

HIPAA Enforcement in the Spotlight

PART I: HIPAA Has New Civil Enforcement Regulations

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Covered entities can now get a better picture of how civil enforcement of HIPAA complaints will take place. On April 18, 2005, HHS issued proposed civil enforcement procedures covering privacy, security, and TCS investigations under HIPAA. The proposed rules contain a number of critical dates and steps that covered entities will need to be mindful of so as not to forfeit rights to effectively defend themselves.

Recall that HIPAA is backed up by both civil and criminal penalties. On the civil side, the Secretary "shall impose" a civil monetary penalty of \$100 per violation (up to \$25,000 per calendar year for similar violations) on a covered entity. If a particular alleged violation includes a criminal element, the civil enforcement rules do not apply and the complaint is investigated by other agencies.

The rules first clarify how penalties are to be assessed when two or more covered entities are involved in a violation. If the entities are related to one another by common ownership or control (for example, as an affiliated covered entity or merely as parent and subsidiary), the Secretary is limited to imposing a single civil monetary penalty for the violation. The responsible covered entities are jointly and severally liable, however.

On the other hand, if covered parties are not related by common ownership or control, the Secretary is to impose separate penalties on each responsible party. Thus, separate covered entities in an OCHA, or separate covered entities doing business with one another, could each be subject to the \$100/\$25,000 CMP for their role in a violation. This clarification strongly reinforces the notion that each covered entity has a legitimate stake in knowing that other covered entities with which they do business take compliance seriously.

Under the proposed rules it is a defense that the person "did not know and by the exercise of reasonable diligence would not have known" that the person violated HIPAA. Practically speaking, this puts a premium on making an effort

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to comply and deploying what appear to be (and are documented as) reasonable safeguards. Logically, a party would not be expected to know that conduct constitutes a violation if the party has reason to believe the party has deployed safeguards to protect against violations.

The Secretary of HHS has subpoena power. When HHS subpoenas a covered entity, the covered entity is to designate a representative or representatives to respond. Implicit in that designation is the understanding that the designated individual(s) are in a position to know the facts and answer questions. This effectively places a burden of preparation on selected representatives.

At the conclusion of an investigation, HHS makes a proposed determination. If adverse, the covered entity has a short time frame in which to request a hearing. The request for hearing “must clearly and directly admit, deny or explain each of the findings of fact contained in the notice of proposed determination.” The response must also set out any “affirmative defenses” on which the covered entity will rely at hearing—for example, no knowledge, no relationship to the responsible party, or failure due to reasonable cause and not willful neglect.

The rules will permit parties, including covered entities, to issue “requests for production.” In other words, covered entities may conduct certain reasonable discovery in preparation for a hearing. If another party will not comply, an administrative law judge has authority to issue a subpoena, if persuaded the request is reasonable. The administrative law judge may also sanction a person, including a party, for misconduct.

With the new proposed rules, covered entities need to be mindful that they are in the midst of a formal investigative and adjudicative process when they respond to a complaint and participate in an investigation or hearing.

PART II: Department of Justice Limits Criminal Enforcement To “Covered Entities”

Less than a year after the DOJ wrapped up its first criminal prosecution under HIPAA of an employee of a Seattle cancer treatment center for stealing a

patient’s identity and charging thousands of dollars in purchases, a new memorandum opinion issued by the Department of Justice has called that prosecution into question.

The memorandum opinion issued on June 1, 2005, now says that only “covered entities” under HIPAA may be criminally prosecuted for violations of HIPAA. The opinion echoes what many experts in the HIPAA area have long thought the law allowed. If only “covered entities” can violate HIPAA, only “covered entities” can be criminally prosecuted. So what does that mean for institutional health care providers such as hospitals, long term care facilities and the like. The Department of Justice opinion states:

“When the covered entity is not an individual, principles of corporate criminal liability will determine the entity’s liability and the potential liability of particular individuals who act for the entity. Although we do not elaborate these principles here, in general, the conduct of an entity’s agents may be imputed to the entity when the agents act within the scope of their employment, and the criminal intent of agents may be imputed to the entity when the agents act on its behalf...In addition, we recognize that, at least in limited circumstances, the criminal liability of the entity has been attributed to individuals in managerial roles, including, at times, to individuals with no direct involvement in the offense.”

The opinion also addresses possible criminal liability under principles of aiding and abetting the commission of an offense under HIPAA as well as conspiracy principles.

While most managers, administration and even directors may feel the pressure of what this opinion appears to mean, the bulk of health care workers, e.g., a billing clerk, cannot face criminal prosecution under HIPAA according to this opinion. A significant amount of conduct that is clearly wrong will fall outside the criminal reach of HIPAA. It’s important to keep in mind, however, that there may be various other vehicles for criminally prosecuting the really rogue case where patient identity has been compromised for the financial gain of another.

But where does this leave health care providers in terms of what level of knowledge of employee

actions is necessary to subject management to criminal prosecution? The opinion confirms that the covered entity is liable for a “knowing” violation of the facts that constitute a violation of HIPAA. It is not necessary for the government to show that the covered entity knew the act violated HIPAA. If you are like most of the rest of the country trying to understand what this opinion means, your mind is likely wobbling at the distinction. Certainly you can envision some situations where a covered entity could truly know the facts that constitute the offense. The Gibson case in Seattle is the perfect example. Or, suppose a physician gives medical information on a patient to the patient’s spouse to be used against the patient in connection with a divorce action. These would be clear violations, and criminal penalties would probably be justified in such cases.

Certainly there are lots more cases where a covered entity may be justifiably confused over whether a particular course of action would be a HIPAA violation. We receive calls daily from clients trying to find the black or white (can I or can I not disclose to law enforcement in this case?) in regulations that are very grey in many circumstances. We would assume that some degree of prosecutorial discretion would be exercised in such cases. The message of the DOJ is that “ignorance of the law” is no defense.

The other message from this opinion is that it has confirmed the criticality of having clear privacy policies and confidentiality agreements in place with employees so that you can show that any employee who misuses protected health information has done so in violation of the privacy policies and has done so outside the scope of his or her employment with the entity.

Vickie Brady and Kelly Clarke

Assistance To LEP (Limited English Proficiency) Individuals-A Requirement For All Medicare and Medicaid Providers

Title VI of the Civil Rights Act of 1964 requires recipients of federal funds to provide meaningful access to services by persons with limited English proficiency. The Department of Health and Human Services (“DHHS”) is one of several federal agencies

that has issued guidance to recipients of federal funds on compliance with this requirement. The DHHS LEP guidance was first issued on August 30, 2000, and was reissued in revised form on August 30, 2003.

The requirements set out in the 2003 Guidance apply to any health care provider that is a recipient of Medicare, Medicaid or other federal funds. This includes both institutions and individual providers such as physician offices, although providers have been given substantial leeway under the Guidance to develop an LEP plan that fits their situation and resources. A LEP person is defined by the Guidance as a person who does not speak English as his or her primary language and who may have a limited ability to read, write, speak or understand English.

JCAHO standards have incorporated LEP requirements and include a standard that accredited organizations effectively communicate with patients (e.g., Hospital Standard RI. 2.100) via language accommodations.

Self-Assessment. Each provider subject to the LEP Guidance is advised to conduct a self-assessment of the following factors to determine the extent of their obligations.

1. The number or proportion of LEP persons likely to be encountered or served as patients; including consideration of individuals residing in the provider’s service area who may not be accessing services due to language barriers. LEP individuals who may need services are not only patients, but parents of minor patients and persons wishing to participate in community/wellness programs.

2. The frequency with which LEP individuals come in contact with the provider’s program, activity or service. The program developed by the provider should be tailored to the frequency of encounters with particular languages. Less intensive alternatives such as phone interpretation services may be sufficient for infrequently encountered languages, but interpreter services may be more appropriate for high-volume encounters.

3. The nature and importance of the provider’s program, activity or service. Emergency and urgent programs and important functions, such as obtaining informed consent, should have proportionate resources

directed to enhanced language services for pertinent populations.

4. The resources available to the provider and the costs. This is the essence of the “reasonableness” requirement. Smaller providers are not expected to provide the same level of language enhancing services as larger entities serving a significant number of LEP individuals.

Types of Language Assistance Services. Oral interpretation and written translation are the two primary means of providing language services to LEP individuals. The mix of services provided is less important than the quality of the service. Not every speaker of a language is qualified to serve as an interpreter or translator, particularly when technical and complex subject matters are involved. The Guidance recognizes that individual providers may refer patients to one another to permit LEP individuals to obtain the benefit of bilingual staff.

The Guidance explores the considerations in obtaining interpretation services through hiring bilingual staff, hiring or contracting for interpreters, use of telephone interpreter services, community volunteers and use of family and friends as interpreters. The Guidance is explicit that LEP persons should be offered an interpreter or other alternative by the provider and should not be required to use a family member or friend as the sole means of interpretation. Even when the LEP individual prefers a relative or friend as interpreter, the provider needs to assess whether that individual’s interpretation will be of sufficient quality and will be appropriate under the circumstances.

Translation services are required where the provider has determined through its self-assessment that an effective and reasonable LEP plan will include the translation of “vital” written materials into the language of each frequently encountered LEP group. The Guidance gives as possible examples of vital documents – consent forms, complaint forms, written notices of rights, including notices about free language assistance. Through self-assessment, providers will identify vital documents for patient access in their organization.

Is a Written Plan Necessary? In almost all case, yes. It is possible that an individual provider could

determine that he or she has such limited resources and encounters with so few LEP individuals that a written plan will not be necessary, although the provider will nonetheless be required to meet the Title VI obligation to provide meaningful access to its programs and services.

Elements of a Written Plan. The Guidance indicates that the first step in the plan is a means to identify LEP individuals who need language assistance. This step is closely related to the step of providing notice of available LEP services and may be indistinguishable in practice. It appears to be most commonly accomplished through posted notices in commonly encountered languages and the use of “I speak...” cards to help individuals identify their primary language to the provider. The LEP plan should include a description of the types of language services available, procedures for accessing such services and steps that will be taken to assure the competency of interpreters and translators. Training of staff is another essential element. Finally, the Guidance urges periodic review and updating of the LEP plan to respond to changes in patient demographics, the types of services offered, addition of new vital documents and so forth. Community input to the plan at all phases is strongly encouraged.

Enforcement. Enforcement is by the Office of Civil Rights (OCR) under Title VI implementing regulations, with a strong emphasis on voluntary compliance. The OCR will investigate complaints and other information indicating noncompliance and will attempt to achieve voluntary compliance through informal means (education and technical assistance). If voluntary compliance efforts fail, OCR will attempt to terminate federal assistance to the provider through an administrative hearing process or refer the matter to the Department of Justice for enforcement. To date, there are no reported administrative cases involving LEP violations.

What About Disclosures to Interpreters under HIPAA? Is an individual’s authorization required to disclose information to an interpreter? No. When a covered health provider uses an interpreter to communicate with an individual, the individual’s authorization is not required if the provider meets the following conditions:

- The interpreter (translator) is a member of the covered entity's workforce, such as a bilingual employee, a contract interpreter or a volunteer; or

- The covered entity engages a person or entity who is not considered a member of the workforce to perform interpretation (or translation) services as a business associate under a business associate agreement.

In addition, a covered entity may, without the individual's authorization, disclose protected health information to the patient's family member, close friend, or any other person identified by the individual as his or her interpreter.

There is also an exception for telephone interpretation services. A provider may connect a patient with a telephone-accessed interpreter to explain the availability of interpretation services. If the provider reasonably concludes that the patient wants to continue the encounter using the interpreter, and thereby infers that the patient does not object to the disclosure, the provider may disclose protected health information to the interpreter without a business associate agreement.

All providers are advised to be sure they have an LEP plan in place that reflects current provider demographics and community needs.

LEP Resources. www.LEP.gov is a federal interagency Web site that includes guidance documents and technical assistance resources including links to interpretation and translation services. This Web site also includes "I speak..." cards in 38 languages. www.hhs.gov/ocr/lep is the DHHS Web site with links to guidance documents and other resources.

Julie A. Knutson

UPCOMING BAIRD HOLM SPEAKING ENGAGEMENTS

July 20

"Legal Issues for Non-Profit Associations"

-Kelly Clarke

National Rural Health Association

August 8

"EMTALA and Behavioral Health Patients"

-Barbara Person

Iowa Hospital Association Behavioral Health Group

August 17

"Updates on HIPAA, Stark, LCDs, Workers' Compensation Issues and OIG Compliance Guidance"

-Barbara Person

Heartland Health Alliance Compliance Officers Program

November 18

Save the date for the Baird Holm Health Law Forum

BAIRD HOLM

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