



OUTSIDE COUNSEL

BY LINDA A. MALEK AND STACEY GOLDSTON

HIPAA: Enforcement for Violations by Covered, Noncovered Entities

Currently pending publication in its final form, the proposed HIPAA enforcement regulations (the Enforcement Rule or rule) were published in the Federal Register on April 18, 2005 by the U.S. Department of Health and Human Services (HHS).

This latest version of the rule modifies the proposed rule of 2003 by expanding its applicability to all of the HIPAA Administrative Simplification Regulations (Health Insurance Portability and Accountability Act of 1996).

The new rule also provides additional information with respect to the calculation of civil monetary penalties (CMPs) and mandates that the identity of entities which have received such CMPs be made publicly available. The liability of covered entities for HIPAA violations by business associates and agents generally is also addressed by the rule, which essentially states that to the extent that the covered entity is compliant with the HIPAA business associate requirements it will not be exposed to penalties solely by virtue of its relationship with a business associate that is in violation of HIPAA. Other changes include the addition of information with respect to hearings and the investigation process as a whole.

Federal Authority

The Enforcement Rule provides for both civil and criminal penalties, with civil

Linda A. Malek, a partner at Moses & Singer, is chairwoman of the health care practice group and co-chair of the privacy practice group. **Stacey Goldston** is an associate in the health care practice group at the firm.

penalties administered by the Office of Civil Rights of HHS (OCR) and criminal penalties administered by the U.S. Department of Justice (DOJ). Until recently it was unclear which entities or individuals, specifically covered entities only or covered as well as noncovered entities, could be subject to the imposition of such penalties for violations of HIPAA. The DOJ's Office of Legal Counsel clarified this issue in a Memorandum Opinion issued on June 1, 2005 (the memorandum).

The proposed HIPAA enforcement regulations modify the proposed rule of 2003 by expanding its applicability to all of the HIPAA Administrative Simplification Regulations.

Prior to the issuance of the memorandum, OCR had maintained that the imposition of CMPs would be limited to noncompliant covered entities while the DOJ indicated that its enforcement authority extended to both covered and noncovered entities with respect to the imposition of criminal penalties for HIPAA violations. The memorandum clarified the DOJ's position by explaining that criminal penalties authorized by the Enforcement Rule would only be imposed upon covered entities. However, the DOJ went on to state that pursuant to applicable principles for aiding and abetting liability or conspiracy liability the imposition of criminal penalties on entities or individuals that are not covered entities by the DOJ was also authorized.¹

• **Standard for Federal Criminal Liability.** The memorandum also offers clarification, on the proper interpretation of the "knowingly" element of the Enforcement Rule. Specifically, the memorandum explains that such standard refers only to the knowledge of the facts that constitute the offense. The Enforcement Rule provides in relevant part, "a person who knowingly and in violation of [HIPAA]...uses or causes to be used a unique health identifier...obtains individually identifiable health information relating to an individual; or discloses individually identifiable health information to another person, shall be punished...." 42 USC §1320d-6(a). The DOJ analyzed and rejected the notion that in order to satisfy the "knowingly" element of the rule, there also had to be knowledge that the conduct violated HIPAA. The result of the DOJ's interpretation is that prosecutions of covered entities for HIPAA violations are a realistic possibility in instances in which the entity's knowledge is limited to the facts that make up a violation; whether or not the entity actually had knowledge that such facts constituted a violation of HIPAA appears to be immaterial.

State Law Statutory Violations

A violation of HIPAA may sometimes also constitute a violation of the law in the state in which the conduct occurred. Therefore, covered entities may face the imposition of state confidentiality law penalties in addition to those imposed pursuant to the Enforcement Rule which can result in a sizeable increase in the amount of potential monetary penalties incurred by such entities. Moreover, a number of states allow for private rights of action

in instances in which an individual's right to privacy has been breached and these actions can exponentially increase a covered entity's potential exposure for violations of HIPAA.

California, Texas and New York are examples of states in which state law provides for civil penalties for violations of state confidentiality statutes. California's Confidentiality of Medical Information Act (CMIA) provides that civil penalties resulting therefrom are in addition to those imposed pursuant to any other law. Monetary penalties pursuant to the CMIA parallel those authorized by HIPAA, and range from \$100 to \$25,000, depending on the circumstances attendant to the violation. Therefore, if an entity violated both HIPAA and the CMIA, such entity could potentially be exposed to significant penalties under both sets of laws. Moreover, as discussed in more detail below, a private right of action is also authorized under the CMIA. If such an action is commenced and its outcome is successful, a covered entity² could potentially be subject to greater liability.

Like the CMIA, the Texas Medical Privacy Act (MPA) is modeled after HIPAA and imposes civil penalties which, when combined with those authorized by HIPAA, could be significant. The MPA provides for penalties of up to \$3,000 for a single violation and of up to \$250,000 for violations that constitute a pattern or a practice. One substantial difference between the MPA and HIPAA lies with the MPA's definition of a "covered entity," which is considerably broader than HIPAA's and includes any individual who, "for commercial, financial, or professional gain, monetary fees, or dues, or on a cooperative, nonprofit, or pro bono basis, engages, in whole or in part, and with real or constructive knowledge, in the practice of assembling, collecting, analyzing, using, evaluating, storing, or transmitting protected health information" and also includes business associates, schools and governmental units. Tex. Health & Safety Code Ann. §181.001(b)(2)(A)(2003). Accordingly, under Texas law, a number of entities that are not "covered entities" pursuant to

HIPAA would be considered "covered entities" under the MPA and as a result, could be subject to civil penalties for violations of the MPA.

New York law differs from both California and Texas law in that it does not have specific civil penalties for violations of confidentiality laws. Instead, in instances in which penalties for violations are not expressly set forth in the text of a statute or regulation New York law provides for a general penalty not to exceed \$2000 for each violation of certain provisions of the Public Health Law. Included among the provisions to which this general penalty applies are those relating to the confidentiality of medical records. In addition, like the CMIA and as discussed below, New York case law has recognized a private right of action for individuals whose medical information is wrongfully disclosed.

• **State Law Private Rights of Action.**

While not provided for by the Enforcement Rule, another avenue of liability potentially faced by some covered entities is through private rights of action that are allowed by some states in addition to the imposition of civil and criminal penalties. As mentioned above, California permits an individual whose medical information has been used or disclosed in violation of the CMIA to bring an action against the entity that improperly handled the information if the individual has experienced economic loss or personal injury as a result of the violation. While New York also allows for a private right of action for violation of state confidentiality laws, unlike California, New York's private right of action is not expressly authorized by statute but rather has been implied by the courts of the state based upon a common-law duty of confidentiality. Since the range of possible awards from private causes of action can vary greatly and when not expressly authorized, the permissibility of such actions is unclear and may not be known until such a case is commenced, adjudicated and ruled upon by a court of the state, determining or even estimating an entity's resulting liability is uncertain at best.

Conclusion

The issuance of the memorandum has

implications both for covered entities and noncovered entities. The DOJ's interpretation of the "knowledge" standard will make prosecuting covered entities for violations of HIPAA potentially easier than previously thought since the DOJ has adopted the position that if a covered entity has knowledge of the facts that constitute an offense the "knowledge" element of the Enforcement Rule has been satisfied. Noncovered entities don't escape prosecution for like violations even though such entities are outside the jurisdiction of the Enforcement Rule. Instead the DOJ has expressed that other legal theories, namely aiding and abetting liability and conspiracy liability can be used as a vehicle to impose criminal penalties on noncovered entities that engage in conduct that would constitute a HIPAA violation(s) if engaged in by covered entities.

Steps to Take

It would be prudent for covered and noncovered entities to respond to the publication of the Enforcement Rule as well as the issuance of the memorandum by considering implementation of new, or the updating of existing, policies and procedures for handling protected health information and HIPAA violations. Such policies and procedures should also reflect corresponding state law as applicable. In addition, covered entities and noncovered entities should consider implementing or augmenting their training initiatives in order to provide workforce members with the most current and comprehensive information regarding what functions and activities are and are not permissible pursuant to HIPAA.

.....●.....

1. Memorandum Opinion for the General Counsel Department of Health and Human Services and the Senior Counsel to the Deputy Attorney General, Scope of Enforcement Under 42 U.S.C. §1320d-6 (June 1, 2005).

2. The term "covered entity" is used throughout this article as it is defined in HIPAA. The CMIA regulates entities based upon their category of licensure under California law and does not use the term "covered entity."