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A newsletter on the current legal issues facing today's health care industry

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Achieving Privacy & Security with Electronic Health Information Exchange

by Helen Oscislawski

In 2004, President Bush issued a directive for interoperable electronic health records to be a nation-wide reality by 2014. Since then, health information exchange (HIE) has received significant national attention, and HIE initiatives are gaining momentum across the nation.

There are many potential benefits to making patient information more readily available to providers at the point of care through electronic HIE. First, the quality of care may be improved through greater access to relevant information. This can lead to improved patient experience with the provider and result in higher patient satisfaction overall. Costs may be reduced through both efficiency and productivity gains because finding, faxing, and managing paper records takes more time and administrative support. Costs also may be reduced because redundant provider and diagnostic services can be avoided. Finally, providers participating in state-wide HIE or a "Regional Health Information Organization" or "RHIO" may find opportunities for new revenue streams through potential business opportunities that can be created through the network.

In New Jersey more and more providers are participating in cooperative HIE. Currently, there is increased movement and discussion to potentially create a state-wide HIE system through the establishment of a RHIO. Although the functions and purposes of RHIOs vary, if a New Jersey RHIO is established, this is one source that providers could look to for guidance on developing best practices regarding maintaining the privacy and security of health information in connection with electronic HIE.

HIPAA Privacy

The Health Information Portability and Accountability Act of 1996 and its related regulations set forth the minimum protections and standards for health information that is created, used and disclosed by covered entities, which include most health care providers. Under HIPAA, a provider cannot disclose health information about an individual unless the disclosure is permitted under one of the several exceptions and is not otherwise prohibited under state law. If a particular disclosure does not fit within one of the enumerated HIPAA exceptions, a written authorization must be obtained from the individual.

Treatment, Payment, Health Care Operations

The broadest exception under HIPAA allows providers to use and disclose health information to third parties for purposes of treatment, payment, or health care operations.

With regard to treatment, HIPAA does not require a provider to obtain written authorization from the individual before using and/or disclosing an individual's health information for treatment activities with respect to such individual (the Treatment Exception). HIPAA defines "treatment" activities to include the *provision, coordination, or management of health care and related services by one or more health care providers*, including:

- the coordination or management of health care
- consultation between health care providers
- the referral of a patient for health care

HIPAA also does not require a provider to obtain written authorization from the individual before disclosing an individual's health information to a health plan or another provider for payment activities (the Payment Exception). Payment activities can include, but are not limited to:

- a provider attempting to obtain reimbursement
- coordination of benefits
- claims adjustment
- review of services for medical necessity
- utilization review

Health plans that are subject to HIPAA's rules include group health plans, health insurers, HMOs, Medicare, Medicaid, any Medicare supplemental policy, among others.

Finally, with certain additional requirements, HIPAA does not require a signed HIPAA authorization for a provider to use or disclose health information for its own internal health care operations, including its own business management and planning activities, general administrative activities, quality assessment and improvement activities,

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auditing functions, as well as others (the Operations Exception). Providers also can disclose health information to a third party, such as a contractor, in order to have the contractor perform any health care operations task on the provider's behalf. However, in this situation the provider must obtain a signed HIPAA "Business Associate Agreement" from the contractor requiring compliance with HIPAA.

HIE Under The HIPAA Exceptions

The primary purpose of most HIEs and RHIOs is to give providers access to relevant information about the patients they are treating. As a result of the Treatment Exception, HIPAA generally *will not be a legal barrier* to the exchange of information between providers, as long as such exchange is limited to purposes related directly to treatment of the person.

If a RHIO is created as a separate legal entity for the purpose of facilitating and supporting the exchange of health information between providers, the Operations Exception under HIPAA generally would allow providers to make discloses to the RHIO as their "HIPAA Business Associate" so that the RHIO can perform health care operations activities on behalf of the providers. For each provider contracting with the RHIO for such purpose, a HIPAA Business Associate Agreement must be signed.

To the extent that the foregoing paints a picture that HIPAA may actually pose minimal privacy compliance barriers to providers participating in a state-wide HIE or RHIO, this picture is not complete. New Jersey law adds a second layer of restrictions and requirements that must be complied with.

New Jersey Privacy Laws

New Jersey law affords a number of additional privacy protections to certain health information. However, the specific restrictions and requirements vary somewhat depending on if the information is maintained by a:

- licensed health care or diagnostic facility (the Facility Laws)
- individual health care provider (the Provider Laws)
- health care program or service (e.g., Medicaid, WIC, hospice etc.) (the Program Laws)

In addition, certain information that is considered "highly-sensitive," such as HIV/AIDS, genetic information, and sexually-transmitted diseases, are guarded under New Jersey law *regardless* of who the holder of such information is (the Sensitive-Info Laws). Within these categories of state law, there are a number of provisions that require patient consent before health information can be shared with a third party, including, in some instances, other providers.

For instance, under New Jersey's Hospital Licensing Standards, every patient has the right to confidential treatment of his or her information, which includes the right that a hospital generally *not* release the patient's record to anyone *outside* the hospital without the *prior approval* of the patient. Similarly, under the Standards for Licensure of Ambulatory Care Facilities, a licensed ambulatory care facility must implement policies and procedures to obtain a patient's *written consent* for release of medical record information. Skilled Nursing Facilities generally may not disclose a resident's information without the *resident's approval*, and licensed assisted living facilities must obtain the resident's written consent for release of his or her records to any individual outside the facility.

The exceptions under the Facility Laws are narrow, and generally are limited to allowing disclosures without prior patient approval or consent only in cases of transfer of the patient to another health care facility, or if the disclosure is required by law, third-party payor, or authorized government agencies[i]. Unlike HIPAA, the Facility Laws do not contain a "blanket" exception that would permit licensed health care facilities to share information with third parties in connection with treatment activities without first obtaining patients' approvals and written consents.

Similar restrictions are found under New Jersey's Provider Laws. For example, psychologists, therapists, and social workers are prohibited from disclosing to a third party any information that is considered a *privileged communication* with a patient. Physicians and dentists are required to keep their patient's information confidential, however they are permitted to release pertinent information about the patient's treatment to another licensed health care professional who is providing or who has been asked to provide treatment to the patient, or whose expertise may assist the physician or dentist with his or her rendition of services. Thus, the exception for physicians and dentists resembles the Treatment Exception under HIPAA and supports such providers participating in HIE for treatment purposes that benefit their patients.

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[i] See N.J.A.C. 8:43G-4.1(a) 21 (Hospital can release, without patient approval, the patient's medical record to another health care facility to which the patient was transferred that requires the information, or if the release of the information is required and permitted by law, a third-party payment contract, a medical peer review, or the New Jersey State Department of Health); N.J.S.A. 30:13-5(g) (Skilled Nursing Facility may disclose record to another nursing home or health care facility on transfer, or as required by law or third-party payment contracts); and N.J.A.C. 8:36-15.3(b) (Assisted Living Facility may release information without written consent in case of the resident's transfer to another health care facility, or as required by law, third-party payor, or authorized government agencies).

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HIPAA Health Law Blog

Need information about the legal developments, issues, and other pertinent information relating the creation, use, and exchange of health information? Look to Fox's Helen Oscislawski, author of the HIPAA Health Law blog. Join Helen as she discusses topics such as EHRs and PHRs; HIEs, RHIOs, and EHR networks; privacy and security; breaches; and recent legislation.

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Anatomy of a Pennsylvania Hospital Relocation

By Victoria H. Johnson

While new hospitals open and existing hospitals close in Pennsylvania on a fairly routine basis, it is a rare occurrence for an existing hospital to relocate into a brand new facility. Such relocation involves significant coordination with various Pennsylvania state agencies including the Department of Health, the Department of Public Welfare, the Department of Environmental Protection and the State Board of Pharmacy, as well as federal agencies such as the Centers for Medicare and Medicaid Services, the U.S. Drug Enforcement Administration, and the U.S. Occupational Health and Safety Administration.

Tackling Relocation

The first major task in tackling a hospital's relocation is to ensure that all appropriate state agencies are notified of the relocation and that all required state and local licenses, permits, and registrations are updated to reflect the location and characteristics of the new facility. The initial step in this process is to notify the Pennsylvania Department of Health of the anticipated relocation and request that the hospital's license be transferred from the old facility to the new. The Pennsylvania Health Care Facilities Act and the Pennsylvania hospital licensure regulations do not specifically address the process for transferring a hospital's license in the event of a relocation. There are only certain notification requirements that apply to certain aspects of the relocation, such as 60-days notice to add new services or increase the facility's bed complement, 30-days notice to schedule a clinical inspection for new or relocated services, and so on.

The Department of Health views the relocation of a hospital as a process involving the closure of an existing hospital facility and the simultaneous opening of a new hospital facility. All of the requirements to close the existing facility and to safely and effectively transfer patient care to the new facility must be met, while the new facility must be inspected carefully to ensure full compliance with the Pennsylvania hospital licensure regulations. Notwithstanding this process, a relocating hospital is permitted to keep its old license number, which is removed from the old facility on the date of closure and reissued with the address and bed count for the new facility on the date of reopening. While a full licensure survey by the Department of Health is not needed in connection with the relocation, a comprehensive clinical inspection of the new facility is performed by the Division of Acute and Ambulatory Care of the Department of Health. Any deficiencies from the old facility will carry over to the new facility.

Transferring the hospital's license ultimately involves a three-step process. First, the Division of Safety Inspection of the Department of Health performs an onsite survey of the construction and fire safety aspects of the new facility and grants an occupancy approval. Following receipt of the occupancy approval, the Division of Acute and Ambulatory Care of the Department of Health conducts a clinical life safety inspection of the new facility. The last step in the process involves a "close-out" survey of the old facility by the Division of Acute and Ambulatory Care of the Department of Health.

Coordination and Communication are Key

The relocation of a Pennsylvania hospital requires frequent communications and written updates to the Department of Health regarding the status of the relocation. In addition, the Department of Health requires that a relocating hospital put together a detailed "closure plan" that addresses such issues as the re-routing of patients from the old facility to the new facility, locking the doors and providing additional security at the old facility, provision of adequate nursing and staff coverage during the relocation, communications with the public, emergency service providers and various government officials, and maintaining infection control procedures, among others.

In addition to coordinating with the Department of Health, it is also important to coordinate with several other Pennsylvania state agencies. In order to update the hospital's clinical laboratory permit and CLIA certificate of accreditation, a "change in status" form must be submitted to the Department of Heath, Bureau of Laboratories. It is also necessary to request amendments to the hospital's registration for radiation-producing machines and license to posses radioactive materials from the Pennsylvania Department of Environmental Protection.

If the hospital has a pharmacy, it will be necessary to submit a new pharmacy application to the Pennsylvania State Board of Pharmacy. The Department of Agriculture may need to be contacted in connection with the opening of the hospital's new cafeteria.

In addition to handling the hospital's state licenses, permits, and registrations, it is also necessary to coordinate with PennDOT and the local municipality(ies) in which both the old facility and new facility are located in order to update the signage on adjoining state and local roads leading patients and emergency providers to the hospital.

Depending on the scope of services provided by the hospital, it may be necessary to coordinate with the Division of Nursing of the Department of Health, the Pennsylvania Department of Public Welfare, Office of Mental Health and Substance Abuse Services, and the Pennsylvania Department of Aging.

In addition to notifying the various state agencies as discussed above, it is also necessary to update a relocating hospital's licenses, permits, and certifications from various federal agencies. For instance, it is necessary to request an amendment to the hospital's radioactive materials license from the U.S. Nuclear Regulatory Commission and the hospital's blood lead analysis registration with the federal Occupational Safety and Health Administration. If the hospital participates in research studies, the hospital may also need to update its Office for Human Research Protections institutional review board and federalwide assurance registrations from the U.S. Food and Drug Administration. The hospital's licenses for

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The Fight over Report Cards on Doctors

By Dean H. Wang

On October 30, 2007, New York Attorney General Andrew Cuomo announced a "first-of-its-kind" agreement with Cigna Corp. (Cigna) over the use of a physician-rating system. The deal follows on the heels of the Attorney General's August letters to various health insurers demanding "full justification" of their use of ranking systems. The letters highlighted concerns over whether the ranking systems rated physicians accurately, since certain rating systems seemed to concentrate more on cutting costs than improving the quality of care.

A Growing Concern

This agreement is an example of the growing contention over the use of physician-rating systems. While many consumers want to ensure that they select a good doctor, the systems in place are often inconsistent. Critics argue that many systems contain significant weaknesses, including the use of outcome-oriented matrices that judge doctors based on how well patients responded to their prescribed treatment, and that such results may not reflect the quality of care given. Physicians who receive below-average results from this matrix argue that they treat sicker patients who have more complications, which naturally results in lower scores.

Many physicians have taken it upon themselves to fight these rating systems. Last year, six Seattle-area doctors sued Regence BlueShield when it cut 500 physicians from its networks based on quality and efficiency ratings. The suit alleged defamation and deceptive business practices. Regence settled the suit, scrapped its ranking system, and agreed to solicit physician input for any future rankings system. The company also set up an external appeal process for physician rankings.

In addition, the Fairfield County Medical Association and members of the Connecticut Family Orthopedics P.C. filed suit against Cigna and United Health in Connecticut state court earlier this year. Their suit, based on similar grounds to the Regence BlueShield case, is alleging libel and unfair trade practices. The physicians, who are seeking class-action status for the suit, argue that the practice of labeling certain physicians as "elite" is based on financial incentives and not quality measurements.

The Cigna Agreement

In its agreement, Cigna addressed many of the New York Attorney General's concerns, but the settlement falls short of fully protecting physicians. First, the agreement aims to create more transparency in the rating system by informing physicians of its use of measures, processes, or other criteria. However, transparency itself is not sufficient to ensure a fair, unbiased system. Under the agreement, Cigna is only required to give notice 45 days prior to implementation of any system – a measure that simply informs physicians, after the fact, that a plan has been adopted. The agreement offers no comment period where physicians may voice their concerns over new adoptions. It also has no method by which physicians can appeal or protest the adoption of a rating system.

The agreement also calls for the appointment of a Ratings Examiner, which shall be a "nationally-recognized standard-setting organization" that will be nominated and paid for by Cigna. Other than stating that the Ratings Examiner must be a non-profit organization and nationally recognized, there are no other qualifications, which gives Cigna great flexibility in its choice. There is no requirement that the organization be composed of physicians or other medical professionals.

Fortunately, the agreement makes some improvements to more accurately and consistently measure physician quality within the system. It demands that Cigna make appropriate risk adjustments to account for the characteristics of a physician's patient population, and also states that when measuring cost-efficiency, Cigna will compare physicians within the same specialty in the same geographic market. Cigna also must describe the statistical basis and reliability of a physician's quality performance. Despite these provisions, the agreement does not specify how this data is reviewed and analyzed. Physicians need to know who is measuring the data and how it is measured. Will the data be reviewed by peers or will it be reviewed other health care professionals? What are the qualifications of the individuals who will review the data? These are important questions that remain unanswered.

Finally, the agreement states that Cigna shall disclose to consumers the amount of which any ratings system is based on cost, and in addition, Cigna must fully explain rating system in detail, including methodologies and measurements. Cigna also will indicate that any rating system simply serves as a guide, may have a risk of error, and should not be the sole basis of selecting a doctor. While increased transparency will help to create a fair, unbiased system, it assumes that the consumer will understand the extent of what the system does or does not measure. If the consumer has no other source of information to determine the quality of a particular physician, the consumer will rely on the rating system

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Physician Law Blog

For those seeking current news and updates on legal issues affecting physicians and non-institutional providers in both their personal and professional lives, Fox's Physician Law blog is for you. Attorney Todd A. Rodriguez offers his insights and tips on new legislation and legal issues relating to practice management, billing and coding, ancillary services, malpractice insurance, fraud and abuse developments, and other important legal issues.

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By far the most difficult privacy minefield to maneuver in New Jersey is with regard to the Sensitive-Info Laws. Under New Jersey's AIDS Assistance Act, any identifying information about an individual who has or is suspected of having HIV or AIDS generally cannot be disclosed to anyone except with the *written consent* of the person. The AIDS Assistance Act does provide a limited exception for qualified personnel to receive such information without the individual's specific consent, however the recipient must be *directly involved* in the diagnosis and treatment of the individual. Similarly, any person who has information regarding an individual known or suspected to have a venereal disease may not disclose that information to anyone without the individual's consent, except to the individual's personal physician. Finally, New Jersey's Genetic Privacy Act requires that an *informed consent that complies with specific regulatory requirements* be signed by the individual before disclosing any genetic information about the individual upon whom a genetic test has been performed.

The difficulty that the Sensitive-Info Laws pose with respect to HIE is that the restrictions and consent requirements are specific and attach to the information, wherever it may be embedded. Therefore, even though a general "blanket consent" obtained from the patient should be sufficient to allow facilities and providers to share patients' general health information through electronic HIE, the consents that must be obtained from patients in order to share highly-sensitive information must be specifically tailored and comply with regulatory requirements. If such specific consent is not obtained and sensitive information is introduced into a patient's record and shared through the HIE, disclosures may be considered privacy violations even though blanket general consents were obtained upon initiation of treatment. One way to attempt to address this issue is to develop consents that are comprehensive and contain specific language to address each potential scenario. Another possibility is to exclude sensitive information from being shared through an electronic HIE. In any case, how a provider decides to approach handling sensitive information in connection with electronic HIE must be carefully implemented and consistently applied.

Paving the Path for the Future

The privacy obstacles faced by providers wishing to participate in electronic health information exchange in New Jersey are surmountable. The first step towards clearing the HIPAA hurdle is for providers to gain a full *and accurate* understanding of what the applicable laws allow, prohibit, or require in connection with maintaining the privacy and security of health information. Widespread misinterpretation and misapplication of HIPAA and related state laws has created significant confusion among providers and patients alike. Education and training provided by individuals with a strong understanding of these laws is essential. A clear understanding of these laws also will facilitate the development of appropriate privacy policies, procedures and agreements that would apply to participants in electronic HIE and, potentially, a RHIO.

With strong commitment from the health care community and sound guidance from leaders and advisors, not only can privacy and security be achieved with electronic HIE, but health care in New Jersey may be improved through providers' participation in HIEs and RHIOs.

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wireless medical telemetry devices and microwave radio communications from the Federal Communications Commission will also need to be updated, as well as the hospital's controlled substances registration from the U.S. Drug and Enforcement Administration.

Billing, Compliance & Accreditation

A significant aspect of the relocation process involves coordination with the hospital's various government and third party payors in order to ensure a seamless transition for the hospital's billing and collections. First, a completed Medicare enrollment application on Form CMS-855A should be submitted to the hospital's fiscal intermediary in order to update the hospital's provider enrollment information on file with the Centers for Medicare and Medicaid Services. Similar enrollment application forms also should be submitted to the Pennsylvania Department of Public Welfare, Office of Medical Assistance Programs, in order to update the service locations for the hospital's Medicaid provider numbers.

Next, the hospital needs to ensure that it is in compliance with the terms and provisions of the participating provider contracts between the hospital and its third party payors. For many hospitals, this could involve notification to dozens of payors. The payors each have varying notification requirements so it is important to begin this process as soon as possible. The hospital also needs to notify its significant suppliers, vendors, and equipment lessors of the relocation.

It is necessary to coordinate with the hospital's various accreditation agencies in order to ensure compliance with their respective accreditation requirements. These agencies may include the Joint Commission, the College of American Pathologists, the American College of Radiology, the AABB, the American Osteopathic Association, the Joint Review Committee on Education in Radiologic Technology, and the Intersocietal Commission for the Accreditation of Vascular Laboratories.

The relocation of a hospital is a complex, detailed process. It is extremely important to begin the regulatory and administrative notification efforts as soon possible following the decision to relocate in order to allow sufficient time for the updating and transfer of the hospital's various licenses, permits, registrations, and accreditations.

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provided by the insurer – even if a portion of such a system is based on cost and not quality.

Physician Voices Should Be Heard

As insurers begin adopting physician-rating systems, it will become increasingly important that doctors' voices be heard. Doctors' concerns will reach new levels if regulators adopt rules for a nation-wide ranking system standard, particularly since the Cigna settlement already has begun such a movement – its current system reaches 28 states. This rating system, as approved by the New York Attorney General, could serve as a blueprint for a national, industry-wide standard. Given such a trend, physicians should be involved in the process of developing such a standard.

To evaluate a ratings system, physicians may want to consider the following:

1. What data does the system collect? Does this data include the physician's fees as a measurement? Does it depend on the physician's participation in the network?
2. Will the data used be up-to-date? Is it accurate and collected consistently?
3. What methodologies are being used to determine a physician's rating?
4. Who reviews the data and what are their qualifications?
5. Is there an independent appeal process to appeal the rating?

These rating systems, if not properly created, may damage a physician's reputation and also mislead consumers. Fox Rothschild's team of experienced health law attorneys can help physician and physician groups negotiate with insurers. Whether such negotiations involves filing suit to bring insurers to the bargaining table or active, purposeful negotiations with insurers while they develop rating systems, our attorneys are experienced in a wide variety of health care related issues and can help physicians plan and navigate a proper course of action.

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For more information about any of the articles in the Health Law newsletter, please contact any member of the Fox Rothschild Health Law Practice. Visit us on the web at www.foxrothschild.com.

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