PRACTICAL ADVICE

FROM THE HEALTH LAW DEPARTMENT

Fox Rothschild LLP
ATTORNEYS AT LAW

HEALTH INFORMATION EXCHANGE THROUGH A RHIO: A LEGAL "LOOK BEFORE YOU LEAP"

Imagine an electronic system where your facility or practice can log in and access patient information from another unaffiliated provider across the state and be able to immediately retrieve a patient's allergies, prescription list and medical history before providing treatment. Do you ever wish you could review the results of that diagnostic test the patient had completed in an emergency room last week? Would it help to have immediate access to a discharge summary of your patient who was recently hospitalized? These are some of the goals of RHIOs, and how HIE can improve health care delivery.

What Is a RHIO?

While there is no legal definition of either a Health Information Exchange (HIE) or a Regional Health Information Organization (RHIO), the National Alliance for Health Information Technology (HIT) led workgroups of national experts to define such key terms. That effort resulted in proposed definitions for several terms, HIE being generally defined as "the electronic movement of health related information among organizations according to nationally recognized standards," and RHIO being generally defined as "a health information organization that brings together health care stakeholders within a defined geographic area and governs HIE among them for the purpose of improving health and care in that community."

Benefits of HIE

There are now many widely recognized benefits of cooperative HIE among health care providers. It allows for the participating health care stakeholders to share information such as health records of patients (as permitted) in order to provide more timely, informed and coordinated care. The Office of the National Coordinator (ONC) for Health Information Technology supports that widespread use of HIT for management of medical information and secure exchange between health care consumers and providers will reduce health care costs (e.g., avoiding unnecessary emergency room visits; reducing duplicative testing), prevent medical errors, improve health care quality and increase administrative efficiency.

The RHIO Bandwagon

The proliferation and growth of HIE and RHIOs nationwide is being driven by the nearly $49 billion American Recovery Reinvestment Act (ARRA) for HIT adoption. In New Jersey specifically, a grant application dated October 16, 2009 (the "New Jersey Plan for Health Information Technology"), was submitted to ONC for ARRA money to support RHIO development and deployment in the state. The HIT Plan initially recognized the readiness of four out of ten regional projects within the state as the foundation of the statewide proposal, but other RHIOs continue to develop. Recent determinations by the IRS granting RHIOs tax-exempt status under IRS Code 501 (c)(3) has also spurred RHIOs to apply to the IRS for preferential tax status.

RHIO Planning

The following areas will need to be addressed in the planning of HIE through a RHIO:

Governance: Participating stakeholders should first determine how to define their relationship to one another for purposes of engaging in cooperative HIE. The RHIO may wish to formalize relationships by forming a separate entity responsible for planning and oversight. Other governance considerations include:

- Selecting an initial board to serve the RHIO;
- Developing bylaws;
- Establishing committees and developing governance guidelines for each;
- Obtaining IRS approval for 501(c)(3) tax-exempt status, if desired; and
- Insurance coverage issues.

Legal Policy: RHIOs will need to develop written policies, procedures and other documents to address issues such as:

- Patient consent and opt-in/opt-out issues;
- Compliance with HIPAA, HITECH and other applicable federal and state privacy and security laws;
- Business associate agreements;
- Joint notice of privacy practices to permit certain desired joint health care operations;
- Defining permitted and prohibited uses of data obtained through the network;
- Minimum standards for RHIO participants; and
- Measures of compliance and mechanisms for enforcement.

RHIO Agreements: A RHIO will need to develop and implement several contracts, including:

- **Participation agreements** establishing respective terms and conditions for a health care stakeholder's participation in the RHIO and responsibilities in terms of compliance, technology and authorized users.
- **Vendor agreements** that establish the terms and conditions for participants' use of the HIT, availability of vendor's HIT for use by RHIO participants and specified vendor services, such as maintenance of HIT, among others.

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- **Electronic health record (EHR) subsidy program agreements** would be required if the RHIO or qualified "donor" subsidize any portion of the costs for recipients (i.e., physicians) to purchase and implement an EHR. Such agreements must comply with the Stark Exception and Anti-Kickback Safe Harbor for EHR donations or otherwise be determined to not violate federal and state fraud and abuse laws.
- **Co-management agreements** may be utilized to define how health information and relationships should be defined to maximize quality, savings and other goals. Examples of some services and responsibilities that can be co-managed include: processes for clinical improvements; best practice standards, benchmarks and performance review processes; educational plans to improve health care provider "buy-in" and acceptance for HIT/EHR implementation and use; and marketing plans for physician community relations; among others.

Other Issues To Consider: RHIOs may also need to consider:

- Adherence to grant terms and conditions;
- Vetting fraud and abuse issues relevant to payment arrangements between referring RHIO participants;
- Tax issues, including maintaining 501(c)(3) tax exemption; and
- Intellectual property issues relating to software development as well as medical record ownership.

RHIO Experience

In order to successfully form and "deploy" a RHIO and engage in HIE, participating health care stakeholders must truly understand the specific legal issues RHIOs face. Obtaining sound legal guidance on how to address such RHIO-specific issues is essential. Over the last several years, Fox Rothschild attorneys have been advising and guiding RHIOs and their health care stakeholders on governance, privacy and security, vendor agreements, fraud and abuse laws, as well as other relevant legal issues. Fox Rothschild attorney, Jill Ojserkis, was instrumental in vetting and developing the legal policies and other documents for one of the first RHIOs in New Jersey. A team of Fox Rothschild attorneys (the "RHIO attorneys") now collaborate across practice group areas and regional offices in order to provide multidisciplinary legal support to clients that are implementing HIT, engaging in HIE and or developing a RHIO. The RHIO attorneys bring to the table many years of experience with laws applicable to health care, corporate governance, privacy and security, tax and nonprofit entities, intellectual property, among other areas.

The Team

David Soklolow (dsokolow@foxrothschild.com)
David is co-chair of the firm's Health Law Group and represents all types of health care stakeholders. He concentrates his practice in a variety of regulatory and transactional areas and is widely recognized in particular for his experience with fraud and abuse, physician self-referral and false claims issues. David also has specific experience with advising RHIOs on RHIO-specific fraud and abuse issues.

Michael Kline (mkline@foxrothschild.com)
Michael is the former chair of the firm's Corporate Department and a long-time member of the firm's Health Law Practice Group. He is responsible for starting and developing the firm's HIPAA practice in 2001 and continues to stay abreast of cutting-edge developments in privacy and security issues in health care as well as their interrelationships with governance and compliance issues of institutional providers. Michael counsels and assists hospitals, nonprofit foundations, skilled nursing facilities and others in handling overlapping business, financial, governance and legal issues. For more than 25 years, he has served as general counsel to Deborah Heart and Lung Center and Deborah Hospital Foundation in Brown Mills, NJ.

William Maruca (wmaruca@foxrothschild.com)
Bill represents all types of health care clients ranging from physician practices to hospital systems and has extensive experience in Medicare and Medicaid compliance, the Stark physician self-referral law, the Medicare Anti-Kickback law, the False Claims Act and CLIA, HIPAA, EMTALA and other federal and state regulatory requirements. He also counsels clients on contractual relationships and compliance with federal and state regulations, fraud and abuse and professional licensure.

Patricia McManus (pmcmanus@foxrothschild.com)
Patricia concentrates her practice in health law with an emphasis on federal and state health care regulatory issues, HIPAA, privacy and security breach matters and nonprofit organizations. She also has experience with health care litigation at the federal and state level. Patricia contributed to a "Privacy and Security Update" manual for the New Jersey Hospital Association and has authored several articles on New Jersey health care legislation for *Garden State Focus*, a publication of the New Jersey chapter of the Health Care Financial Management Association.

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