

January 6, 2003

Specialty Laboratories Client
Attn: HIPAA Privacy Officer

Re: HIPAA Business Associate Contracts With Specialty Laboratories

Dear Client:

As I am sure you are aware, the effective date of the privacy regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") is fast approaching. Specialty Laboratories, Inc. ("*Specialty*") has been preparing for the various requirements of HIPAA for more than a year, and *Specialty* is fully committed to meet the April 14, 2003 deadline for implementation of these privacy regulations.

As the April 14 deadline approaches, we have received requests from several of our hospital and laboratory clients who believe it is necessary to enter into a Business Associate contract to comply with the provisions of 42 CFR §164.500 *et seq.* Recently, however, the Office for Civil Rights ("OCR") of the Department of Health and Human Services, which is responsible for enforcement of the privacy regulations, provided guidance regarding the need for Business Associate contracts between certain covered entities for treatment of individual patients.

Specifically, the OCR has determined that a Business Associate contract is not required for disclosures by a covered entity to a health care provider for treatment of an individual. The OCR provided some examples of the exception to the Business Associate contract requirement, and stated that "[a] **hospital laboratory is not required to have a business associate contract to disclose protected health information to a reference laboratory for treatment of the individual.**"

Because *Specialty* is a covered entity under HIPAA, under the OCR guidelines there does not appear to be any need for you to enter into a Business Associate contract with *Specialty* in its capacity as a provider of laboratory testing services. For your reference, I have enclosed an excerpt from the OCR guidelines as they relate to Business Associate contracts. The entire document is posted on the *Specialty* Web site under "What's New". The OCR guidelines, which were issued on December 3, 2002, are also available at www.hhs.gov/ocr/hipaa/privacy.html. Please also see 45 C.F.R. §164.502(e)(1)(ii)(A)), which states that the Business Associate contract standards do not apply to "disclosures by a covered entity to a health care provider concerning the treatment of the individual."

As a leading provider of reference laboratory testing services, *Specialty* is committed to implementing specific measures relating to the security and privacy of individually identifiable health information, within the meaning and requirements of HIPAA. We look forward to ensuring that our clients will continue to have at their disposal the tools to meet the evolving needs of patients, and the requirements of federal regulations. If you have any questions regarding any of the above, please feel free to contact me at any time, and I will be happy to assist you.

Sincerely,



Nicholas R. Simmons, Esq.
Assoc. General Counsel & HIPAA Privacy Officer

Attachment

BUSINESS ASSOCIATES

[45 CFR 164.502(e), 164.504(e), 164.532(d) and (e)]

Background

By law, the HIPAA Privacy Rule applies only to covered entities – health plans, health care clearinghouses, and certain health care providers. However, most health care providers and health plans do not carry out all of their health care activities and functions by themselves. Instead, they often use the services of a variety of other persons or businesses. The Privacy Rule allows covered providers and health plans to disclose protected health information to these “business associates” if the providers or plans obtain satisfactory assurances that the business associate will use the information only for the purposes for which it was engaged by the covered entity, will safeguard the information from misuse, and will help the covered entity comply with some of the covered entity’s duties under the Privacy Rule. Covered entities may disclose protected health information to an entity in its role as a business associate *only* to help the covered entity carry out its health care functions – not for the business associate’s independent use or purposes, except as needed for the proper management and administration of the business associate. [...]

Exceptions to the Business Associate Standard. The Privacy Rule includes the following exceptions to the business associate standard. See 45 CFR 164.502(e). In these situations, a covered entity is not required to have a business associate contract or other written agreement in place before protected health information may be disclosed to the person or entity.

- Disclosures by a covered entity to a health care provider for treatment of the individual.
For example:
 - **A hospital** is not required to have a business associate contract with the specialist to whom it refers a patient and transmits the patient’s medical chart for treatment purposes.
 - **A physician** is not required to have a business associate contract with a laboratory as a condition of disclosing protected health information for the treatment of an individual.
 - **A hospital laboratory** is not required to have a business associate contract to disclose protected health information to a reference laboratory for treatment of the individual. [...]

BUSINESS ASSOCIATES

Frequently Asked Questions [...]

Q: When is a health care provider a business associate of another health care provider?

A: The HIPAA Privacy Rule explicitly excludes from the business associate requirements disclosures by a covered entity to a health care provider for treatment purposes. See 45 CFR 164.502(e)(1). Therefore, any covered health care provider (or other covered entity) may share protected health information with a health care provider for treatment purposes without a business associate contract. However, this exception does not preclude one health care provider from establishing a business associate relationship with another health care provider for some other purpose. For example, a hospital may enlist the services of another health care provider to assist in the hospital’s training of medical students. In this case, a business associate contract would be required before the hospital could allow the health care provider access to patient health information.

Q: May a covered entity share protected health information directly with another covered entity’s business associate?

A: Yes. If the HIPAA Privacy Rule permits a covered entity to share protected health information with another covered entity, the covered entity is permitted to make the disclosure directly to a business associate acting on behalf of that other covered entity.