Risk Rx

UNIVERSITY OF FLORIDA

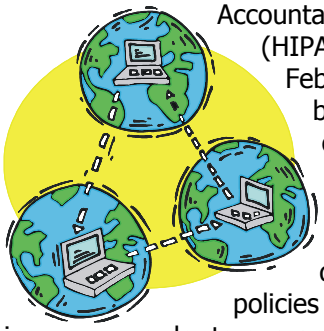
HSC Self-Insurance Program

Vol. 2 No. 2 April-June 2005

HIPAA Final Security Regulations

Gregory A. Chaires, Esq.

The final Security Standards under the Health Insurance Portability and Accountability Act (HIPAA), published in February 2003, become effective on April 20, 2005. All covered entities are required to develop security policies and procedures in order to guarantee compliance with the HIPAA Security Rule. Covered entities include a health plan, a health care clearinghouse, and a health care provider who transmits any health information in electronic form. The date of compliance is only two weeks away and all compliance measures are required to be in place and instituted by that time (except for small health plans, which have an additional year). It is critical that all covered entities have policies and procedures in place to implement the required security measures.



HIPAA security covers a wide spectrum of physical, technical, and administrative safeguards that are put in place to protect electronic Protected Health Information (ePHI). Covered entities are required to ensure the confidentiality, integrity, and availability of all ePHI that they create, receive, maintain, or transmit. A covered entity has an affirmative obligation to protect against any plausible threats or hazards to the security of the information. It must protect against any reasonable expected uses or disclosures of the information. The covered entity must also ensure that its workforce is in compliance. Although all covered entities are required to comply with the applicable standards, implementation specifications, and other requirements with respect to ePHI, each organization can decide for itself how to implement the standards. However, the covered entity must establish and follow security measures.

Covered entities may use any security measure that allows them to reasonably and appropriately employ the standards and implementation specifications required under the Security Rule. When deciding which security measures to use, the following factors should be considered:

1. Size,
2. Complexity,
3. Capabilities of the entity,
4. Technical infrastructure,
5. Hardware and software security capabilities,
6. Costs of security measures, and
7. Probability and criticality of potential risks to electronic protected health information.

The Security Rule is broken down into physical, technical, and administrative safeguards. Within the safeguards there are 17 individual standards that discuss how the organization should address compliance. Within the 17 standards there are required and addressable implementation specifications. When a specified standard includes a required implementation specification, a covered entity must carry out the implementation specification. When the standard includes addressable implementation specifications, a covered entity must assess whether each implementation specification is a reasonable and appropriate safeguard in its environment. If it is deemed unreasonable, the covered entity must document why and,

Risk Rx

UNIVERSITY OF FLORIDA

Vol. 2 No. 2 April-June 2005

HSC Self-Insurance Program

if possible, implement an equivalent alternative measure.

The Physical Safeguards protect ePHI from unauthorized disclosure, modification, or destruction. This includes standards for Facility Access Controls, Workstation Use, Workstation Security, and Device and Media Controls. The Facility Access Controls describe what the organization should do to appropriately limit physical access to the information systems contained within its facilities while ensuring that properly authorized employees can physically access such systems. Workstation Use and Workstation Security apply to what the organization should do to appropriately protect the organization's workstations through implementation of policies and procedures for workstation use, as well as the physical safeguards for those workstations. The Device and Media Controls discuss what the organization should do to appropriately protect information systems and electronic media containing ePHI that are moved to various organizational locations. The required implementation specifications within this section include what each organization should do to appropriately dispose of information systems and electronic media containing ePHI when it is no longer needed. It also includes what the organization should do to erase ePHI from electronic media before reusing the media.

The Technical Safeguards are primarily the automated processes used to protect data and control access to data. These include using authentication controls to verify that the person signing onto a computer is authorized to access that ePHI or ensuring encryption and decryption of the data as it is being stored or transmitted.

The Administrative Safeguards are the administrative functions that should be implemented to meet the security standards. These include assignment or delegation of security responsibility to an individual, as well as security training requirements. Within the Administrative Safeguards there are nine standards, including Security Management Process, Assigned Security Responsibility, Workforce Security, Information Access Management, Security Awareness and Training, Security Incident Procedures, Contingency Plan, Evaluation, and Business Associate Contracts and Other Arrangements.

The Security Standards are quite extensive. That is why every organization, if it has not begun to do so already, must immediately implement policies and procedures to comply with the standards and implementation specifications. To comply with the Security Rule, each covered entity should evaluate the security measures that are presently in place and perform a complete risk analysis to determine what additional measures must be taken to be compliant. To do this, each office should have in place a designated person who is responsible for conducting HIPAA compliance activities. To assist in the compliance efforts, there is compliance program guidance for individual and small group physician practices that was created by the Department of Health and Human Services (HHS). Among the list of components suggested, HHS includes conducting internal monitoring and auditing, implementing compliance and practice standards, conducting appropriate training and education, responding appropriately to detected offenses, and developing corrective actions.

Risk Rx

UNIVERSITY OF FLORIDA

Vol. 2 No. 2 April-June 2005

HSC Self-Insurance Program

Examples of some specific activities to assist with getting started in your HIPAA compliance efforts include:

1. Starting with an initial review of the practice's business operations and the HIPAA Electronic Transactions and Code Sets;
2. Communicating with your vendors, billing services, and clearinghouses;
3. Testing your office operations and insure that those who electronically process claims on your behalf have a testing plan in place; and
4. Investigating and understanding the Trading Partner Agreements with your health plans.

Keep in mind the Security Rule sets a minimum standard of security for entities to comply with. It is always the entity's choice to implement more stringent standards if it feels stronger protections are needed. It is a good idea to assess the potential risks and vulnerabilities of your organization to ensure that the rules you set in place are right for your office.

Failure to comply with the Security Rule can result in severe civil and criminal penalties. Civil penalties include $100.00 per violation with a cap of $25,000.00 per year. Criminal penalties include a $50,000.00 fine and one-year imprisonment for violations and a $250,000.00 fine and ten years imprisonment if the violations were committed for gain or malicious intent. It is important that every covered entity take seriously its requirements to comply with the Security Rule.

For a complete review of the HIPAA Security Standards, please visit http://www.cms.hhs.gov/regulations/hipaa/cms0003-5/0049f-econ-ofr-2-12-03.pdf, or contact your facility Privacy Officer.

"What we've got here is a failure to communicate."

Larke A. Nunn
LHRM, CPHRM

Introduction

Besides being one of the most recognized movie lines of all time, it is a perennial truth for physicians and their patients. The gap between patient expectations and health care system delivery still exists despite ongoing risk management efforts. Lack of informed consent remains the most common secondary allegation in malpractice claims involving physicians. Advanced technology and pharmaceutical advertising make it increasingly difficult to manage patient expectations about potential treatment outcomes. Compounding the problem is the fact that case law is constantly evolving in today's liability climate. That necessitates performance improvement in virtually every aspect of health care, including the informed consent process.

Patients want to know the truth.

Studies show that patients have always wanted to know the truth and be involved in their own care. Patients want to make their own decisions and have a full understanding of what is being recommended. The more severe and likely the potential complications, the more they want to know about them. Florida Patient's Bill of Rights and Responsibilities, §381.026, Florida Statutes, states: "A patient has the right to be given by his or her health care provider information concerning diagnosis, planned course of treatment, alternatives, risks, and prognosis, unless it is medically inadvisable or impossible to give this information to the patient, in which case the information must

Vol. 2 No. 2 April-June 2005

be given to the patient's guardian or a person designated as the patient's representative."

A process, not just a form

In today's litigious environment, one should understand that informed consent is the ***process*** wherein the physician pre-operatively provides the patient with all of the information needed to make a knowledgeable (informed) decision about the recommended care. Proper informed consent also presumes that the patient has an opportunity to have all questions answered to full satisfaction by the physician prior to signing the consent form. Federal law 42CFR482.51(b)(2), Condition of Participation: Surgical services, requires "A properly executed informed consent form for the operation must be in the patient's chart before surgery, except in emergencies." The purpose of the form is to help the physician ***document*** the process – what information was shared with the patient in the discussion – and to provide a rebuttable presumption that the consent was valid. In the event the patient experiences a complication and files a subsequent malpractice claim, the burden of proof rests with the plaintiff.

The Florida Medical Consent Law, §766.103, Florida Statutes, defines informed consent as including three basic elements: "A reasonable individual…would have a general understanding of the procedure, the medically acceptable alternative procedures or treatments, and the substantial risks and hazards inherent in the proposed treatment or procedures…." ***Does this mean we have to tell the patient about every possible thing that could happen?*** No, the patient only needs to know about those risks the physician considers significant. ***What makes a risk significant?*** Based upon case law interpretation to date, a significant risk is one that occurs often enough to be considered "known and recognized." Or, although occurring infrequently, it is of a serious enough nature to be considered significant, such as stroke, heart attack, or death.

Non-delegable physician duty

Obtaining consent is a *physician duty* (allopathic physician, osteopathic physician, chiropractic physician, podiatric physician, and dentist). Florida law is devoid of any mention that someone other than these individuals may be designated to obtain consent. Florida Statutes, §458.331(1)(w), states that delegating professional tasks to an individual who the professional "…knows or has reason to know that such person is not qualified by training, experience, or licensure to perform…" is grounds for disciplinary action by the state board. This is not to imply that nurses and physician extenders cannot assist in the process by having the form signed by the patient so long as that individual has first confirmed with the patient that the physician has in fact spoken with the patient and that the patient has no remaining questions. If the physician has not spoken to the patient or if the patient has additional questions, then the physician must be summoned to speak with the patient before proceeding any further.

Florida Administrative Code 64B8-9.007, Standards of Practice, (1) states that the ultimate responsibility for diagnosing medical and surgical problems rests with the physician who is to perform the procedure. Additionally, it assigns responsibility to the surgeon or the physician's designee (another attending or resident) to explain the procedure to and obtain the informed consent of the patient. The most cited example in case law is *Cedars Medical Center v. Ravelo* (3rd DCA 1999) wherein a patient in her late 20s sued the hospital and

Risk Rx

Vol. 2 No. 2 April-June 2005

UNIVERSITY OF FLORIDA

HSC Self-Insurance Program

a general surgeon, alleging medical negligence during an exploratory laparotomy in which an abdominal mass and certain affected organs were removed. The patient signed a consent form that was provided and witnessed by the prepping nurse. During the course of exploration, the surgeon encountered an ovarian mass as well as an unanticipated large amount of blood and adhesive tissue that required draining and lysis. An OB/GYN intra-operative consult was obtained and the two physicians agreed it was necessary to remove the ovaries, the fallopian tubes, and the uterus. The jury found that the surgeon did not fall below the standard of care in his treatment of the patient. However, they returned a $2 million joint verdict against the surgeon and the hospital based on negligence for not obtaining the patient's informed consent to remove all of her reproductive organs. The case was subsequently appealed by the hospital which argued that as a matter of law, it had no duty to obtain the patient's informed consent for procedures performed by the surgeon. The appeals court ruled that Florida law confines liability for a failure to obtain informed consent to the physician, not the hospital.

Process elements

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO), under the "Patient Rights and Organizational Ethics" chapter, requires that patients be involved in decisions about care, treatment, and services provided and that informed consent be obtained. The informed consent discussion must include the nature of the proposed care; potential benefits, risks or side effects, including potential problems related to recuperation; the likelihood of success; reasonable alternatives to the proposed care; the relevant risks, benefits, and side effects related to the alternatives, including possible results of non-treatment; and, when indicated, any limitations on the confidentiality of information learned from or about the patient (RI.2.30. RI.2.40). RI.2.70 states that patients have the right to refuse care, treatment, and services in accordance with law and regulation. The patient should also be informed as to:

- The name of the physician or other practitioner primarily responsible for his/her care;
- The identity and professional status of the individuals responsible for authorizing and performing the procedures and treatments;
- Any professional relationship to another healthcare provider or institution that might suggest a conflict of interest;
- Any relationship to educational institutions involved in the patient's care; and
- Any business relationship between individuals treating the patient or between the organization and any other health care, service, or educational institutions involved in the patient's care (RI.2.60).

The interpretative guidelines for 42CFR482.51(b)(2), COP, lists the following additional information as being included in a "properly executed informed consent"

- Date/time consent obtained.
- Statement that the procedure was explained to patient.
- Signatures of person providing consent and witness thereof.
- Name of hospital.

Risk Rx

UNIVERSITY OF FLORIDA

HSC Self-Insurance Program

Vol. 2 No. 2 April-June 2005

- Name of physician(s) performing the procedure(s) or important aspects of the procedure(s).
- Names and the specific significant surgical tasks that will be conducted by practitioners other than the primary surgeon or other physician.

Significant tasks include opening; closing; harvesting grafts; dissecting, removing, or altering tissue; and implanting devices. Documentation relative to these items is often included in other areas of the patient's chart rather than on the consent form.

Mandatory reporting

The Florida Internal Risk Management Program, §395.0197, Florida Statutes, requires that a report (Code 15) be filed with the Agency for Health Care Administration (AHCA) when a complication not specifically addressed in the ***documented*** informed consent for a surgical procedure occurs and requires surgical repair. If a patient requires specialized medical attention or surgical intervention resulting from a complication from a planned medical intervention (interpreted as any form of treatment) that was not addressed in the documented informed consent, then it must be reported to AHCA on the facility's annual report of incidents.

AHCA shares information with the Florida Department of Health, which, if the information is legally sufficient, conducts its own investigation to determine if licensees such as a physician or nurse violated their individual practice act.

Nurses can be investigated to determine whether or not they followed the hospital's policies related to making sure all the required paperwork was present and appropriate before the procedure was performed.

Physicians can be investigated for not obtaining complete informed consent.

At the conclusion of the Department's investigation, the probable cause panel of the applicable board determines if probable cause exists to initiate a disciplinary action against the health care provider. If the panel finds probable cause and directs the initiation of a disciplinary action, ten days thereafter the entire investigative file of the Department becomes public record and a plaintiff's attorney can obtain the file. Disciplinary actions can result in penalties such as a letter of concern or reprimand, monetary fine and payment of costs, additional training requirement, community service, suspension, and revocation of a license.

Conclusion and resources

The consent process is the physician's opportunity to build rapport and establish clear lines of communication with the patient. If the patient likes the physician, the patient is less likely to litigate. If the physician does not take the time to talk and listen to the patient and there is a bad outcome, it is more likely that the patient will hire a lawyer and complain to a regulatory agency. With properly documented informed consent, a

Risk Rx

UNIVERSITY OF FLORIDA

Vol. 2 No. 2 April-June 2005

HSC Self-Insurance Program

malpractice lawsuit or board investigation can be defended.

The Shands Intranet contains links to the applicable laws and regulations as well as the available forms. The consent form template has blank areas to capture data for each of the elements required by the medical consent law. The form has been approved by the appropriate committees for "stand alone" use, with the information written in, or as a template to create customized forms for specific procedures. It is highly recommended that each department develop customized forms for procedures that are performed often, that are complex, or that subject the patient to significant risk (frequency/severity). For educational presentations on this or other topics or assistance in developing customized consent forms, contact the UF Self-Insurance Program, Risk Management and Loss Prevention at (352) 273-7006 for Gainesville or (904) 244-3568 for Jacksonville. Should informed consent questions arise during the provision of care, please contact Shands Legal for assistance at (352) 265-8051 for Gainesville or (904) 244-2861 for Jacksonville.

References

1. Medical Risk Management Advisor, "Informed Consent Update," Volume 13, Number 1, 1st Quarter 2005, pp 1-2.
2. Dodge, A. When Good Doctors Get Sued, www.dodgeconsulting.com.
3. Scott, R. Legal Aspects of Documenting Patient Care, Aspen Publishers, Inc., 1994.
4. Colon, V. Medical Malpractice Risk Management, American College of Physicians' Publications, 2001.
5. Pozgar, G. Legal Aspects of Health Care Administration, 7th Edition, 1999.
6. 2004 Florida Statutes, Chapters 380, 395, 458, 766.
7. 2004 Florida Administrative Code, Chapter 64.
8. 2005 U.S. Federal Register, Title 42, Chapter IV.
9. State of Florida Operations Manual, Appendix A, Survey Protocol, Regulations and Interpretative Guidelines for Hospitals, Revision 1, 5/21/04.
10. Hospital Accreditation Standards, Joint Commission on Accreditation of Health Care Organizations, 2005.

Golden Rules of Chart Documentation

Jan Rebstock
RHIT, LHRM, CPHRM

For those who have worked in health care a few decades, reflecting over the past often lends credence to the old saying that "the more things change the more they stay the same."

The significant uses of the medical record and principles of chart documentation are as old as dirt, yet achieving consistent adequate, accurate, and legible documentation seems to be an elusive goal. Ergo, constant reinforcement and diligence is required.

Consider the following uses of the medical record:

Continuum of Care: Health care providers make clinical decisions based on what has been documented by other care providers. Poor or inaccurate documentation of assessments can result in unnecessary duplicative tests, delays, and errors in diagnosis.

Risk Rx

UNIVERSITY OF FLORIDA

Vol. 2 No. 2 April-June 2005

HSC Self-Insurance Program

Legal: Recognizing that memory dims over time and most cases are tried in court years later, it is easy to understand why many are lost or result in unnecessary negotiated settlements because of poor documentation.

Billing: Significant payment denials are frequently made by third party payers due to the inability to verify services rendered because of scanty documentation.

Research: Reliance on inaccurate, insufficient documentation can result in wrong conclusions that could have far reaching deleterious effects.

Regulatory Compliance: Findings of non-compliance can often be attributed to lack of documentation resulting in citations, fines, and, in some instances, program termination.

Some Shalts and Shalt Nots:

1. *Thou Shalt Document Timely, Adequately, and Accurately.*
2. *Thou Shalt Write Legibly.*
3. *Thou Shalt Document Objectively and Factually.*
4. *Thou Shalt Not Intentionally Alter The Medical Record.*
5. *Thou Shalt Not Use Unapproved Abbreviations.*
6. *Thou Shalt Not Leave Blank Spaces on Required Forms.*
7. *Thou Shalt Not Use "White Out" to Make Corrections in the Chart.*
8. *Thou Shalt Date, Time, and Sign All Record Entries.*
9. *Thou Shalt Read What Thou Co-signs.*
10. *Thou Shalt Not Use Pencils To Document.*

"So let it be written. So let it be done."
Yul Brynner

Legal Case Review

Cristina Palacio, Esq.

John Insinga v. Michelle LaBella, et al. (Fla S. Ct. 1989)
In this case, the Florida Supreme Court ruled, for the first time, that the doctrine of corporate negligence was applicable to a hospital for failure to properly credential a physician on its staff. Since this case arose prior to the existence of the current statutory imposition of liability on hospitals for negligent credentialing, the question posed to the Court was whether hospitals have a common law duty to their patients to select and retain competent physicians who, although they are independent practitioners, provide in-house patient care through their hospital staff privileges.

Case Summary: On January 19, 1981, "Dr. Michelle LaBella" admitted 68-year-old Mildred Insinga to Biscayne, a hospital in North Miami. Mrs. Insinga died in the hospital on February 6. Subsequently, it was discovered that Dr. LaBella was really Morton Canton – who was not a doctor, but rather a fugitive who had been indicted in Canada for the manufacture and sale of illegal drugs. Canton had fraudulently obtained a medical license from the state and staff privileges at the hospital using the name of a deceased physician. Mr. Insinga sued Canton, the state, and Humana, the corporation that owned the hospital. He alleged that the hospital was negligent in failing to follow its own procedures to verify "LaBella's" application and in granting Canton privileges and that negligence had caused his wife's death. It was noted that

Vol. 2 No. 2 April-June 2005

Mrs. Insinga had sought treatment from "Dr. LaBella" for her illness several months before she was ever admitted to the hospital. Her husband claimed, however, that he and Mrs. Insinga relied on LaBella's representations that he had staff privileges at Biscayne in selecting him as her physician.

Insinga argued that had the hospital properly verified "LaBella's" credentials, in keeping with prevailing national and state standards, as well as the hospital's own bylaws, it would have discovered or should have discovered that LaBella was an imposter and not competent to provide medical services in its facility. The hospital countered that because Mildred Insinga retained the services of LaBella before she was admitted to the hospital, creating a doctor-patient relationship outside the hospital, there was no duty of care on its part regarding LaBella's credentials.

The Court first reviewed the copious case law supporting the view hat a hospital is not liable for the negligent actions of private physicians whom it privileges, because it lacks the requisite control of the physicians' actions to be held vicariously liable. However, the Court distinguished those cases from the present case, finding that in this scenario the theory is that the hospital's liability is based not in vicarious liability, but in a duty of care it owes directly to patients to assure the competence of its medical staff through the credentialing process. Thus, the Court held, a hospital can be held responsible for negligence of an independent physician if it has failed to exercise due care in the selection and retention of the physician on its staff. This concept has been recognized in subsequent Florida cases, see, e.g., *Cedars Medical Center v. Ravelo* (3rd Cir. 1999) and *Maksad v. Kaskel et al.* (4th Cir. 2002).

Case Analysis: While it may often appear burdensome to the practitioner applying for privileges, this case underscores the importance of having a vigorous credentialing process that ensures primary verification of every significant detail regarding the practitioner's education, training, and experience (not to mention current existence!). It is unclear from the facts set forth by the Court what particular part of its process the hospital failed to follow. But, it is significant that the fact that the state had issued a license to Canton, as LaBella, was not sufficient to shield the hospital from its own failure in assuring that Canton was fully qualified. It is also noteworthy that the Court states that "a hospital can be held responsible for negligence of an independent physician if it has failed to exercise due care in the selection and retention" of a physician on its staff. This indicates that reasonable scrutiny is important not only at initial appointment, but at reappointment and in-between appointment through an ongoing peer review process to avoid hospital liability for negligent credentialing.

Florida statute now expressly codifies the "common-law" doctrine found by the Court in *Insinga*. F.S. §766.110 provides that"

(1) All health care facilities, including hospitals and ambulatory surgical centers…have a duty to assure…the competence of their medical staff…through careful selection and review, and are liable for a failure to exercise due care in fulfilling these duties. These duties shall include, but not be limited to:

(a) The adoption of written procedures for the selection of staff members and a periodic review of the medical care and treatment rendered to patients by each member of the medical staff….

Risk Rx

UNIVERSITY OF FLORIDA

HSC Self-Insurance Program

Vol. 2 No. 2 April-June 2005

> Each such facility shall be liable for a failure to exercise due care in fulfilling one or more of these duties when such failure is a proximate cause of injury to a patient.

Risk Reduction Strategies: While we all have our concerns as to what impact Amendment 7 may or may not have on the continuing privilege granted by Florida statute to peer review activities, this case is extremely important to remind us that failure to properly carry out common-law and statutory obligations to assure that our patients receive care from competent physicians has real liability risks.

Physicians involved in credentialing should ensure that all the information required to be verified by JCAHO standards, which arguably establish the "standard of care," have been so verified before making a recommendation to the board. In addition, it is important to scrutinize education, training, and experience to assure that the practitioner has adequately demonstrated the competence to exercise each and every specific privilege being requested. Remember, the burden is on the applicant to provide adequate documentation to prove competency; the credentialing committee should not feel compelled to grant privileges unless the applicant has met the burden to its satisfaction.

Assuring continued competency is equally important. Physicians involved in peer review have a duty to assure that physicians on staff maintain competency. The purpose of peer review is to identify deficiencies in competency so that they can be quickly addressed – most likely by recommending education or training to bring a physician under review "back up to snuff" so that patients receive care that is at standard or above. Sometimes, though rarely, it can only be addressed by removing the physician from the staff.

Failure to do "due diligence" to ensure a practitioner's competency at all times while on staff can lead to a finding of liability on the part of the corporation owning the hospital. While this does not have a direct financial impact on the medical staff members of the committees charged with making credentialing recommendations to the hospital board (as they are, in that capacity, acting essentially as "agents" of the hospital), it does have a practical and emotional impact, as the lawsuit is unpleasant for all involved, regardless of the ultimate financial responsibility for the liability.

Contact us at rmeduc@shands.ufl.edu with comments or article suggestions.