HIPAA and Drug Company Interactions With Physicians—Beyond Clinical Research

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Pharmaceutical companies, like other sectors of the healthcare industry, have geared up for the April 14, 2003 compliance date for the federal Standards for Privacy of Individually Identifiable Health Information, promulgated under the authority of the Health Insurance Portability and Accountability Act of 1996 (the HIPAA Privacy Standards).[1] Of the considerable volume of government guidance, articles by healthcare industry experts, and recent seminars, conferences, and teleconferences on the Privacy Standards, only a small portion has related to the activities of pharmaceutical companies, and the preponderance of that has focused on clinical research. Of course, drug companies have other—nonresearch-related—relationships with physicians and other healthcare providers, in which the companies receive and use individually identifiable patient information, but the effect of the Privacy Standards on these activities has largely been ignored.

This article focuses on three such common activities: indigent patient assistance programs, reimbursement assistance programs, and preceptorships. For each activity, the article examines the implications of the HIPAA Privacy Standards and the measures, if any, that drug companies should take to comply with the Standards.

Background

Because the fundamentals of the HIPAA Privacy Standards have been described in numerous articles,[2] they are outlined only briefly here. The Privacy Standards apply only to "covered entities." Under the Standards, covered entities may use and disclose protected health information (PHI)[3] for purposes of treatment, payment, and healthcare operations without obtaining an authorization from the individual who is the subject of the information.[4] For most other uses and disclosures, the patient must authorize the use or disclosure of PHI.[5] A "covered entity" is defined as 1) a health plan, 2) a healthcare clearinghouse, or 3) a healthcare provider that transmits health information "in electronic form" in connection with standard transactions that are identified in the regulation and that relate to the financing of healthcare.[6] It is the third definition that is of interest to pharmaceutical companies.

The preamble to the December 2000 final rule[7] makes clear that "drug, biologics, and device manufacturers are not healthcare providers simply by virtue of their manufacturing activities."[8] For a manufacturer to be considered a healthcare provider, the manufacturer must provide healthcare supplies or services "related to the health of a particular individual."[9] Even a pharmaceutical manufacturer that is a healthcare provider is not a "covered entity" unless the company also engages in standard transactions using electronic transmissions. A drug company that met both of these criteria for a covered entity would be subject to all of the requirements and penalties of HIPAA and the Privacy Standards.[10]

Patient Assistance Programs

Many drug companies operate indigent patient assistance programs (PAPs) that provide free drugs for indigent patients who are not insured or whose insurance will not cover the company's drug. Where a PAP sends, or arranges for the sending of, the prescribed drug to a physician for a specifically

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designated patient enrolled in the program, the manufacturer might be considered a healthcare provider because it is providing drugs "related to the health of a particular individual."[11] Moreover, some PAPs provide assistance in determining whether an applicant's or enrollee's insurer provides coverage for the drug, in following up on insurance claims, or in seeking alternative sources of funding. These activities may involve contacting private and government health or pharmaceutical assistance plans on behalf of the patient. Such contacts may constitute "standard transactions."[12] If the company provides healthcare *and* engages in standard transactions through the transmission of PHI in electronic form, it is a covered entity. It is important to note that if a drug company were considered a healthcare provider by virtue of its PAP, it could not avoid covered entity status merely by retaining an outside vendor to conduct standard transactions.[13]

Certain precautions can reduce the likelihood of a drug company being considered a covered entity by virtue of operating a PAP. Companies are less likely to be considered healthcare providers if the program is structured so that the drug company itself is not distributing drugs designated for particular patients (e.g., by outsourcing the program eligibility determination and drug distribution functions).[14] In addition, the Office of Civil Rights' (OCR's) current informal policy is that paper-to-paper fax systems and telephone calls are not considered electronic transmissions for purposes of the Privacy Standards.[15] Therefore, standard transactions "in electronic form" can be avoided if communications on behalf of a PAP applicant or enrollee to insurers, health plans, and government programs concerning eligibility and claims are limited to telephone and paper-to-paper faxes, without the use of e-mail, fax-back systems, or Internet-based communications.

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Regardless of whether the drug company is a covered entity, physicians who disclose PHI to a PAP in order to enroll patients or obtain drug products for them almost certainly will be covered entities. The question therefore arises whether the physicians will be required to obtain authorizations from patients in order to make such disclosures. The preamble to the December 2000 final rule makes clear that no authorization is necessary in these instances, because the disclosure is for the purpose of treatment, i.e., obtaining pharmaceuticals to treat the patient.[16]

Reimbursement Assistance Programs

Many pharmaceutical companies offer reimbursement assistance to their healthcare provider customers. Typically, this assistance takes the form of hotline services that physicians or their staff can call for assistance in coding, making insurance eligibility inquiries, submitting claims and supporting information, appealing claim denials, and the like. PHI is often conveyed by the physician's office in the course of seeking assistance from the program. Such a program conceivably could engage in standard transactions in electronic form if contacts were made through electronic transmissions to a patient's insurance company regarding, for example, claim status or eligibility. Nevertheless, unlike PAPs, which provide or arrange for the provision of product, reimbursement assistance programs are unlikely to be considered to provide healthcare, and pharmaceutical companies therefore will not become covered entities by virtue of the latter programs.

Although reimbursement assistance programs are unlikely to render a drug company a covered entity, the providers who disclose their patients' PHI to the program most likely *are* covered entities. The physicians arguably are permitted to make these disclosures without a patient authorization, because the disclosures are for payment purposes.[17] However, the company will be providing physicians with assistance involving the use of PHI, which raises the question of whether a business associate agreement is required between the company and the provider. A business associate agreement is an agreement between a covered entity and another entity that performs an activity involving the use or disclosure of PHI "on behalf of" the covered entity.[18] Business associates must commit in the agreement to adopt adequate safeguards to appropriately handle and protect the privacy of the PHI.

Because the Privacy Standards do not define the term "on behalf of," it is unclear whether using PHI to provide reimbursement assistance to a physician's office might be construed as a function performed "on behalf of" the physician, as contemplated under the business associate requirement. Such an interpretation would require drug companies to enter into business associate agreements with every provider who calls for reimbursement assistance and discloses patient information—a burdensome undertaking. Although such an interpretation is possible, OCR guidance suggests that a business associate arrangement is rather a commercial relationship involving the payment of compensation: "'[B]usiness associates' are contractors or other non-workforce members *hired* to do the work of, or for, a covered entity . . ."[19]

Consistently, all of the examples of business associate arrangements in the HIPAA Privacy Standards and the Guidance involve compensation. Moreover, a HIPAA Privacy Standards transition rule and a model business associate agreement issued by OCR appear to presuppose that there will in many cases be an underlying written service contract between the business associate and the covered entity.[20] The typical reimbursement assistance offered as an adjunct to the marketing of pharmaceuticals involves neither compensation nor a service agreement, and therefore arguably does not rise to the level of a business associate relationship.

Preceptorships

Certain pharmaceutical companies engage physicians as preceptors to assist in the training of sales representatives. Preceptorships generally involve pharmaceutical sales representatives accompanying a physician during rounds or in the treatment of patients, in order to educate the representative about how the condition of interest is treated and how the company's therapy is used in the clinic. The sales representative is exposed to PHI if he or she is present during any examination or discussion between patient and physician. Because the disclosure of PHI to the representative is not for purposes of treatment, payment, or healthcare operations, the Privacy Regulation will require the physician to obtain a patient authorization. The authorization must be HIPAA-compliant, and also should comply with state laws governing the disclosure of medical information by healthcare providers.[21]

Conclusion

Pharmaceutical companies (in conjunction with investigative sites and institutional review boards) have paid considerable attention to bringing their clinical research activities into compliance with the HIPAA Privacy Standards. Drug companies should not neglect to examine other activities that involve the receipt of individually identifiable patient information from physicians. These activities should be reviewed to assess whether the activity could cause the drug company to be considered a covered entity or a business associate, and whether a patient authorization is necessary in order to engage in the activity.

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[1] Pub. L. No. 104-191, 110 Stat. 2021 (1996).

[2] *See, e.g.,* Naomi Halpern, *Implications of DHHS Medical Privacy Rule for Pharmaceutical and Medical Device Manufacturers*, FDLI UPDATE, Nov./Dec. 2002, at 12-14.

[3] Protected Health Information" is health information that is created by a healthcare provider, health plan, employer, or healthcare clearinghouse; relates to the health or provision of healthcare to an individual or payment for healthcare for the individual; identifies the individual; and is transmitted or maintained in any form or medium. 45 C.F.R. §§ 160.103, 164.501.

[4] 45 C.F.R. § 164.502(a)(1)(ii).

[5] *Id.* § 164.508(a)(1). Authorizations must be in writing and must contain the elements identified in 45 C.F.R. § 164.508.

[6] 45 C.F.R. § 160.103.

[7] The HIPAA Privacy Standards were finalized in the waning days of the Clinton Administration. *See* 65 Fed. Reg. 82,462 (Dec. 28, 2000). The Bush Administration proposed modifications, 67 Fed. Reg. 14,776 (Mar. 27, 2002), and finalized the modifications in August 2002. 67 Fed. Reg. 53,182 (Aug. 14, 2002).

[8] 65 Fed. Reg. at 82,568.

[9] *Id.*

[10] These requirements include, among other things, issuing and maintaining a notice of privacy practices, making PHI in designated record sets available for review and amendment by the individual that is the subject of the PHI, providing an accounting for the individual of certain disclosures of the PHI, and complying with the rules for use and disclosure of PHI.

[11] 65 Fed. Reg. at 82,568.

[12] *See, e.g.,* Eligibility for a Health Plan Transaction, 45 C.F.R. § 162.1201; Healthcare Claim Status Transaction, 45 C.F.R. § 62.1401.

[13] *See* 65 Fed. Reg. at 82,477.

[14] Under these circumstances, the outside vendor might be considered a covered entity if it is engaging in standard transactions using electronic transmissions.

[15] Based on presentation of J. Goldstein, OCR, to the D.C. Bar Health Law Section, Washington, D.C. (Sept. 20, 2002). OCR is responsible for implementing and enforcing the HIPAA Privacy Standards.

[16] 65 Fed. Reg. at 82,614.

[17] The physician must make reasonable efforts to limit the PHI disclosed to the minimum necessary to permit the pharmaceutical company to provide the assistance. 45 C.F.R. § 164.502(b)(1).

[18] 45 C.F.R. § 160.103.

[19] OFFICE OF CIVIL RIGHTS, STANDARDS FOR PRIVACY OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION [Guidance], Dec. 3, 2002, at 48 (emphasis added), *available at* www.hhs.gov/ocr/hipaa/guidelines/guidanceallsections.pdf.

[20] *See* 45 C.F.R. § 164.532(e) (transition rule refers to underlying "written contract or other written arrangement"); 67 Fed. Reg. at 53,265 (model business agreement provision refers to underlying agreement).

[21] Note that certain states recently have revised their medical information confidentiality statutes in light of HIPAA. *See, e.g.,* CAL. CIV. CODE § 56.102 (Deering 2003), TEX. HEALTH & SAFETY CODE ANN. § 181.001 *et seq.* (2002).