



MENTOR CORPORATION'S STATEMENT OF COMMITMENT TO THE PROTECTION OF THE PRIVACY OF PATIENT HEALTH INFORMATION

Background

Mentor Corporation develops and manufactures medical devices and sponsors clinical trials to bring new products to market. Also, Mentor conducts retrospective studies on certain of its products as required by the FDA. In performing their duties, representatives of Mentor Corporation ("Mentor Representatives") frequently visit and consult with, or receive information from, Mentor's customers such as physicians, hospitals and various healthcare dealers, such as group purchasing organizations. Due to the fact that Mentor Representatives are sometimes given access to patient health information in performing these activities, several of Mentor's customers have requested that Mentor execute a "business associate agreement" pursuant to the business associate requirements under the Health Insurance Portability and Accountability Act of 1996, as amended (the "HIPAA Privacy Regulations").

Mentor is not a "Business Associate" under the HIPAA Privacy Regulations

Mentor Corporation is aware of the many legal responsibilities of and the challenges faced by health care providers with respect to protecting the privacy of patient information, including complying with the HIPAA Privacy Regulations. Mentor has reviewed the HIPAA Privacy Regulations with outside legal counsel and has concluded that Mentor is not a "business associate" of its customers in the above-described situations because Mentor is not performing services, functions or activities for or on behalf of its customers. The definitions in the HIPAA Privacy Regulations make clear that medical device manufacturers are not considered "business associates" in their capacity as sponsors of clinical research. This also applies when Mentor is conducting FDA-required retrospective studies. Similarly, when one of Mentor's customers provides patient health information to a Mentor Representative so that Mentor can provide a product replacement, handle a product warranty claim, or provide other information about its products, the disclosure of information concerns the treatment of the patient and Section 164.502(e) of the HIPAA Privacy Regulations specifically excludes such disclosures from the business associate contract requirements.

Mentor Representatives may also inadvertently view or overhear patient health information when they visit a customer's site. When this occurs, Mentor Representatives are not materially different from other office visitors who may be inadvertently exposed to patient health information such as cleaning staff or patients. The Department of Health and Human Services has recently indicated that such disclosures are permissible under the HIPAA Privacy Regulations and it merely expects healthcare providers to take reasonable steps to minimize such inevitable exposures. In any event, a business associate relationship is not created by such inadvertent disclosures.

Mentor's Commitment to Privacy

Even though Mentor is not acting as a business associate of its customers when Mentor Representatives are engaged in the activities discussed above, Mentor is committed to assisting its customers in protecting the privacy of patient information and in complying with laws concerning the use and disclosure of patient health information. Therefore, Mentor's policy is to keep confidential and not disclose any patient information that it receives from its customers, except as permitted or required by law.



Compliance Officer