

BLAME IT ON THE

# RHIO

## <sup>1</sup> *Potential Liability Concerns with Electronic Health Information Exchange*



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### I. Introduction

The future of healthcare over the next decade will be inextricably bound to the development of technology organizations that can assure the efficient, private, secure, and accurate exchange of electronic health information. In 2001, the Institute of Medicine, a branch of the National Academy of Sciences, called for a “nation-wide commitment to build an information infrastructure to support health care delivery.”<sup>2</sup> In the 2004 State of the Union Address, President Bush laid out his goal that, within the next decade, almost every American will have an electronic, interoperable health record capable of exchange among healthcare providers utilizing diverse technological platforms and architectures.<sup>3</sup> In the 2006 annual survey on health information technology conducted by *Modern Healthcare*, healthcare executives indicated that the development and exchange of electronic healthcare records is their number one priority.<sup>4</sup>

Whether these organizations that facilitate the exchange of electronic health records are called health information networks (HINs), regional health information organizations (RHIOs), or labeled with some other moniker and resulting acronym, health information exchange will prove to be as complex legally as it is advanced and sophisticated technologically. RHIOs<sup>5</sup> will face a myriad of legal issues: Health Insurance Portability and Accountability Act (HIPAA) privacy and security, intellectual property, tax-exemption, labor and employment, antitrust, anti-kickback and self-referral, and liability issues will all have to be addressed for a RHIO to be legally compliant. While the issues collectively can fill a substantial monograph (and the American Health Lawyers Association has in fact published such a comprehensive monograph<sup>6</sup>), this article will focus solely on potential liability issues for RHIOs.

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## II. RHIO Basics

RHIOs may be loosely defined as local organizations engaged in the creation and exchange of electronic health records (EHRs) among healthcare providers in a regional area. RHIOs hopefully will eventually serve as a platform for a national “network of networks” linking doctors, hospitals, laboratories, and pharmacies throughout the nation, currently being referred to as the national health information network, or NHIN.

The parties involved in a RHIO generally fall into three categories: (1) data contributors; (2) data managers; and (3) data users.

- Data contributors include the individuals and entities that contribute health information to an information repository that is managed by the RHIO. Such data contributors generally include healthcare providers and healthcare plans, including both independent and employer-based plans that hold the individual patient’s health information in various forms. The patient, who generally has access to and the right to edit the EHR, can also be a data contributor.
- Data managers include the individuals responsible for managing the data that is in the possession of the RHIO. This can include employees of the RHIO as well as outside vendors with whom the RHIO contracts for hardware, software, service support, and hosting.
- Data users are those persons or entities that will use the data from the RHIO’s network to provide and participate in the delivery of healthcare. This can include hospitals, physicians, pharmacies, and laboratories.

When a patient is injured and believes the cause is, in whole or part, due to information obtained from the RHIO, the patient will look to the RHIO for recompense. While it is possible for the RHIO to be legally at fault, it may also be one or more of the other parties to the data exchange (the data contributors, users, or managers) that may bear some or all of the liability. The rest of this article discusses possible scenarios in health information exchange that can result in injury to the patient, analyzes which party or parties may be legally at fault, and suggests steps RHIOs can take to protect themselves from liability.

## III. Potential Liability Concerns and Risk Mitigation Strategies

Before a RHIO can be found legally liable, the injured patient must state a legal cause of action. With RHIOs this will generally mean some type of negligence or contract claim. The particular state in which a RHIO is incorporated and/or conducts a substantial part of its business will ordinarily dictate the specific liability concerns for a RHIO. However, common principles of tort and contract law offer a glimpse of the general liability issues facing the RHIO.

### A. Tort and Contract Liability

#### *Negligence Generally*

A RHIO may face liability under general negligence theories. The elements of a negligence claim are duty, breach, causation, and damages.<sup>7</sup> While breach, causation, and damages are issues of fact, law will dictate the specific duty owed by a RHIO.

The relationships between a RHIO and the individuals or entities using its services arguably create a variety of affirmative duties between the parties. Generally, when a party undertakes to render services to another, there is a duty to use reasonable care in providing such services.<sup>8</sup> From this duty to use reasonable care in providing services could be implied various correlative duties such as a duty to ensure the integrity of the electronic data disseminated to the data users, the duty to provide adequate technical support to maintain the data exchange network, or the duty to provide data users with the necessary training to properly use the data exchange network. Such duties will be owed to the individuals for whose benefit the services are rendered.<sup>9</sup> In the case of a RHIO, this duty may be owed to the data users to whom a patient’s health information is transmitted or to the patients treated by such data users.

#### *Medical Malpractice*

Although a RHIO could potentially face liability under state medical malpractice laws, it is unlikely because a RHIO would probably not qualify as a healthcare provider under most state medical malpractice statutes. In some states, a medical malpractice statute may specifically exclude RHIOs from the definition of a healthcare provider.<sup>10</sup> Further, state law may require a doctor-patient relationship or some affirmative communication between

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a doctor and a patient prior to imposing medical malpractice liability. A regional repository for a patient's health information is not likely to satisfy the doctor-patient relationship or be considered a healthcare provider. Thus, in many (or most) jurisdictions, a RHIO is not likely to be subject to liability under that state's medical malpractice laws.

*Negligent Hiring, Retention, Training, and Supervision*

A theory of liability that has gained popularity in the last decade is based on an entity's duties with respect to its employees. Specifically, an organization may be held liable for negligence in hiring or retaining employees who lack the necessary qualifications or in failing to provide adequate training and supervision of such employees in the performance of their jobs.<sup>11</sup> Because electronic data exchange is so technologically sophisticated, a RHIO could be liable for failure to hire, retain, train, or supervise employees who are technologically competent to provide the services the RHIO promises, or the failure to contract with competent third-party vendors who can supply such services in the absence of RHIO employees providing the services.

*Invasion of Privacy and/or Emotional Distress*

If a RHIO improperly discloses a patient's health information, the RHIO could be liable under an invasion of privacy action<sup>12</sup> (not to mention civil penalties under HIPAA). Similarly, the RHIO could be liable under an infliction of emotional distress claim.<sup>13</sup> Some states only recognize an intentional infliction of emotional distress while others recognize a merely negligent infliction of emotional distress. Further, some states do not allow damages for emotional distress absent physical injury.<sup>14</sup> In such states, it is possible that the RHIO's negligent disclosure of a patient's sensitive health information could lead to the patient's emotional distress but not to a physically manifested injury. Thus, in such states the existence of physical injury could be determinative of the RHIO's liability.

*Breach of Contract and Breach of Warranties*

The RHIO will likely have a contractual relationship with data contributors, data users, data managers (such as an information technology service providers), and, most importantly for determining liability for patient injury, contracts with patients. Patients who are injured may bring a breach of contract or breach of express or implied warranty claim against the RHIO. For example, the agreement between the RHIO and the patient may allow the patient to block certain sensitive parts of the patient's EHR (e.g., information related to substance abuse, mental health issues, or STDs). Disclosure of information the patient has requested to be blocked could result in a breach of contract claim. The RHIO may also claim that its e-prescribing function will identify and warn against potential adverse drug interactions between two drugs being prescribed to the same patient. If the software fails to identify and/or warn about an adverse interaction, an injured patient may bring a breach of warranty claim.

**B. Risk Mitigation and Limitation Strategies**

As with any business that faces potential tort or contractual liability, there are a number of steps a RHIO can take to limit or mitigate its risk exposure.

*Arbitration Clauses*

A RHIO may wish to incorporate arbitration clauses into its contracts with various parties, including patients. If a patient is injured, the RHIO may well desire to have the decision maker be an arbitrator versus a jury. State law will dictate whether an arbitration clause is binding and the kinds of actions that an arbitration clause may cover. For instance, in some states, the court will only allow arbi-

tration clauses to cover actions arising from breach of contract claims but not from tort claims.<sup>15</sup>

### *Jurisdiction and Venue*

If the RHIO operates in multiple states, it may want to put a jurisdiction and venue clause in its contracts. One state may have more favorable tort and/or contract laws that would affect jurisdiction selection. Similarly, if a jury trial cannot be avoided, one county's juries may be more pro-defense or pro-plaintiff and this may affect venue selection. The enforceability of jurisdiction and venue selection provisions will vary from state to state.

### *Disclaimers*

Parties to a contract often include provisions disclaiming or limiting liability. The enforceability of such provisions may vary from state to state.<sup>16</sup> Often, state law requires such provisions to be clear and unequivocal, particularly where a party is attempting to release itself from liability for its own negligence.<sup>17</sup> Complete disclaimers of liability may raise public policy issues that could affect their enforceability. What is more common, and more commonly enforceable, is a disclaimer of express and implied warranties. Thus, for example, a RHIO might disclaim any express or implied warranty regarding the ability of its software system to properly identify potential adverse drug interactions between two drugs being prescribed to the same patient.

### *Indemnity Provisions*

A RHIO may wish to include indemnity language in its contracts with the various RHIO parties. For example, the RHIO may seek an indemnity from data contributors for any damages resulting from incomplete or inaccurate data, from data users (such as a physician) for any damages resulting from the physician's use of the data in the delivery of healthcare, and from the data manager (such as a technology service provider) for any damages resulting from the failure of the software (e.g., the failure to identify a potential adverse drug interaction).

### *Waivers*

Because a RHIO is often merely a passive conduit of information flowing between various healthcare providers and health plans, the RHIO should consider obtaining waivers of liability from patients whose information is stored on its network. The theory is that inaccurate or incomplete data would be the fault of the data contributor and lapses in the delivery of care would be the fault of

data users. By the patient waiving any claims against the RHIO, the patient is forced to proceed directly against the parties at fault (the data contributors and/or users) rather than against the RHIO who would then be forced to seek indemnity from the parties at fault.

Although waivers may be obtained by the traditional written signature, the electronic nature of EHRs creates the possibility of obtaining "click-through" waivers from patients. For example, in order to activate or access an EHR on the RHIO's network, the patient would have to agree to waive liability. With the click of a mouse, patients could agree to terms and conditions which would include, among others, a waiver presented in electronic form. Such automated transactions are contemplated under the Uniform Electronic Transactions Act (UETA), which was designed to facilitate the use of technology by providing for the enforceability of electronic transactions.<sup>18</sup> In states that have adopted the UETA, a RHIO may be able to use click-through waivers as well as enforce transactions formed using electronic signatures.

Finally, the RHIO may also want to seek waivers, written or electronic, from data users and data contributors. For example, the RHIO may want the data user to waive any liability for incomplete or inaccurate data since that would presumably be the fault of data contributors.

### *Insurance*

As with any business facing risk, a RHIO may seek insurance (general liability, medical malpractice, etc.) to help minimize its risk. As a nascent industry, with unknown risks and claims histories, such insurance may be harder to get or subject to higher premiums, but as the industry matures and risks and claims histories become more predictable, the number of underwriters willing to insure RHIOs should increase and the cost of premiums should decrease.

### *Immunity*

Both the federal and many state governments are considering legislation to accelerate the adoption of technologies that will foster the exchange of EHRs. If governments are sincere in the belief that this is a public good, and if the policy argument can be made that RHIOs are merely passive conduits of information from one user to another, then some legislatures may consider granting immunity, or limited immunity, to RHIOs. RHIOs or associations of RHIOs may want to consider lobbying for such immunity.

## IV. Practical Suggestions to Specific Concerns

### *Integrity of Data Issues*

The data disseminated from a RHIO is only as reliable as the data coming into a RHIO. False, incomplete, inaccurate, and untimely data will always pose potential problems for RHIOs and could conceivably result in harm to a patient. To mitigate against this risk, the RHIO should attempt to get indemnification from any data contributors in the event they submit corrupt data or from data managers (such as software vendors) in the event the hardware or software corrupts the data. Further, the RHIO should also seek to get waivers from data users and patients releasing the RHIO from any liability for corrupt data that is the fault of data contributors or data managers.

### *Service Provider Issues*

While some RHIOs may perform all technology functions in house, the more likely scenario, at least at the early stages, is that the RHIO will contract with outside vendors for software and hardware support, internet hosting, and other IT services. It is easy to imagine potential problems that could result in injury to patients: a physician could request information on Patient A but get information on Patient B (the so-called “false match” problem); the internet host could be down making access to the system impossible; promised features of the software such as the ability to identify potential adverse drug interactions may not perform as promised, and on and on. To mitigate against these risks, the RHIO needs to seek indemnification from its vendors in their service contracts. As mentioned above, the RHIO also may want to seek waivers or releases of liability from both data users and patients for such errors that are the fault of third-party vendors and outside the control of the RHIO.

### *Patient Restrictions in Use of Data*

The more options given to patients to block some or all of their EHR, the more potential liability the RHIO is exposed to for disclosures of the blocked information. For example, patients may choose to block their whole record or just sensitive parts (e.g., mental health or substance abuse information), and the improper disclosure of blocked information could expose the RHIO to liability. HIPAA grants many of these rights to patients so not allowing the patient to require such blocks may not be an option. If the RHIO outsources all of its IT support, it

may want to consider seeking indemnity from the service providers against improper disclosures. Further, the RHIO may want to seek a waiver from data users and the patient for any improper disclosures that are the fault of the service providers.

### *Quality of Care Issues*

Ultimately, quality of care rests with the data user or physician. While RHIOs hold great promise in facilitating the exchange of health information and improving the quality of care, nothing is an adequate replacement for the traditional doctor-patient relationship. Thus, while there may be system down time, the doctor and the patient should not abdicate their traditional responsibilities, of the doctor to ask probing questions and of the patient to provide full medical histories. While the software may fail to identify a potential adverse drug interaction, doctors cannot evade their responsibilities to analyze what medications patients are taking before prescribing more medications, nor can patients evade their responsibilities to give full and complete disclosure to their doctors about the medications they are taking. To protect against such quality of care concerns, the RHIO should seek indemnification from the data users/physicians and waivers of liability from patients.

## V. Conclusion

RHIOs have the potential to serve as catalysts for transforming the delivery of healthcare in our communities. RHIOs have the potential to reduce errors and improve the quality of care. However, given the newness of the concept of a regional network of health information, let alone a national network, the potential for liability is a concern for the RHIO. Any party undertaking the development of a RHIO must carefully consider the potential areas of liability discussed herein when designing the structure of the RHIO.

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## Endnotes

- 1 With due apologies to Stanley Donen (director), Michael Caine (actor), Larry Gelbart (writer), and all the others who made the 1984 20th Century Fox film *Blame It On Rio*.
- 2 Institute of Medicine, *Crossing the Quality Chasm: A New Health System for the 21st Century* 1, 5 (Mar. 2001), available at [www.iom.edu/Object.File/Master/27/184/Chasm-Spager.pdf](http://www.iom.edu/Object.File/Master/27/184/Chasm-Spager.pdf).
- 3 See *Transforming Health Care: The President's Health Information Technology Plan*, available at [www.whitehouse.gov/infocus/technology/economic\\_policy200404/chap3.html](http://www.whitehouse.gov/infocus/technology/economic_policy200404/chap3.html).
- 4 Joseph Conn, *EHRs: Still in hot pursuit, Annual IT Survey Shows continuing focus on patient-care improvements, Modern Healthcare*, Feb. 13, 2006 at S1.
- 5 For consistency, the authors use the acronym RHIO throughout to refer generically to any organization or joint venture engaged in the creation and exchange of electronic health records.
- 6 See Marilyn Lamar and Kristen Rosati, Eds., *The Quest for Interoperable Electronic Health Records: A Guide to Legal Issues in Establishing Health Information Networks*, available at [www.healthlawyers.org](http://www.healthlawyers.org).
- 7 RESTATEMENT (SECOND) OF TORTS, § 328 A (1965).
- 8 *Id.* at § 323.
- 9 *Id.* at §§ 323, 324 A.
- 10 See e.g., MO. ANN. STAT. § 538.205 (4) (2005).
- 11 See e.g., RESTATEMENT (SECOND) OF TORTS, § 877.
- 12 See *id.* at §§ 652A-E.
- 13 See e.g., *id.* at § 46.
- 14 RESTATEMENT (SECOND) OF TORTS, § 436 A.
- 15 See e.g., *Rhodes v. Omega Mobile Home Sales, Inc.*, 2006 Mo. App. LEXIS 80, \*11 (Mo. App. 2006).
- 16 In Missouri, parties may limit their liability through contracts so long as the terms are clearly stated. See *Purcell Tire & Rubber Co. v. Executive Beechcraft, Inc.*, 59 S.W.3d 505, 509 (Mo. 2001).
- 17 See e.g., *Util. Serv. & Maint., Inc. v. Noranda Aluminium, Inc.*, 163 S.W.3d 910, 913 (Mo. 2005).
- 18 See e.g., MO. ANN. STAT. § 432.225 (2005).

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