE and some of the factors that distinguish payers from providers as related to the use of EHRs. These factors highlight the importance of informed consent but also reaffirm the importance of an approach that combines robust consent and stringent privacy protection. Section B then concludes by addressing the feasibility and implications of consent for payer inclusion in HIE, including what this consent process looks like functionally in relation to the process by which providers obtain consent.

A. *The Payer “Dilemma”*

The role of the payer is only recently becoming a focus in the HIE discussion, but it must be considered carefully. Payer access affects many

161. See BERG ET AL., *supra* note 1, at 171 (explaining that through continued communication, informed consent can be a process rather than an event); Greenbaum et al., *supra* note 40, at 4-1, 5-4 to -5 (noting the important role of education in engaging patients in HIE, a goal for which many state-level education committees have been formed).

162. For discussion of patients serving as means rather than ends and deriving only indirect benefits in the research context, see Jay Katz, *Human Experimentation and Human Rights*, 38 ST. LOUIS U. L.J. 7, 12–17 (1993), reprinted in CARL H. COLEMAN ET AL., *THE ETHICS AND REGULATION OF RESEARCH WITH HUMAN SUBJECTS* 307–09 (2005).

163. See Campbell Jones et al., *supra* note 154, at 76–77 (describing public health benefits that may accrue from interoperable EHRs).

aspects of the envisioned goal—from HIE long-term viability, to improved care and reduced hospital encounters for patients, to the willingness of patients and providers to participate.¹⁶⁴ While this Comment addresses payer involvement primarily insofar as it has bearing on patient informed consent, it is worth describing briefly the relationship between payer participation and HIE generally; this macro view illustrates why payers are important to HIE and consequently, why the issue of consent must be at the forefront of the conversation.

1. What Payers Bring to the Table

Current HIE initiatives cite funding and sustainability as top challenges to HIE development.¹⁶⁵ Achieving a financially and structurally sustainable business model is a goal for which payers are slated to be of aid: “Lowering the costs of care by reducing duplicate tests and identifying diseases earlier can enable payors to invest in strategies that can engender long-term loyalty among plan providers and patients.”¹⁶⁶ Beyond assuaging cost concerns, the aggregated health information databases of payers—largest among HIE stakeholders—are a potentially invaluable contribution to the HIE data pool.¹⁶⁷ In addition, payers and employers may be effective in engaging patients to sign up to participate in HIE during plan enrollment.¹⁶⁸ Accompanying these benefits offered by payer participation are benefits to be reaped by the payers in participation: payers, like providers, are concerned with health care quality, which directly affects their expenditures.¹⁶⁹ To this end, some payers have been encouraging their members to create payer-based health records to store

164. Daniel et al., *supra* note 8, at 830–31.

165. EHEALTH INITIATIVE, *supra* note 16, at 30.

166. DELOITTE & TOUCHE USA LLP, *supra* note 2, at 9; see Jan Walker et al., *The Value of Health Care Information Exchange and Interoperability*, HEALTH AFF., W5-10, W5-15 (Jan. 19, 2005), <http://content.healthaffairs.org/content/early/2005/01/19/hlthaff.w5.10.short> (projecting savings of around twenty billion dollars for the nation with a highly interoperable system of provider-payer transactions).

167. Lynne Dunbrack, *The Future of Payer-Sponsored Electronic Health Records*, EXECUTIVE HEALTHCARE, Q4 2008, at 114, 114, available at <http://www.executivehm.com/article/The-Future-of-Payer-sponsored-Electronic-Health-Records/> (last visited Mar. 15, 2012); Caralyn Davis, *Health Information Exchanges: Multiple Benefits, No Downside to Early Payer Involvement*, FIERCEHEALTHPAYER (Jun. 21, 2010, 8:44 AM), <http://www.fiercehealthpayer.com/story/health-information-exchanges-multiple-benefits-no-downside-early-payer-involvement/2010-06-21>. But see Joy M. Grossman et al., *Information Gap: Can Health Insurers Personal Health Records Meet Patients’ and Physicians’ Needs?*, 28 HEALTH AFF. 377, 385 (2009) (“Most physicians had serious concerns about the validity of claims data for treatment purposes.”).

168. Joseph Goedert, *The Payer Role in HIEs*, HEALTH DATA MGMT. (June 1, 2009), http://www.healthdatamanagement.com/issues/2009_67/-28270-1.html.

169. GOLDSTEIN, *supra* note 7, at 27.

members' information (for example, lab tests, recent diagnoses, medical histories).¹⁷⁰ Providers can access these records to gain a clearer picture of a member's health without ordering extra tests, etc.¹⁷¹ Access to EHRs would open another channel for reduced payer costs.¹⁷² There is also likely to be a high return on investment for payers, with a net value from HIE participation and investment of more than twenty-one billion dollars predicted at one point.¹⁷³

2. What Payers May Take from the Table

With great power comes great responsibility, and payers are no exception. While they have the potential to catapult HIE success,¹⁷⁴ their participation should prompt other stakeholders to give pause. This section identifies three ways in which payer access to EHRs is distinguished from provider access.

(1) *Trust*. The ONC Health IT Committee's Tiger Team on Privacy and Security has identified the attainment of patient trust as a key goal during continued HIE development.¹⁷⁵ Patients often view payers with mistrust due to payers' well-documented reputation as self-interested.¹⁷⁶ Giving patients the option to choose when and to what degree to incorporate their health records into an exchange is one way in which patients maintain control when faced with the prospect of their EHRs being accessed by a mistrusted source.¹⁷⁷ As with patients, providers' trust is crucial to successful HIE, and "providers know that the payers' bottom line and what's best for the patient don't always

170. *Id.*

171. Dunbrack, *supra* note 167, at 114–15.

172. GOLDSTEIN, *supra* note 7, at 27.

173. Walker et al., *supra* note 166, at 15. Despite promised financial return on investment ("ROI"), analysts note the high start-up costs of HIE as a disincentive for payer participation, explaining that strictly financial ROI may be only a long-term reality. Laura Kolkman, *Expanding the HIE Funding Pool by Redefining ROI*, HEALTHCARE INFO. MGMT. SYS., <http://www.himss.org/ASP/ContentRedirector.asp?ContentID=68449> (last visited Mar. 15, 2012). To secure payer incentive, some encourage a redefining of ROI with a focus beyond the financial return. *Id.*

174. See Davis, *supra* note 167 (noting that payer participation can aid in reducing medical costs and improving outcomes).

175. Letter from Paul Tang, *supra* note 66, at 3.

176. See generally Elizabeth A. Pendo, *Images of Health Insurance in Popular Film: The Dissolving Critique*, 37 J. HEALTH L. 267 (2004) (describing the "villainized" portrayals of health insurers in three films, *Critical Care*, *The Rainmaker*, and *John Q.*, and suggesting that the films are exaggerated but nonetheless supported in reality).

177. Eramo, *supra* note 67, at 25 (explaining that according to an online survey, seventy-eight percent of those polled felt that physicians should have access to EHRs, while only thirty percent felt that insurers should have access).

jibe.”¹⁷⁸ While payers are positioned to offer huge amounts of patient data, providers must be willing to trust the data before it becomes beneficial.¹⁷⁹ One hope, which would bolster both provider and patient trust in payer data, is that

[P]rivate payers will follow the lead of the Centers for Medicare & Medicaid Services (CMS) . . . in making quality of care a priority, and setting up incentives for doctors to make it their priority too. . . . [D]octors and their provider brethren may end up learning to trust payers, reaping the fruits of the patient data that payers are collecting already.¹⁸⁰

(2) *Motive*. While the point on trust above addresses a perhaps unjustified perception of payers, actual questionable motives are a legitimate source of concern for stakeholders. Today, payers have huge market control and thus the ability to impact both cost of care and treatment decisions.¹⁸¹ As described by American Medical Association President Cecil B. Wilson, “[w]hen insurers dominate a market, people pay higher health insurance premiums than they should, and physicians are pressured to accept unfair contract terms and corporate policies, which undermines the physician role as patient advocate.”¹⁸² Will payers use their access to EHRs in order to more scrupulously monitor physicians and further dictate patient treatment to be as cheap as possible?¹⁸³ MedChi, the Maryland State Medical Society representing over 22,000 physicians, has expressed the concern that payers will manipulate EHRs so that patient treatment is aligned with payers’ interests: “The battle over who is in charge of treating the patient is being played out through EHRs.”¹⁸⁴

(3) *Expansion beyond Treatment Circle*. Related to points (1) and (2) above is the reality that payers operate outside of the direct treatment context. Patients do not derive a direct benefit from payer access to EHRs; rather, the resulting benefits will flow primarily to a payer’s bottom line, the insurance

178. Don Fluckinger, *Merging Payer, Provider Data in EHR Systems*, HEALTH IT PULSE (June 3, 2010, 8:00 AM), <http://searchhealthit.techtarget.com/healthitexchange/healthitpulse/merging-payer-provider-data-in-ehr-systems/>.

179. See Grossman et al., *supra* note 167, at 385.

180. Fluckinger, *supra* note 178.

181. Press Release, American Med. Ass’n, *New AMA Study Finds Lack of Competition Among Health Insurers* (Feb. 1, 2011), available at <http://www.ama-assn.org/ama/pub/news/news/competition-health-insurers.page>.

182. *Id.*

183. See Reed Abelson, *Insurers Test New Cancer Pay Systems*, N.Y. TIMES, Oct. 20, 2010, at B1 (describing insurers’ efforts to decrease physician dependence on individualized and expensive cancer treatment plans).

184. Patty Enrado, *Maryland Physicians Worry About Payer Influence*, EHRWATCH (Nov. 1, 2010, 12:25 AM), <http://www.ehrwatch.com/blog/maryland-physicians-worry-about-payer-influence>.

industry, and society.¹⁸⁵ Patients will indirectly benefit from payer access, but expansion of HIE participation beyond the treatment context is also accompanied by special risks to all involved. As information is aggregated and stored electronically, it becomes a sort of attractive nuisance.¹⁸⁶ The risk of breach, addressed in Part III, is correlated with the number of stakeholders in HIE,¹⁸⁷ and expanding EHR access to payers brings new opportunities for breach. A corollary to the risk of breach, expansion beyond the treatment context, may lead to undesirable but authorized use of EHRs if there are insufficient mechanisms in place to control the ways in which non-provider “qualified organizations” use the information accessed. Prior to the ARRA, there were troublesome vacuums in HIPAA’s Privacy and Security Rules protection as related to health information sharing—notably marketing exceptions and the exclusion of de-identified information from HIPAA protection.¹⁸⁸ HIPAA limits marketing measures using protected health information without patients’ authorization,¹⁸⁹ but it defines “marketing” so as to allow exceptions when marketing for covered entities is for “health care operations.”¹⁹⁰ De-identified information is excluded from HIPAA protection,¹⁹¹ and so HIPAA does not preclude covered entities and non-covered entities alike from exchanging de-identified health information.¹⁹² This presents a major privacy risk because de-identified information is often easily re-identified,¹⁹³ and if an entity not bound by HIPAA obtains the information, that entity is not bound by HIPAA to protect the information.¹⁹⁴ In response to the new HIT terrain that is HIE, there have been calls for new or revised privacy protections to cover those areas where HIPAA may be inadequate.¹⁹⁵ Through the ARRA, HITECH has strengthened HIPAA’s

185. See *supra* notes 161–62 and accompanying text.

186. See Gilman & Cooper, *supra* note 11, at 321–23 (comparing the difficulties involved with unauthorized access to paper records with that of electronic records, along with the increased value of information once aggregated).

187. Terry & Francis, *supra* note 68, at 724; Tripathi et al., *supra* note 35, at 439.

188. See, e.g., McGraw et al., *supra* note 94, at 419; Weiser, *supra* note 117 at 207; Deborah C. Peel, Presentation to the Texas Public Health Committee, Patient Expectations for HealthIT: Control over Health Records Privacy Solutions for HIE (May 11, 2010) (unpublished report), available at <http://patientprivacyrights.org/wp-content/uploads/2010/05/PH-Committee-May-11-2010.pdf>.

189. 42 U.S.C. § 17936(a) (Supp. III 2010); 45 C.F.R. § 164.501 (2010).

190. 45 C.F.R. § 164.506(c) (2010).

191. 45 C.F.R. § 164.514(a) (2010).

192. McGraw et al., *supra* note 94, at 419.

193. Peel, *supra* note 188.

194. McGraw et al., *supra* note 94, at 419.

195. David B. Kendall, *Protecting Patient Privacy through Health Record Trusts*, 28 HEALTH AFF. 444, 444–46 (2009) (calling for the creation of health information trusts controlled by patients as an improvement on current federal privacy laws); McGraw et al., *supra* note 94, at

Privacy and Security Rules.¹⁹⁶ For example, business associates of covered entities are now directly bound by the Rules¹⁹⁷ and will be subjected to civil monetary penalties for non-compliance,¹⁹⁸ and HITECH expands “business associates” to include all entities that transmit and routinely access protected health information.¹⁹⁹ HITECH further limits HIPAA-permitted marketing uses of protected health information and, with limited exceptions, requires authorization when an entity will receive payment for the marketing use.²⁰⁰ Finally, covered entities and business associates are now required to not only exchange the “minimum necessary” protected health information for business purposes, but also to consider whether a partially de-identified “limited data set” could accomplish the purposes.²⁰¹ Still, legal uncertainty regarding the new terrain that is the future NHIN, these new provisions, and potential loopholes stack the deck in favor of requiring informed consent.

B. Nuts and Bolts of Consent to Payer Access

Informed consent has heightened importance when patients will not directly benefit from another’s access to and use of patients’ EHRs. Payers illustrate this point. This Comment concludes here by considering the nuts and bolts of obtaining informed consent for payer access to EHRs.

One possibility for facilitating consent to payer participation is allowing payers to piggyback on providers, with both stakeholders obtaining consent via a single consent form presented to the patient in a clinical encounter. The form could give patients the option to fully opt in to HIE in which both providers and payers will access EHRs. Alternatively, it could include granular options so that patients would consent separately to provider and payer access. While combining both stakeholders in a single form is straightforward, red patient flags abound. Patients will affirmatively manifest their consent for both stakeholders, but if they have only one choice—either allow both stakeholders access or do not participate—they may feel stuck between a rock and a hard place; either ignoring their discomfort with payers or forgoing participation altogether. A granular approach within a single form addresses this difficulty,

420–23 (postulating that privacy and security enhancements, currently lacking under HIPAA, will help to engage patients in HIE); Latanya Sweeney, GAO Appointee to the Privacy and Sec. Seat of the Fed. HIT Policy Comm., Statement before the 21st Century Healthcare Caucus Roundtable: Designing a Trustworthy Nationwide Health Information Network (NHIN) Promises Americans Privacy and Utility, Rather than Falsely Choosing Between Privacy or Utility (Apr. 22, 2010).

196. See 42 U.S.C. § 17931 (Supp. III 2010).

197. *Id.*

198. *Id.* § 17939(d)(4).

199. *Id.* § 17938.

200. *Id.* § 17935(d)(1).

201. 42 U.S.C. § 17935(b)(1)(A).

but it does not solve the broader problem. It blurs the purpose of participation for treatment to combine both clinical and non-clinical uses into a single consent form. If a patient is to give autonomous authorization rather than merely a signature, the object of the authorization should be clearly delineated and contextualized—here, the provider for clinical purposes only. Further, if a patient does not fully grasp that she is consenting to access by both providers and payers, she may feel surprised and violated when she discovers that her provider granted her payer this access, with a resulting harm to the physician-patient relationship.²⁰² This is not to say that consent to all secondary uses of EHRs should occur outside the clinical context. For example, it may be appropriate to include in a provider's consent form that the government may use data from EHRs for quality improvement, which relates directly to the care the patient has received, or for information-based research.²⁰³

The alternative to the single encounter consent, then, is to require payers to obtain consent on their own and outside of the clinical context.²⁰⁴ This is certainly feasible. Each year, members re-enroll in an insurance plan, whether through their employers or independently.²⁰⁵ Thus, payers have an opportunity to obtain member consent without establishing a new and burdensome process. In New York, for example, payers seeking authorization to access EHRs must obtain consent independently from providers.²⁰⁶ This is true even if payers are seeking access only for quality improvement, care management, and insurance coverage review purposes, what New York describes as “Level 1 uses.”²⁰⁷ If a payer is also seeking access for payment, researching, and marketing purposes, it must obtain a further level of consent through a “Level 2 use” consent form.²⁰⁸ Level 1 and Level 2 uses cannot be collapsed into a single consent form, so a payer seeking access for both quality improvement and payment purposes must obtain member consent documented in two separate forms.²⁰⁹

202. Francis, *supra* note 3, at 40.

203. *Id.* at 45.

204. See, e.g., N.Y. EHEALTH COLLABORATIVE, MODEL LEVEL 1 PAYER CONSENT FORM (2011), available at http://www.nyehealth.org/images/files/Policies/level_1_payer_consent_form%20v%202.1.doc [hereinafter LEVEL 1 PAYER CONSENT FORM].

205. See, e.g., GIC Mandates that State Employees Re-enroll in their Health Care Plans, MASS. SOC'Y PROFESSORS, http://umassmsp.org/gic_mandates_that_state_employees_re-enroll_in_their_health_care_plans_-_failure_to_do_so_will_negatively_affect_your_coverage (last visited Mar. 15, 2012).

206. Compare LEVEL 1 PAYER CONSENT FORM, *supra* note 204 (Level 1 form used by payers), with MULTI-PROVIDER CONSENT FORM, *supra* note 129 (Level 1 form used by providers).

207. N.Y. EHEALTH COLLABORATIVE, *supra* note 118, at 6.

208. N.Y. EHEALTH COLLABORATIVE, MODEL LEVEL 2 PAYER CONSENT FORM FOR PAYMENT (2009), available at http://nyehealth.org/images/files/Policies/doc%207c_level_2_payer_consent_form_for_payment.doc.

209. N.Y. EHEALTH COLLABORATIVE, *supra* note 118, at 12.

Payers might react adversely to being required to implement robust consent.²¹⁰ Alternatively, this may prove to be no problem at all, with one big caveat: member consent to payer access becomes a condition of coverage.²¹¹ If payer access becomes a condition of member coverage, payers will have near full participation because, applying a cost-benefit analysis, members would be extremely unlikely to forego coverage.²¹² And members will be left with no meaningful choice at all, which is to say, no ability to preclude payers from accessing their EHRs. The option to get coverage through an alternative payer may be diminished as HIE grows on a national level and becomes an integral aspect of healthcare in the United States.²¹³ Thus, it seems there is a risk that patient consent to payer participation may become a moot point. One way to check payer participation is to place limitations on the uses of HIE for which patients may consent.²¹⁴ In this way, when patients authorize a payer to access their EHRs, patients are not consenting to a free-for-all use of their health information. HITECH's strengthening of HIPAA is a start. While such limitations appease some privacy concerns, however, they facilitate merely the legal doctrine of informed consent and do little to carve out a role for autonomous authorization. To carve out this role, policymakers should follow the model of New York and preclude payers from making member consent a condition of coverage.²¹⁵

CONCLUSION

As HIE initiatives yield to exchange on a national level, the role of informed consent must not yield to administrative ease, technological expediency, or privacy and confidentiality assurances. Informed consent has an independent and irreplaceable role in carving out a place for patient autonomy in healthcare, including HIT. The success of HIE depends in large part on patients participating in the creation of accurate and complete EHRs.

210. GOLDSTEIN, *supra* note 7, at 27 (“Ultimately, payers hope to realize the benefits of electronic exchange through reductions in their own expenditures. For these reasons . . . payers generally would prefer low-resistance consent models that yield high participation and data volume.”).

211. New York, which has successfully implemented robust consent requirements for payer access to EHRs, see *supra* notes 203–08 and accompanying text, precludes payers from making consent a condition of a member’s health plan enrollment and receipt of benefit. LEVEL 1 PAYER CONSENT FORM, *supra* note 204; N.Y. EHEALTH COLLABORATIVE, *supra* note 118, at 12.

212. See Terry & Francis, *supra* note 68, at 726 (describing generally the powerful affect of a NHIN on the healthcare industry and noting if a NHIN becomes standard, patient choice may “become illusory”).

213. See *id.*

214. *Id.* at 730–35 (discussing legal mechanisms by which EHR use may be limited in order to protect patient confidentiality).

215. N.Y. EHEALTH COLLABORATIVE, *supra* note 118, at 12.

Facilitating patient participation through autonomous authorization is an important first step in this direction. Having a patient affirmatively opt in to HIE will help to ensure that the patient is meaningfully participating in the exchange, aware of uses, risks, and benefits that may result. Payers should independently obtain this consent so as to insulate clinical from non-clinical uses of EHRs. As payers take on this task, the lingering and pressing question remains whether this solution is actually a catch twenty-two; that is, whether patient participation becomes a condition of coverage such that informed consent has no bite. This question may be a helpful testing ground for whether patient autonomy holds water as HIE develops beyond the treatment context—if payers are able to exercise this control over patients' EHRs, perhaps patients will have been left in the back seat.

SARAH R. RUPP*

* 2012 J.D. Candidate at Saint Louis University School of Law. I would like to thank Professor Sandra Johnson, whose guidance and encouragement proved invaluable to this Comment. I would also like to thank my family for their unfailing love and support.

