



HIPAA AND ROUTINE INTERACTIONS BETWEEN PHYSICIANS AND PHARMACEUTICAL SALES REPRESENTATIVES

OVERVIEW

New federal privacy standards for healthcare providers and others have been issued by the Department of Health and Human Services under the Health Insurance Portability and Accountability Act (HIPAA). The HIPAA "Privacy Rule", as it is commonly called, aims to protect the privacy of individually identifiable health information of patients and research subjects. This type of information is called protected health information or "PHI" under the Privacy Rule. Compliance with the Privacy Rule is required by April 14, 2003.

The Privacy Rule sets limits on the use and disclosure of PHI by "covered entities." Regardless of the size of their practice, most health care providers that engage in electronic transactions – such as billing and submitting insurance claims – are considered covered entities under the Privacy Rule. While there are many issues faced by covered entities under HIPAA, this document addresses the effect of HIPAA on interactions between health care providers, such as physicians and hospitals ("providers"), and pharmaceutical sales representatives.

As explained below, the Privacy Rule does not interfere with a provider's ability to:

- ▶ meet with pharmaceutical sales representatives in physicians' offices,
- ▶ obtain scientific and educational information from pharmaceutical sales representatives about pharmaceutical products,
- ▶ seek support or guidance from a pharmaceutical sales representative regarding the proper use of the pharmaceutical company's products,
- ▶ report adverse events to manufacturers and the FDA.

BASIC HIPAA CONCEPTS

The term "covered entity" is defined to mean a health plan, a health care clearinghouse, or a health care provider conducting certain types of financial and administrative transactions electronically.¹

Covered Entity

Health care providers who transmit the following types of information are included: health care claims or equivalent encounter information; health care payment and remittance advice; coordination of benefits; health care claim status; enrollment and disenrollment in a health plan; eligibility for a health plan; health plan premium payments; referral certification and authorization; first report of injury; and health claims attachments.

Under the Privacy Rule, a covered entity is required to enter into a written agreement with its “business associate” before disclosing PHI to that business associate.¹ Among other things, a business associate agreement establishes limitations on the use and disclosure of PHI by the business associate.

Business Associates

Pharmaceutical sales representatives are not business associates of providers.

Business associates are contractors or other non-workforce members hired to conduct functions or activities “on behalf of” a covered entity that involve the use or disclosure of PHI.² Business associates are also persons or organizations that provide certain services “to or for” a covered entity that involve the use or disclosure of PHI.³

Pharmaceutical sales representatives do not perform functions or services “on behalf of” providers. Instead, pharmaceutical sales representatives meet with providers to give them product information, answer questions regarding their products, and deliver product samples. Business associate agreements between providers and pharmaceutical sales representatives in this context are not appropriate.

Patient Authorizations

The Privacy Rule permits covered entities to use and disclose an individual's PHI if that individual signs a HIPAA compliant patient authorization form permitting the use and disclosure. However, not all uses and disclosures of PHI require that covered entities obtain a patient authorization.

ACTIVITIES PERMITTED WITHOUT OBTAINING PATIENT AUTHORIZATIONS OR BA AGREEMENTS

Informational Presentations

Business associate agreements and patient authorizations are not required when pharmaceutical sales representatives meet with providers to share with them information regarding prescription medicines.

Pharmaceutical sales representatives inform providers about product benefits and risks, and, in turn, obtain valuable product feedback and advice. During these kinds of discussions, it is generally unnecessary for physicians or their staff to disclose any PHI about particular patients. In situations like this, when PHI is neither used nor disclosed, the Privacy Rule standards do not apply.

² The Privacy Rule defines such functions and activities to include, among others, claims processing or administration; data analysis, processing or administration; utilization review; quality assurance; billing; benefit management; practice management; and repricing. 45 CFR § 160.103.

³ These services are defined as legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, and financial services. 45 CFR § 160.103.

Incidental Disclosures of PHI

Incidental disclosures of PHI in a provider's office are often unavoidable. Business associate agreements between providers and pharmaceutical sales representatives are neither appropriate nor required to protect PHI that is inadvertently disclosed to pharmaceutical sales representatives.

The Privacy Rule requires providers to put in place reasonable safeguards to protect the privacy of PHI.⁴ This standard requires that covered entities make reasonable efforts to prevent uses and disclosures of PHI not permitted by the Privacy Rule. However, the Privacy Rule does not require that all risk of disclosure be eliminated or that structural or systems changes be made to avoid all overheard communications.⁵ HHS anticipates that certain disclosures of information are unavoidable in a treatment environment such as a physician's office or hospital. For instance, the Privacy Rule explicitly permits incidental disclosures that may result from such practices as using patient sign-in sheets and calling out patient names in waiting rooms.⁶ These types of disclosures are permissible if the covered entity has implemented reasonable safeguards to protect PHI.

In order to perform their routine activities in providers' offices, pharmaceutical sales representatives generally do not require access to PHI. The Department of Health and Human Services has clearly stated that,

A business associate contract is not required with persons or organizations whose functions, activities, or services do not involve the use or disclosure of protected health information, and where any access to protected health information by such persons would be incidental, if at all.⁷

Business associate agreements between providers and pharmaceutical sales representatives are not appropriate. More information describing examples of appropriate reasonable safeguards may be found in the OCR HIPAA Privacy Guidance Document on pp. 14 – 20 (December 2002).

Treatment Consultations

Disclosures of PHI by a provider for the treatment of an individual can take place without business associate agreements or patient authorizations.

Health care professionals sometimes seek the advice of pharmaceutical sales representatives on the appropriate uses of a manufacturer's products for a patient's treatment. In certain cases, providers may reveal PHI about a patient to a pharmaceutical sales representative in order to obtain specific advice about the proper use of a product.⁸ The Privacy Rule does not impede these kinds of consultations. The Department of Health and Human Services has stated

“[T]his rule permits a covered entity to disclose protected health information to any person for treatment purposes, without specific authorization from the individual. Therefore, a covered entity is permitted to disclose protected health information to a

⁴ 45 CFR § 164.530(c).

⁵ Id. at pp. 14-16, 20. See also 45 CFR § 164.502(a)(1)(iii).

⁶ Id. at p. 17.

⁷ See the OCR HIPAA Privacy Guidance Document, p. 48 (December 2002).

⁸ The pharmaceutical company's policies with respect to patient-specific consultations may limit the representatives' ability to engage in these types of consultations.

pharmaceutical manufacturer for treatment purposes.”⁹

A business associate agreement is not required for these consultations. The business associate requirements do not apply to disclosures by a health care provider to another entity concerning the treatment of an individual.¹⁰

Adverse Event Reporting

The Privacy Rule permits providers to continue to report adverse events in the same way they always have.

Adverse event reporting by providers is critical for detecting potential problems with a prescription medicine. The Privacy Rule allows providers to continue to report issues related to the quality, safety, or effectiveness of prescription medicines to the company responsible for the product as listed on the label.¹¹ This company will be either the manufacturer or distributor of the product. Patient authorizations and business associate agreements are unnecessary in such circumstances.

SUMMARY

While the new HIPAA Privacy Rule will impact providers and other covered entities in many significant ways, the typical interactions between providers and pharmaceutical sales representatives may continue to occur without the need for patient authorizations or Business Associate agreements. The Privacy Rule continues to allow physicians and pharmaceutical sales representatives to meet in physicians' offices and discuss product information, appropriate uses of a manufacturer's products for patient treatment, and adverse events.

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This paper has been prepared by the International Pharmaceutical Privacy Consortium. The member companies of the International Pharmaceutical Privacy Consortium appreciate the importance of safeguarding the privacy of patient health information, and each company is implementing its own procedures under HIPAA. This document is for educational purposes only and is not intended as legal advice, which may often turn on specific facts. Readers should seek specific legal advice before acting with regards to the subjects mentioned in this document.

⁹ 65 Fed. Reg. at 82569.

¹⁰ 45 CFR § 164.502(e)(1)(ii)(A).

¹¹ Id. at p. 78; see also § 164.512(b)(1).