HIPAA Privacy Rule — Consent Is the Key

There are some simple truths about the privacy regulations made effective this past April by the Department of Health and Human Services (HHS) pursuant to the Health Insurance Portability and Accountability Act (HIPAA). They are outrageously detailed and complex and they are extremely long (particularly when coupled with the regulations’ narrative preamble).

If the regulations had gone on an extended “require further study” hiatus for a couple of years, few tears would have been shed by hospitals or physicians. But that was not to be.

The privacy regulations became final in April and will be effective in April 2003. When the regulations were finalized, HHS promised further materials to help make the regulations (also known as the Privacy Rule) more clear and user-friendly.

The good news is that the Office of Civil Rights (OCR), the HHS agency given the responsibility to clarify, implement and enforce the Privacy Rule, issued “Standards for Privacy of Individually Identifiable Health Information” in July. This is the first of what the OCR says will be a series of helpful materials. And, unlike the regulations, these Standards are written in plain English and do provide helpful information.

Because the regulations are so complex, an entire HIPAA industry has been born, spewing out vast amounts of information. With all the HIPAA hype, it’s easy to get lost in the details.

Consent

Instead of focusing on all of the technicalities, focus first on the primary requirement of the Privacy Rule — obtaining the patient’s written consent to use or disclose his or her “protected health information” (PHI) to carry out “treatment, payment or health care operations” (TPO). A patient consent authorizes the hospital to do just about anything it needs to do — or could do — with patient information, short of selling it.

(One of the first key areas developed under what was once called “hospital law” was the doctrine of informed consent. It is interesting that, in the Age of HIPAA, we are right back where we started, with a valid consent being the paramount starting point.)

There are certainly legitimate criticisms to make of the Privacy Rule. But perhaps the most important thing that its writers did was to create, at the initial contact point between the patient and the hospital, the means by which the hospital can be authorized, through consent, to do much, if not most, of its work. And the hospital or physician practice must obtain the patient’s consent only one time. The patient does not have to sign an HIPAA consent form at every point while a hospital patient, or at every doctor’s visit.

The Privacy Rule protects a patient’s (PHI). PHI is individually identifiable health information transmitted or maintained in any form or medium. “Health
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"information" relates to a. health or condition; b. provision of health care; and c. payment.

"Covered entities" (hospitals, physician practices, and health plans) may not use or disclose PHI except as permitted or required by the Privacy Rule. One of those permitted uses, with the patient’s consent, is “treatment, payment or health care operations.”

Under the Privacy Rule, “health care operations” of the hospital include:
- quality assessment;
- public health activities;
- reviewing competence or performance;
- underwriting and premium rating;
- medical review, legal services or auditing;
- business planning;
- general administration.

Continue digging into the Privacy Rule’s definitions, and you find that “general administration” includes:
- customer service;
- internal grievances;
- due diligence;
- fund-raising and marketing;
- creating de-identified information.

Hospitals need to pay particular attention to policies on obtaining consent and training for the people who will be involved in getting consents. Here are some key rules:
1. The consent form must be accompanied by a Privacy Notice;
2. HIPAA consent must be separate from the normal informed consent for treatment;
3. The consent must be in plain language and signed by the patient; and
4. The patient may revoke that consent at any time.

And here is an absolute key: the health care entity may condition treatment on the patient’s consent. If the patient refuses, the full range of necessary treatment, payment and health care operations cannot be performed. The drafters of the Privacy Rule realized this. A patient who wishes to be treated must consent to this use of his or her PHI. If the patient does not consent, the hospital or physician practice can refuse to treat him or her. It is a fair *quid pro quo.*

Given that the patient will be signing a consent form based, presumably, on his or her reading of the hospital’s Privacy Notice and consenting to what is in it, the Notice would seem to be an all important, perhaps the most important, feature of an HIPAA consent. So, what responsibility does the hospital have to ensure that the patient actually reads and understands the hospital’s Privacy Notice? According to the Standards issued in July, not a lot:

“The Privacy Rule does not require that the individual read the notice or that the covered entity explain each item in the notice before the individual provides consent. We expect that some patients will simply sign the consent while others will read the notice carefully and discuss some of the practices with the covered entity.”

The law of informed consent for treatment has been carefully built through the decades, by statutes and case law, in all 50 states. But people often sign consent to treatment forms without paying a great deal of attention to the information on the form or to the person providing the information. Patients pay even less attention to the consent forms they now are routinely asked to sign so their medical records can be released to insurers or other third-party payers. HIPAA authorities have acknowledged that you can bring the Privacy Notice to the patient, but you can’t make the patient read it. The important point is that patients be given the opportunity to read what they are consenting to before signing.

Now, for the other side of the coin: develop a well written Privacy Notice and train a number of hospital employees to answer patients’ or family members’ questions about it. That has to be available at every entry point of the hospital — inpatient admission, outpatient registration, and the Emergency Department.

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**HIPAA and Emergencies**

Mention of the Emergency Department brings us to an important HIPAA consent feature. There is a long-standing legal rule that in an emergency, when the patient is unconscious and there is no one to speak for him, the patient’s consent is implied.

The Privacy Rule maintains that same emergency exception. The emergency provides the HIPAA consent. It’s when the emergency is over, and the patient is stabilized and conscious, that things get interesting. The Privacy Rule states that, at that point, the Privacy Notice must be provided and the patient’s HIPAA consent obtained.

But what if the patient refuses to sign the form but doesn’t refuse treatment, doesn’t leave the hospital and, in fact, is not medically able to leave? Neither the Privacy Rule nor the new Standards answer this. To take the Privacy Rule at its word, the hospital could refuse to treat the patient. But no hospital is going to discharge a patient who is not medically ready to leave because he or she refuses to sign an HIPAA consent form.

So what is the hospital to do? We see only one legally correct and practical answer: as long as the patient remains in the hospital, consent is implied, regardless of whether the consent form has been signed. The hospital simply cannot operate fully in its care and management of the patient unless it can use the patient’s PHI in all the ways mentioned at the beginning of this article. The patient’s decision to stay and receive treatment from the hospital creates the necessary inference that he or she has consented to the use of his or her PHI for treatment, payment and operations. No other answer allows the patient to be treated and the hospital to perform its necessary functions.

**Peer Review**

A patient’s consent clearly authorizes his or her PHI to be used in peer review operations. The patient’s consent cov-
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(continuation)

tion and case management records of health plans, and any other records “used, in whole or in part, by or for the covered entity to make decisions about individuals.” The term “individual,” as used in the regulations, refers to the individual who is the subject of the PHI, such as a specific patient or health plan enrollee.

Most peer review records are not used to make decisions about specific patients or enrollees. They are used after the patient has been discharged to determine if the care provided was appropriate, to see if there is an opportunity for improvement, or to decide if a particular professional should continue to exercise clinical privileges. Such records would not be subject to the right of access provided to individuals under HIPAA.

However, some peer review information may be used to determine what should be done relative to an individual’s care. Department meetings, case reviews, tumor boards and other routine peer review activity may include discussions about specific patients that are aimed not only at monitoring or evaluating care but also at suggesting courses of treatment for specific individual patients.

To the extent that these communications contain information that would be critical of the care already rendered, they would greatly aid a plaintiff in a malpractice case. Even if formal discovery of those records was prohibited by state law, the individual who was referenced in the records could request them under HIPAA and the health care entity would have to turn them over.

Therefore, peer review documents should not contain any patient names or other information that could identify a patient. Patients should be referred to only by number or other code which will not reveal their identity. This is the best way to be sure that the patient’s HIPAA access rights will not apply.

Not All Emergency Departments Are Created Equal

Patients who present to the Emergency Department with psychiatric conditions can pose special EMTALA challenges. The 1994 EMTALA regulations make it clear that psychiatric conditions are considered “emergency medical conditions” and that the screening and stabilizing treatment requirements of EMTALA apply to them.

The Interpretative Guidelines published by HCFA in 1998 state that a patient with psychiatric conditions is considered “stable for transfer” when “he/she is protected and prevented from injuring himself/herself or others” and is considered “stable for discharge” when “he/she is no longer considered to be a threat to him/herself or to others.”

But what is the hospital’s obligation if it does not provide psychiatric services? What screening examination and treatment must be offered in that situation?

Sarah Baker, whose father committed suicide two days after being released from the Emergency Department of Redbud Community Hospital, claimed that the hospital, which does not offer psychiatric services and has no psychiatrists, psychologists or mental health workers on staff, violated EMTALA when it called in a county mental health worker to screen her father for a psychiatric emergency.

The Act itself clearly states that a hospital has a responsibility to provide medical screening examinations “within the capability of the hospital’s emergency department, including ancillary services
routinely available to the emergency department” and stabilizing treatment “within the staff and facilities available at the hospital.” Based on those provisions, the federal district court ruled that the hospital did not violate the Act and granted summary judgment in its favor. Sarah Baker appealed. Baker v. Adventist Health, Inc., No. 00-15273 (9th Cir. August 6, 2001).

The Court of Appeals for the Ninth Circuit first reviewed what happened when Henry Baker arrived in the Emergency Department. The court wrote:

“On September 25, 1996, Henry Baker was brought to the hospital by his former sister-in-law and her fiancé, with whom Baker lived. The nurse who triaged him recorded his chief complaint as 'request mental health evaluation.' The nurse checked his vital signs, noted no obvious physical problems, and classified Baker's triage status as 'delayed,' meaning that he was in a stable condition, was in no distress, and was entitled to less priority than patients with life-threatening or urgent needs.

“About ninety minutes later, Baker was examined by Dr. Wolfgang Schug, an emergency room physician on Redbud's medical staff. Dr. Schug recorded a patient history that includes the notation, 'Last 90 days “apathetic,” unable to communicate, depressed. Suicide “constantly” in back of mind.’ Dr. Schug concluded that Baker had no physical or medical condition requiring immediate care, and recorded his diagnosis as '(1) Depression (2) Medical clearance for Mental Health.’”

Pursuant to hospital policy, Dr. Schug contacted the county to request a mental health examination of Mr. Baker. That policy requires “the emergency department to request a mental health evaluation from Lake County if the medical screening turns up evidence of a ‘psychiatric disturbance’ or symptoms of substance abuse. Patients must be ‘medically cleared’ before Lake County is called to perform a mental health evaluation. The policy provides that the emergency physician’s examination must be ‘sufficient to rule out any organic causes of the aberrant behavior.’”

Within one half hour of Dr. Schug’s phone call, a county crisis worker, Dennis Skinner, and a trainee arrived at the Redbud Community Hospital emergency department to evaluate Mr. Baker. After examining him, Mr. Skinner determined that Mr. Baker “did not constitute a danger to himself or others,” and thus did not meet the criteria for an involuntary hold under state law.

Mr. Baker was released from the emergency department with instructions to go to Lake County the next day “to complete paperwork in order to qualify for medical expenses and social services, and to receive an assessment by a clinician for possible referral to a psychiatrist for the treatment of depression.” Both Dr. Schug and Mr. Skinner signed the discharge record, which included a notation that Mr. Baker was to follow up with the county. Two days later, Mr. Baker hanged himself from a tree.

**Screening Examination**

After reviewing the relevant EMTALA provisions, the appeals court turned to the “novel argument” presented by Ms. Baker: “[T]he hospital should have provided a mental health screening itself rather than calling in the county mental health department.

“This is not a tenable position under the statute,” said the court. “...The hospital did not have the capability to perform a mental health screening. Nor are mental health services listed in Redbud’s written policy detailing ancillary services available to the emergency department. Redbud therefore did not have any duty to provide Baker with a mental health screening.

“...For purposes of our EMTALA analysis,” continued the court, “the mental health evaluation performed by Lake County was entirely gratuitous.”

Ms. Baker argued that “psychiatric services were indeed within the capability of Redbud’s emergency department, continued on page 6
since Dr. Schug took psychiatry courses during medical school and has been exposed to psychiatric patients as an emergency room physician.”

The court rejected that argument, quoting a decision by the Court of Appeals for the Tenth Circuit: “‘[H]ospitals, and not reviewing courts, are in the best position to assess their own capabilities.’ ... A standard screening policy for patients entering the emergency room generally defines which procedures are within a hospital’s capabilities. Here, Redbud’s policy required Lake County crisis workers, rather than Redbud staff, to perform mental health screenings. The uncontested evidence establishes that mental health screenings were beyond the capability of Redbud’s emergency department.”

The appeals court was also unpersuaded by Ms. Baker’s argument that “the hospital violated EMTALA by discriminatorily failing to provide screening for psychiatric emergencies, while it provided screening for physical emergencies.”

“EMTALA explicitly recognizes the differences among the capabilities of hospital emergency rooms,” said the court, “so the statute limits the screening required to one that is within the capability of a given emergency department. ... It follows that Redbud cannot be charged with discriminating against psychiatric patients by failing to provide them with psychiatric screenings, where the hospital lacked any mental health capability.

“More fundamentally,” continued the court, “plaintiff’s argument overlooks the central purpose of EMTALA, which is to forbid hospitals from providing different emergency care to patients on the basis of the patients’ ability to pay. ... Hospitals are not required to provide patients presenting different symptoms with identical screenings. Nor are hospitals required under EMTALA to provide screenings that are beyond their capabilities. The district court properly concluded that Redbud did not violate EMTALA by failing to provide screenings for psychiatric emergencies.”

**Stabilizing Treatment**

Ms. Baker also claimed that Dr. Schug did, in fact, detect an emergency medical condition when he examined her father and that he violated EMTALA by failing to stabilize him before transferring him to Lake County. The court said that Dr. Schug’s testimony that he knew that Mr. Baker suffered from a psychiatric condition that might make him a danger to himself “does not constitute actual detection of an emergency medical condition.” Because Dr. Schug detected no emergency medical condition, no duty to stabilize arose. “But, even if there was such a duty,” said the court, “Dr. Schug’s request for the county to conduct a mental health evaluation of Mr. Baker does not constitute a ‘transfer’ under EMTALA because there was no movement of Baker outside the hospital’s facilities.”

Is a separate policy for each service not provided by the hospital necessary? Should a hospital like Redbud (a 40-bed rural hospital) have formal transfer agreements in place to address patients who need those services?

The policy in this case helped Redbud Community Hospital demonstrate that it acted appropriately in its treatment of Mr. Baker and was critical to the appeals court’s decision that there was no violation. But a separate policy to address transfers of patients requiring services not offered by the hospital is not necessary if the hospital’s on-call policy adequately outlines when and how a patient in an emergency medical condition can be transferred. An appendix to the policy could indicate the hospital or facility where patients are to be transferred for the particular services that are most often needed, for example, burn patients are sent to Memorial, neonates under X grams are sent to Children’s, etc., along with the name of a contact person, a phone number and other pertinent information for each. Psychiatric services could be included in that appendix. (Many

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...states have contracted with specific hospitals to provide psychiatric services for medical assistance patients, which dictates where a hospital must transfer those patients.)

Formal transfer agreements are not required between hospitals. (Centers for Medicare & Medicaid Services (CMS) loves to see them, but they are not required.) However, if a formal transfer agreement would help clarify responsibilities on both sides and facilitate transfers, thus improving patient care, then it would be worth the time to execute one. This is especially true if there have been problems with transfers between the hospitals.