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IMPLICATIONS OF THE PROPOSED HIPAA ENFORCEMENT RULE

Overview of the Proposed Enforcement Rule

On April 18, 2005 the United States Department of Health and Human Services (“HHS”) published the proposed HIPAA enforcement regulations (the “Enforcement Rule”) in the Federal Register. Published in its initial form in 2003, the proposed Enforcement Rule modifies and supplements the initial published version. In its revised form, the Enforcement Rule has been extended to apply to all of the HIPAA Administrative Simplification Regulations as opposed to just the privacy regulations. In addition, the enforcement measures regarding civil monetary penalties (“CMPs”) have been amended and now include further details with respect to how the amount of CMPs will be determined and also contain a new requirement that the identity of covered entities that receive CMPs be made available to the public. The Enforcement Rule also addresses covered entities’ liability for violations of HIPAA by their business associates and agents generally, and clarifies that to the extent a covered entity is in compliance with HIPAA’s business associate requirements, penalties will not be imposed on the covered entity for its business associate’s HIPAA violations. Other significant changes include additional information regarding hearings and the overall investigation process.

The Enforcement Rule provides for both civil and criminal penalties. However, all civil penalties are handled by the Office of Civil Rights of HHS (“OCR”) while criminal penalties are handled by the Department of Justice (“DOJ”). In a Memorandum Opinion issued on June 1, 2005, DOJ’s Office of Legal Counsel clarified an existing inconsistency regarding the entities or persons that could potentially face the imposition of civil and criminal penalties for HIPAA violations¹. Prior to the memo’s release, OCR had maintained that CMPs will be imposed only on covered entities while the DOJ had indicated that it would seek to impose criminal penalties on both covered and *non-covered* entities for violations of HIPAA. The memo clarified that the Enforcement Rule only authorizes the imposition of penalties on covered entities. However, it also stated that individuals or entities that are not covered entities and therefore not subject to prosecution under the Enforcement Rule could be prosecuted by the DOJ under applicable principles for aiding and abetting liability and/or conspiracy liability.

State Privacy Laws

¹ A more detailed analysis of the Memorandum Opinion is forthcoming in a subsequent Client Update.

It is important for covered entities to understand that in many instances a violation of HIPAA will also amount to a violation of the law in the state in which the illegal conduct occurred. As such, penalties imposed pursuant to the Enforcement Rule may be only one part of the penalties an entity that violates HIPAA and state confidentiality laws may face. In these instances, state confidentiality laws can cause a substantial increase in the amount of monetary penalties faced by such entities and the private right of action permitted by a number of states can increase the potential exposure of such an entity.

California is an example of a state in which state criminal and civil penalties could potentially be faced under state law by individuals or entities that violate California's Confidentiality of Medical Information Act ("CMIA"). The CMIA specifies that all civil penalties imposed thereunder are *in addition* to any penalties imposed under any other law and the monetary penalties which range from \$100 to \$25,000 depending on the circumstances of the violation are substantially similar to those authorized under HIPAA. As a result, a violation of HIPAA and the CMIA could potentially result in significant penalties under *both* sets of laws. Moreover, as discussed below, the CMIA also provides for a private right of action which, if pursued and successful, could subject a covered entity² to additional exposure.

Texas is another example of a state that provides for the imposition of civil penalties on covered entities that violate the Texas Medical Privacy Act ("MPA") which, like the CMIA, is patterned after HIPAA, thereby potentially subjecting non-compliant covered entities to substantial penalties. Similar to HIPAA and the CMIA, the MPA authorizes 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. However, the MPA's definition of a "covered entity" is considerably broader than that established by HIPAA 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. Accordingly, entities that are *non-covered* entities under HIPAA could be considered "covered entities" under MPA, thereby being subject to civil penalties for violations under Texas law.

Unlike the Enforcement Rule, in addition to civil and criminal penalties, some states permit a private right of action which is another potential avenue of liability for covered entities covered under such laws. California, as mentioned previously, authorizes an individual whose medical information has been used or disclosed in violation of the CMIA and who has experienced economic loss or personal injury to bring an action against the entity that improperly handled the information. New York also allows for a private right of action for violation of state confidentiality laws. However, unlike California, New York's private right of action is not expressly authorized by

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

statute but rather has been implied by the courts of the state based upon a common-law duty of confidentiality. Ascertaining an entity's potential liability from private causes of action is uncertain at best since the range of awards will likely be great and whether or not a private cause of action is permitted in a state when such a right is not expressly authorized may not be known until such a case is commenced, adjudicated and ruled upon by a court of the state.

Conclusion

The public comment period for the Enforcement Rule will conclude on June 17, 2005 at which time HHS will review and evaluate the comments that were received. When a final rule is issued will depend on the number and nature of comments received, so that a time frame for issuance of the final rule is unclear at this juncture. As a threshold matter, covered entities should begin to contemplate potential revisions to their existing policies and procedures for handling protected health information and HIPAA violations in light of the Enforcement Rule taken together with corresponding state law. As with all other aspects of HIPAA compliance, covered entities must familiarize themselves with all federal and state laws with respect to the confidentiality of protected health information in order to appropriately train personnel with respect to compliance. Therefore, the identification of personnel requiring training on enforcement laws and regulations and the creation of training programs for such personnel should also be commenced in anticipation of the final Enforcement Rule.

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