



DEPARTMENT OF HEALTH & HUMAN SERVICES

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OFFICE OF THE SECRETARY

**Director
Office for Civil Rights
200 Independence Ave., SW Rm 506F
Washington, DC 20201**

March 13, 2003

Mr. Bernie Liebler, Director
Technology and Regulatory Affairs
Advanced Medical Technology Association (AdvaMed)
1200 G Street, NW, Suite 400
Washington, DC 20005

Dear Mr. Liebler:

Thank you for your inquiry about the Health Insurance Portability and Accountability Act's (HIPAA) standards for privacy of individually identifiable health information (Privacy Standards). Your letter requests the Department to clarify whether, according to HIPAA, medical device companies are business associates in their various roles as manufacturers, sponsors of clinical research, providers of training, technical service and support for their products, and FDA-mandated device trackers. This letter responds to your request by explaining the Privacy Standards' requirements in each of the roles outlined in your letter. Please note that in order to determine if a medical device company is a business associate, it is necessary to examine the facts of the particular circumstances in question.

As you suggested in your letter, there are situations in which a business associate relationship does not exist between a covered health care provider and a medical device company. However, in some situations these companies may be acting as business associates, and a business associate agreement would be required for a covered provider to disclose protected health information to the company. There are a number of different types of activities that you mentioned in your letter. Some of them do not seem to create a business associate relationship while others may.

If a medical device company is simply selling a product to a covered provider and the provider does not disclose protected health information to the company, then no business associate relationship is formed and no business associate contract is required. An entity does not become a business associate simply by selling a product to a covered entity.

If a medical device company provides "health care" according to the Privacy Standards' definition, including providing supplies under the Medicare Program, then generally, it is a "health care provider" for purposes of the Privacy Standards (although it may or may not be a covered entity). The Privacy Standards do not require a business associate contract when protected health information is shared by a covered entity with a health care provider for treatment of an individual. 45 CFR § 164.502(e)(1)(ii)(A). Therefore, the covered entity could disclose protected health information, without a business associate contract, to the medical device company if such company is a health care provider and if the disclosure is for treatment of an

individual. For example, this may be the case if the medical device company is fitting a device to the individual. However, if a medical device company is not a "health care provider" then it would not qualify for this exception and is a business associate of a covered entity if it receives or creates protected health information in the performance of functions or activities on behalf of, or the provision of specified services to, a covered entity.

To determine whether or not a medical device company is a business associate of a health care provider, when it uses protected health information from a covered provider to engage in specific services, such as training, technical services, and support for its products provided to a covered health care provider, requires analysis of the facts and circumstances. This analysis includes, among other things, whether the entity is receiving or creating protected health information on behalf of, or to provide specified services to, the covered provider, and whether the company is acting as a health care provider and receiving the information for treatment. If the company is receiving protected health information to provide training to the covered entity, the company would likely fall within the business associate definition.

Medical device companies do not become business associates by virtue of sponsoring research. Disclosures from a covered entity to a researcher for research purposes as permitted by the Privacy Standards do not require a business associate contract. However, as you stated in your letter, an individual's authorization may be required for a covered provider to disclose protected health information to a research sponsor. If a medical device company actually performs research, please be aware that the Privacy Standards do not prohibit a covered entity from entering into a business associate contract with a researcher if the covered entity wishes to do so. *67 Fed. Reg.* at 53252. Also, please note that a covered entity must enter into a data use agreement, as required by Section 164.514 (e), prior to disclosing a limited data set for research purposes to a researcher.

Finally, a medical device company is not a business associate by virtue of collecting information for public health purposes with respect to an FDA-regulated product or service, pursuant to Section 164.512(b)(1)(iii). However, this provision is limited under the Privacy Rule, and clearly does not permit all information to flow to a medical device company for any purpose. Furthermore, "minimum necessary" restrictions would apply to disclosures for public health purposes.

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I trust this information is helpful to you. The Department will continue to issue updated Guidance and frequently asked questions and responses in order to provide assistance to the health care industry as it implements the Privacy Standards. If I can be of further assistance, please contact me.

Sincerely,

A handwritten signature in cursive script, appearing to read "Richard Campanelli".

Richard M. Campanelli, J.D.

Director

Office for Civil Rights