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HIPAA and Disclosure of Protected Health Information

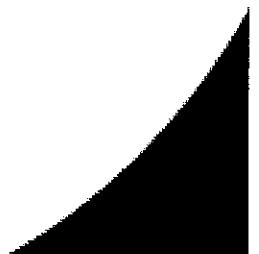
Dear DJO Customers:

As a “covered entity” under HIPAA, DJO LLC has taken the necessary steps to understand our legal responsibilities to OfficeCare customers in respect to the Privacy Rule. The Privacy Rule does not require patient consent for the disclosure of Protected Health Information (PHI) to another covered entity for purposes of treatment, payment and certain health care operations. OfficeCare customers and DJO LLC are both covered entities and may share PHI for these purposes without a Business Associate Agreement. Attached is a document from the Questions and Answers section on the Centers for Medicare and Medicaid Services (CMS) HIPAA website that further clarifies this information.

If you have any questions or concerns about the Privacy Rule and how it applies to our relationship with you, you may contact us or, of course, consult with your own legal counsel.

Sincerely,


Dale Hammer
VP, Corporate Compliance
Privacy Officer
DJO, LLC




Answer ID
490

Category
Privacy of Health Information/HIPAA
Business Associates
Public Health Uses and Disclosures
Treatment/Payment/Health Care Operations

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 **Print Answer**

 **E-mail Answer**

Is an authorization or business associate agreement needed to share information with a medical device company?

Question

When may a covered health care provider disclose protected health information, without an authorization or business associate agreement, to a medical device company representative?

Answer

In general, and as explained below, the Privacy Rule permits a covered health care provider (covered provider), without the individual's written authorization, to disclose protected health information to a medical device company representative (medical device company) for the covered provider's own treatment, payment, or health care operation purposes (45 CFR 164.506(c)(1)), or for the treatment or payment purposes of a medical device company that is also a health care provider (45 CFR 164.506(c)(2), (3)). Additionally, the public health provisions of the Privacy Rule permit a covered provider to make disclosures, without an authorization, to a medical device company or other person that is subject to the jurisdiction of the Food and Drug Administration (FDA) for activities related to the quality, safety, or effectiveness of an FDA-regulated product or activity for which the person has responsibility. See 45 CFR 164.512(b)(1)(iii) and the frequently asked questions on public health disclosures for more information.

In certain situations, a covered health care provider may disclose protected health information to a medical device company without an individual's written authorization only if the medical device company is a health care provider as defined by the Rule. A medical device company meets the Privacy Rule's definition of "health care provider" if it furnishes, bills, or is paid for "health care" in the normal course of business. "Health care" under the Rule

means care, services or supplies related to the health of an individual. Thus, a device manufacturer is a health care provider under the Privacy Rule if it needs protected health information to counsel a surgeon on or determine the appropriate size or type of prosthesis for the surgeon to use during a patient's surgery, or otherwise assists the doctor in adjusting a device for a particular patient. Similarly, when a device company needs protected health information to provide support and guidance to a patient, or to a doctor with respect to a particular patient, regarding the proper use or insertion of the device, it is providing

"health care" and, therefore, is a health care provider when engaged in these services. See 65 FR 82569. By contrast, a medical device company is not providing "health care" if it simply sells its appropriately labeled products to another entity for that entity to use or dispense to individuals.

*The following are some examples of circumstances in which a covered provider may share protected health information with a medical device company, without the individual's authorization:

.A covered provider may disclose protected health information needed for an orthopaedic device manufacturer or its representative to determine and deliver the appropriate range of sizes of a prosthesis for the surgeon to use during a particular patient's surgery .(This would be a treatment disclosure to the device company as a health care provider. Exchanges of protected health information between health care providers for treatment of the individual are not subject to the minimum necessary standards. 45 CFR 164.502(b).) .The device manufacturer or its representative may be present in the operating room, as requested by the surgeon, to provide support and guidance regarding the appropriate use, implantation, calibration or adjustment of a medical device for that particular patient. (This would be treatment by the device company as a health care provider. As noted in the prior example, treatment disclosures between health care providers are not subject to the minimum necessary

standards.)

.A covered provider may allow a representative of a medical device manufacturer to view protected health information, such as films or patient records, to provide consultation, advice or assistance where the provider, in her professional judgment, believes that this will assist with a particular patient's treatment. (This would also be a treatment disclosure and minimum necessary would not apply.)

*.A covered provider may share protected health information with a medical device company as necessary for the device company to receive payment for the health care it provides. (This would be a disclosure for payment of a health care provider and subject to minimum necessary standards.)

.A covered provider may disclose protected health information to a medical device manufacturer that is subject to FDA jurisdiction to report an adverse event, to track an FDA-regulated product, or other purposes related to the quality, safety, or effectiveness of the FDA-regulated product. (This would be a public health disclosure and subject to minimum necessary standards.)

A business associate agreement would not usually be required for the disclosures noted above. For example, a business associate agreement would not be needed for disclosures between health care providers for the treatment of the individual (45 CFR 164.502(e)(1)(ii)(A)). Likewise, a medical device company would not be a business associate of a covered provider with respect to public health disclosures to a device company that is subject to FDA jurisdiction or disclosures to a device company as a health care provider for that company's payment purposes, as in neither case is the device company performing a function or activity on behalf of, nor providing a specified service to, the covered provider. See 45 CFR 160.103. In other circumstances, however, a business associate agreement may be required even if the disclosure were permitted without an

authorization. For example, a business associate agreement would be required if a covered entity asked the medical device company to provide an estimate of the cost savings it might expect from the use of a particular medical device; and to do so, the device company needed access to the covered entity's protected health information. In this case, the medical device company is performing a health care operations function (business planning and development) on behalf of the covered provider, which requires a business associate agreement even though the disclosure is permitted without an authorization.

How well did this answer your question?

- Very Helpful
- Somewhat Helpful
- Not Helpful

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- May health care providers provide information requested by a health plan for HEDIS purposes?
- When is a researcher a covered health care provider under HIPAA?
- During the business associate agreement transition period, what are the covered entity's obligations?

Bottom of Form