

## **The HIPAA Privacy Rule's Impact upon Visits by Sales Professionals to Your Office**

### 1. What is the HIPAA Privacy Rule?

The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule requires covered entities such as physician offices, hospitals and clinics to safeguard patients' protected health information (PHI). PHI includes, but is not limited to, names, birth date, telephone numbers, address, diagnosis and treatments related to the past, present or future physical or mental condition of a patient.

### 2. How does the Privacy Rule impact my office's relationship with pharmaceutical and medical device company sales representatives?

The HIPAA Privacy Rule is intended to safeguard patient privacy, not curtail customary communications between sales representatives and physicians. Pharmaceutical and medical device sales representatives routinely meet with physicians and clinical staff to provide information about the appropriate use of products, to deliver samples and take orders for supplies and products. Because these activities do not typically involve PHI, they should not be affected by the Privacy Rule.

### 3. Does my office need to enter into business associate agreements with pharmaceutical and medical device companies that deliver drugs and supplies to my office?

A business associate is defined in the Privacy Rule as an individual or entity that needs access to PHI in order to conduct a service or function, such as claims processing or billing, "for or on behalf" of a covered entity (e.g., a physician). Business associate contracts establish limitations on the use and disclosure of PHI by business associates. Pharmaceutical and medical device sales representatives do not need PHI to carry out routine activities such as providing prescribing information and samples. However, a pharmaceutical or medical device company may be a business associate if it conducts patient outcomes analyses, benchmarks against standards of care, performs quality improvement analyses for your office or if you participate in a disease management program. If the company is acting as a business associate, you must execute a business associate agreement to ensure your patients' PHI is not inappropriately used by the pharmaceutical or medical device company.

### 4. May I impose restrictions on pharmaceutical and medical device companies visiting my place of business for product presentations and other related activities?

You may tailor reasonable safeguards to fit the unique circumstances of your office. The HIPAA Privacy Rule requires covered entities to implement reasonable administrative, technical and physical safeguards against the

inappropriate use or disclosure of PHI. For instance, locking file cabinets or rooms with medical records, assigning computer access codes to employees, isolating patient exam rooms and escorting sales representatives in patient areas are examples of reasonable safeguards that protect PHI. The Privacy Rule recognizes there is the potential for infrequent, inadvertent disclosures of protected health information. Covered entities must implement reasonable safeguards to limit incidental, and avoid prohibited, uses and disclosures. The Privacy Rule does not require that all risk of protected health information disclosure be eliminated.

5. Do I need my patients to execute a HIPAA Privacy Rule authorization to conduct preceptorship programs with pharmaceutical and medical device companies? Do I also need a confidentiality agreement with the company?

Yes to both questions. Preceptorship programs are great learning opportunities that help sales representatives gain insight into the diagnosis and treatment of various disease states, as well as different aspects of a professional's practice. The HIPAA Privacy Rule provides that a patient must execute a HIPAA Privacy Rule specific-authorization for anything other than treatment, payment, or healthcare operations (these are all defined terms in the HIPAA Privacy Rule). When conducting preceptorships, the patient must sign the HIPAA Privacy Rule authorization (specific items are required in the authorization) before you allow the sales representative access to the patient's PHI or accompany you into an exam room. Under the HIPAA Privacy Rule, you may not condition treatment of the patient upon his or her execution of the HIPAA Privacy Rule authorization. You need a confidentiality agreement with the company to ensure it will not release any of the patient's PHI.

6. May I disclose PHI to a manufacturer for adverse event reporting or product defects?

Yes. The HIPAA Privacy Rule specifically provides that a covered entity may disclose PHI to "a person subject to the jurisdiction of the Food and Drug Administration with respect to an FDA-regulated product or activity for which that person has responsibility, for the purposes of activities related to the quality, safety or effectiveness of such FDA-regulated product or activity." This provision includes reporting adverse events, product defects or problems, tracking FDA-regulated products, and to enable product recalls.

7. Does the HIPAA Privacy Rule impact the federal fraud and abuse statutes or other PhRMA guidance documents?

HIPAA and its Privacy Rule regulations are separate and apart from other federal (and state) statutes and regulations. Whether you are considered a "covered entity" for purposes of the HIPAA Privacy Rule has no bearing on your obligation to comply with all other statutes, including the federal fraud and abuse statutes affecting the health care industry. Moreover, the HIPAA Privacy Rule does not affect pharmaceutical company compliance with the PhRMA Code on Interactions with Healthcare Professionals.

*This UPDATE was prepared by Saul Ewing's Health Law Practice Group. The members of the Group are: Richard T. Frazier, Laura L. Katz, Steven B. Larsen, John B. Reiss, Bruce D. Armon, Marci A. Love and Sabrina Mays-Diagne.*

**SAUL EWING HEALTH LAW ATTORNEYS**

Richard T. Frazier	(215) 972-7828	rfrazier@saul.com
Laura L. Katz	(410) 332-8804	lkatz@saul.com
Steven B. Larsen	(410) 332-8825	slarsen@saul.com
John B. Reiss	(215) 972-7124	jreiss@saul.com
Bruce D. Armon	(215) 972-7985	barmon@saul.com
Marci A. Love	(215) 972-7988	mlove@saul.com
Sabrina Mayes-Diagne	(888) 733-2006 ext. 66096	smays-diagne@saul.com