



MEMORANDUM

Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004
T +1 202 637 5600
F +1 202 637 5910
www.hoganlovells.com

To Katie Furiato

FROM Marcy Wilder **TELEPHONE** 202-637-5729

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SUBJECT Applicability of HIPAA and HITECH Business Associate Provisions to the Musculoskeletal Transplant Foundation

You have asked us whether the Musculoskeletal Transplant Foundation (“MTF”) is a business associate as defined in the federal privacy regulations (the “Privacy Rule”)¹ promulgated pursuant to the Health Insurance Portability and Accountability Act (“HIPAA”)² and the Health Information Technology for Economic and Clinical (“HITECH”) Act³ when it receives information about potential tissue donors from a covered entity. As discussed more fully below, under the Privacy Rule, disclosures of protected health information from covered entities to MTF to facilitate transplants on behalf of donors and potential recipients is permissible and do not create a business associate relationship between the covered entity and MTF.

HIPAA PRIVACY RULE GENERALLY

The Privacy Rule requires covered entities and their business associates to enter into a written agreement that imposes detailed obligations on both parties.⁴ The Privacy Rule further specifies the content of business associate agreements, including that the agreement limit the business associate’s ability to use and further disclose protected health information.⁵ Pursuant to the HITECH Act, portions of the HIPAA Security Rule and the Privacy Rule apply directly to business associates. Thus, MTF’s entering into a business associate agreement where it is not legally required may result in unnecessary risk, burden and expense for both MTF and its customers.

BUSINESS ASSOCIATE RELATIONSHIPS

A business associate relationship is not created every time a HIPAA covered entity discloses protected health information to a third party but rather exists only in limited circumstances. A

¹ 45 C.F.R. parts 160 and 164, subparts A & E.

² Pub. L. No. 104-191.

³ Title XIII of American Recovery and Reinvestment Act of 2009 (“ARRA”), Pub. L. No. 111-5 (Feb. 17, 2009).

⁴ Under the Privacy Rule, “covered entities” are health plans, health care clearinghouses, and health care providers that engage in electronic transactions. 45 C.F.R. § 160.102.

⁵ 45 C.F.R. §§ 164.502(e), 164.504(e).

business associate relationship between a covered entity and a third party arises only in two situations:

- (1) A person, other than a member of the covered entity's workforce—
 - (a) receives protected health information from the covered entity or a business associate of the covered entity
 - (b) in connection with the provision of any of the following services to or for the covered entity: accounting; accreditation; actuarial; administrative; consulting; data aggregation;⁶ financial services; legal; or management services; **or**
- (2) A person, other than a member of the covered entity's workforce—
 - (a) creates, receives, maintains or transmits protected health information
 - (b) in connection with the performance of a function or activity on behalf of the covered entity (e.g., quality assessment analyses, claims processing, utilization review, billing, collections, transcription services).⁷

Both situations have in common two elements, each of which is necessary, but by itself insufficient, to create a business associate relationship. First, the third party may qualify as a business associate of the covered entity only if it creates, receives, maintains or transmits protected health information in connection with the performance of a service, function or activity.

Second, even if the information disclosed constitutes protected health information, the third party may qualify as a business associate only if it performs one of the enumerated services set forth in situation (1) or satisfies the requirements of situation (2) by performing a function or activity on behalf of the covered entity.

In an effort to dispel confusion concerning application of the business associate requirements, the Department of Health and Human Services ("HHS") underscored in guidance accompanying the Privacy Rule that a business associate relationship is not created merely because a covered entity discloses protected health information to a third party:

The business associate relationship does not describe all relationships between covered entities and other persons or organizations. While [the Privacy Rule] permit[s] uses or disclosures of protected health information for a variety of purposes, business associate contracts . . . are only required for those cases in which the covered entity is disclosing information to someone or some organization that will use the information on behalf of the covered entity, when the other person will be creating or obtaining protected health information on behalf of the covered entity, or when the business associate is providing the specified services to the covered entity and the provision of those services involves the disclosure of protected health information by the covered entity to the business associate.⁸

⁶ A Privacy Rule term of art, "data aggregation" means, with respect to protected health information created or received by a business associate, "the combining of such protected health information by the business associate with the protected health information received by the business associate in its capacity as a business associate of another covered entity, to permit data analyses that relate to the health care operations of the respective covered entities." 45 C.F.R. § 164.501.

⁷ See 45 C.F.R. § 160.103 (defining "business associate").

⁸ 65 Fed. Reg. 82,462, 82,476 (Dec. 28, 2000) (emphasis added).

Moreover, HHS noted, whether a covered entity may disclose protected health information to a third party and whether the recipient of the information is a business associate of the covered entity are distinct issues. Thus, unless MTF will provide to or for a covered entity one of the services enumerated in (1), above, or create, receive, maintain or transmit protected health information to perform a function or activity on behalf of the covered entity, the receipt of protected health information by MTF will not trigger the business associate requirements.

APPLICABILITY OF BUSINESS ASSOCIATE PROVISIONS TO TISSUE BANKS

MTF obtains protected health information from covered entities and uses that information to assist in the recovery, processing and distribution of cadaveric tissue for human transplantation. The Privacy Rule specifically permits covered entities to disclose protected health information to organizations engaged in cadaveric tissue procurement, banking or transplantation without obtaining patient authorization.⁹ Moreover, when MTF receives information about potential donors or recipients, it is not doing so to perform business associate functions for or on behalf of the covered entities from whom it obtains such information. Rather, MTF obtains such information to facilitate transplants on behalf of donors and potential recipients. HHS, in response to comments in the final rule, specifically states that “organ procurement organizations and tissue banks are generally not business associates of hospitals.”¹⁰ Thus, a business associate relationship is not established when MTF receives information about potential donors or recipients from covered entities and a business associate agreement is not required. Accordingly, MTF entering into a business associate agreement with covered entities for this purpose would be unnecessary and would likely create unnecessary business risks, administrative burdens and complications for both parties.

⁹ 45 C.F.R. § 164.512(h).

¹⁰ 65 Fed. Reg. at 82,688.