

**HIPAA: Frequently Asked Questions**  
**Covered Entity – Manufacturer Relationships**  
**Under HIPAA**

**Doesn't HIPAA require health care professionals to keep a manufacturer's personnel from being in the office?**

No. The final rule recognizes that many people who are not seeking care have valid reasons for being in hospitals, long term care facilities, clinics and physician offices -- other people's visitors, custodians and delivery personnel, as well as employees of manufacturers and other vendors. The rule specifically provides that it is not unlawful for information about patients to be seen or overheard in these settings, provided that there are safeguards in place so that any such exposure is incidental to an otherwise lawful use or disclosure. [45 C.F.R.

164.502(a)(1)(iii)] Manufacturer personnel visit physicians and hospitals to bring samples, to meet with clinical staff to answer questions and provide information about the use of new products, and to meet with people who may be ordering supplies. Any information seen or overheard in this context is incidental to lawful office activity, which means that it is not a violation, but is an accepted part of operating a hospital, clinic or physician office in accord with the rule.

**Do I need a business associate agreement with manufacturers from whom I obtain drugs and supplies?**

No. A business associate agreement should be used *only* when you intend the other party to have access to patient-identifiable information in order to perform some service for you. [45 C.F.R. 160.103 (defining business associate) This is not what occurs when a covered entity is buying items or accepting samples from a vendor. [45 C.F.R. 164.504(e)(2)(i) (“The contract may not authorize the business associate to use or further disclose the information in a way that would violated the requirements of this subpart, if done by the covered entity”)] It is generally not advisable for a provider or health plan to enter into a business associate agreement with a manufacturer or other vendor from whom it purchases drugs, devices, or supplies, unless the provider or plan also provides patient-identifiable information to the manufacturer in order to perform some *other* service. Examples of services that might require a business associate agreement (or perhaps a data use agreement) include patient outcomes analysis, archiving or processing of medical images, quality improvement analyses, benchmarking against standards of care, and so forth.

**What do I do about the fact that vendors may know or infer dates of service because of the way supplies are ordered and rebates processed?**

A date of service may be protected information when it is part of the record of care provided to an individual, but nothing about the regulation protects dates in their own right. The data provided for processing invoices and rebates is summary data regarding the provider or plan's use of a drug, device or supply in its business; it is not the “individually identifiable health information” intended to be regulated by the HIPAA statute. [45 C.F.R. 160.103 (2)(i) & (ii) (defining individually identifiable health information)] The regulation applies to “protected health information,” which is a *subset* of individually identifiable health information. In fact, even bits of data that might otherwise be protected under the Privacy Rule are explicitly

disclosed without violating the rule as an unavoidable, permissible part of the lawful use of data for treatment, payment and health care operations. So long as a covered entity has safeguards in place to ensure that the minimum necessary information is being used or disclosed for these lawful activities, the Privacy Rule does not require you to end “just in time” ordering of medical products, or prompt invoicing of manufacturer rebates based on the date a drug or supply is used. [*cf. 67 Fed. Reg. at 53252 (discussing the fact that no BA agreement is required for firms that provide custodial services)*]

**May a covered entity impose other requirements on manufacturer personnel that it allows to visit its facility?**

It is entirely possible that HIPAA – plus heightened attention to security generally in the wake of 9-11 – may lead larger institutions to more scrupulously enforce sign-in procedures for all kinds of visitors. Under the Privacy Rule, each covered entity must have procedures for verifying the identity and authority of entities to which it makes disclosures. A covered entity is also required to have safeguards to limit incidental uses or disclosures made in conjunction with a permitted use or disclosure. [*45 C.F.R. 164.530(c)(2)(ii)*]

Although there are no specific requirements, some covered entities may require identification or use a sign in process, or other more specific evidence that manufacturer personnel are, in fact, acting on behalf of the manufacturer than has been customary.

**Aren't the HIPAA rules designed to end informal relationships between providers and manufacturer personnel?**

No. The federal Privacy Rule developed by the Department of Health and Human Services (HHS) does establish strong new requirements that limit health care providers' discretion in deciding how to use and disclose their patients' health information.

But, the Rule is not intended to discourage or prevent a health care provider from seeking advice from the manufacturer of a medical product regarding its appropriate use for an individual patient. As HHS stated in the preamble to the final rule:

“[A] manufacturer that provides support and guidance to doctors and patients regarding the proper use of their products is providing ‘health care’ for the purposes of this rule, and therefore, is a health care provider to the extent that it provides such services . . . . We note that this 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 health care provider is permitted to disclose protected health information to a . . . manufacturer for treatment purposes.” [*65 Fed. Reg. at 82569*]

This policy is explicit recognition of the fact that a drug or device manufacturer's clinical and scientific personnel may provide invaluable information and advice to a physician who is new to using a product, or whose patient presents unique circumstances that may previously have been reported to the manufacturer in research or in another provider inquiry.

**Do providers need a business associate agreement with manufacturers for treatment consultations?**

No. A business associate agreement can be used only if the covered entity has retained a third party to perform some task on the covered entity's behalf. [*45 C.F.R. 160.103 (defining business*

*associate)]* The Privacy Rule specifically states that such agreements are not required for disclosures by a covered entity to another entity involved in treating a specific patient, [45 C.F.R. 164.502(e)(1); 67 Fed. Reg. at 52352] and HHS has determined that a manufacturer's services in supporting appropriate use of its product for a patient are part of the patient's treatment [65 Fed. Reg. at 82569]. The manufacturer does not undertake to provide these consultations "on behalf of" the provider but as part of its own business of ensuring safe and effective use of its products. In fact, a manufacturer typically receives only minimal protected health information incidental to its product support activities. A provider should not be interested in expanding its responsibility through business associate agreements where it is not actually procuring services that involve the use or disclosure of patient information. Rather, it should limit the manufacturer's access to information to the minimum necessary for the manufacturer to provide the necessary product support.

**Does HIPAA permit me to tell the manufacturer about a patient's experiences that may help protect others but that are not for that patient's treatment?**

Yes. HHS has emphasized that the privacy interests of individuals are not the only interests that must be protected - individual privacy interests should be carefully balanced with the general interest in public health and safety. One important area considered by HHS is the flow of essential information that the Federal Food and Drug Administration (FDA) and others need to protect public health and safety with respect to medical products. As HHS has stated: "The Rule is not intended to discourage or prevent adverse event reporting or otherwise disrupt the flow of essential information that the FDA and persons subject to the jurisdiction of the FDA need in order to carry out their important public health activities. [67 Fed. Reg. at 53227] Health care professionals play a vital role in protecting the public that must continue. [See HHS extended discussion of adverse event reporting at 67 Fed. Reg at 53226-53229]

The privacy rule specifically authorizes a provider to disclose protected health information to make reports to protect public health and safety without permission of the patient. For example, a provider may disclose protected information to a manufacturer of a medical product to report a potential problem with a medical product to the manufacturer or the Food and Drug Administration (FDA). [45 C.F.R. 164.512(b)(1)(iii)]

**Which reporting systems are involved and how do they work?**

Under FDA regulations, the system that identifies unsafe or ineffective medical products transforms routine calls to manufacturers from health care professionals and patients – which in fact may start out as complaints or simple questions -- into a critical early warning system for routing information to the FDA. In fact, calls from health care providers to manufacturers regarding the appropriate use of a product for individual patient treatment feed into to this system.

While federal law requires a manufacturer to collect and report information about its products even after the FDA has granted approval for a product's general use, only healthcare professionals and patients are aware of adverse events, problems with the efficacy, or difficulties in using the drugs and devices. Unless they report to manufacturers, other patients and providers will be unaware of issues or concerns. Under the law, the manufacturer is required to systematically collect these reports and questions and make reports to FDA.

Based on these reports, the FDA evaluates the potential seriousness of identified issues and takes any necessary corrective actions, which may include the addition of warnings or precautions, product recalls or withdrawals, or medical alerts.

**So, even though the HIPAA Privacy Rule has strict prohibitions on disclosure, it specifically authorizes a provider to continue to make calls to product manufacturers?**

Yes. The rule allows providers, without authorization from the patient, to disclose protected health information to individuals responsible for ensuring the quality, safety, or effectiveness of an FDA-regulated product or activity. *[45 C.F.R. 164.512(b)(1)(iii)]* HHS has stressed that in the long run, both the individuals who are the subjects of the information and the general public benefit from these disclosures. *[67 Fed. Reg. at 53228]*

Voluntary reports from healthcare professionals and patients of adverse events resulting from prescription drugs and medical products are critical to ensuring the public's health and safety. The Privacy Rule is no reason to curtail these important reporting activities, which are considered professional responsibilities by the American Medical Association and the American Dental Association, among others.

**What can I disclose and to whom can I disclose it?**

The HIPAA Privacy Rule specifically allows health care providers to disclose protected health information to individuals responsible for ensuring the quality, safety, or effectiveness of an FDA-regulated product. *[45 C.F.R. 164.512(b)(1)(iii)]* By law, the person responsible the quality, safety and effectiveness of a product is identified on its label as the manufacturer or distributor of the product. *[67 Fed. Reg. at 53228]*

**Why is it important that I continue to seek the advice of manufacturers for specific patient treatment and report adverse events observed in my practice?**

As medical products grow in sophistication, it is critically important to the patient receiving treatment that the product is being used appropriately. For many products, a manufacturer's clinical personnel may have the greatest familiarity with the medical literature and with the range of special circumstances that can help a professional decide whether to use a product, and if so, how to use it in the way that best meets the needs of the individual patient.

As noted above, our law depends on the voluntary reporting of health care professionals. The AMA has said that physicians who prescribe and monitor the use of drugs and medical devices are best able to observe and communicate information about resulting adverse events. This is a system that works. Voluntary reporting of adverse events has been credited with identifying significant safety issues associated with drugs and medical devices that were not discovered during preapproval testing and enabled the FDA to take important corrective actions. For example, the removal of the antibiotic temafloxacin (Omniflox) from the market, the development of warning labeling for latex products, and research concerning the danger of concurrent use of the antihistamine terfenadine (Seldane) and either the antifungal ketoconazole or the antibiotic erythromycin, all have been attributed to voluntary reporting by health professionals.