

RE: Zimmer Biomet is Not a Business Associate of Providers for its Treatment Activities under HIPAA and HITECH

Dear Zimmer Biomet Customer:

This letter responds to your request that Zimmer US, Inc. and Biomet, Inc. (“Zimmer Biomet”) execute a business associate agreement. Zimmer Biomet specializes in the design and manufacture of orthopedic products in addition to offering personalized, patient-specific products used by healthcare providers during the course of a patient’s treatment. Zimmer Biomet receives protected health information in connection with the ordering of these personalized, patient-specific products, and when Zimmer Biomet representatives provide consultations, including in the operating room, to assist physicians with the safe and effective use of Zimmer Biomet products for a specific patient. The Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and the Health Information Technology for Economic and Clinical Health (“HITECH”) provisions of the American Recovery and Reinvestment Act of 2009 (“ARRA”) make clear that disclosures of protected health information to Zimmer Biomet for these purposes are permissible and a business associate agreement is not required.

Under HIPAA, a health care provider is permitted to disclose protected health information for its own treatment activities or the treatment activities of another health care provider. 45 C.F.R. § 164.506(c)(1)-(2). These disclosures do not require a business associate agreement. Specifically, the Privacy Rule states that the term “[b]usiness associate does not include [a] health care provider, with respect to disclosures by a covered entity to the health care provider concerning the treatment of the individual.” 45 C.F.R. § 160.103. The preamble to the Privacy Rule further states that “[w]ith respect to business associate contracts between health care providers, the Privacy Rule explicitly excepts from the business associate agreements disclosures by a covered entity to a health care provider for treatment purposes.” 67 Fed. Reg. 53,182, 53,252 (Aug. 14, 2002). “Therefore, any covered health care provider (or other covered entity) may share protected health information with a health care provider for treatment purposes without a business associate contract.” *Id.*

Zimmer Biomet is considered a health care provider under HIPAA. HIPAA broadly defines a “health care provider” as a “person or organization who furnishes, bills, or is paid for health care in the normal course of business.” 45 C.F.R. § 160.103. “Health care” is defined as “care, services, or supplies related to the health of an individual.” *Id.* Zimmer Biomet, like other medical device manufacturers, furnishes and is paid in the normal course of business for supplies related to the health of individuals. Therefore, Zimmer Biomet is a health care provider under the Privacy Rule.

Furthermore, in a frequently asked question (“FAQ”) guidance, the Department of Health and Human Services (“HHS”) concludes that a device manufacturer is a health care provider “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.” *See FAQ entitled “When may a covered health care provider disclose protected health information, without an authorization or business associate agreement, to a medical device company representative?” available at [http://www.hhs.gov/ocr/privacy/hipaa/faq/business associates/490.html/](http://www.hhs.gov/ocr/privacy/hipaa/faq/business%20associates/490.html/).*

In the FAQ, HHS also concludes that a device manufacturer is a health care provider, when it “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.” In addition, covered entities “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.” A representative of a device manufacturer also “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 [a] particular patient.” HHS states clearly that a business associate agreement is not required for covered entities to disclose protected health information to device manufacturers for these purposes.

A covered entity also may disclose protected health information to a provider for the provider to obtain payment for health care services. Specifically, the Privacy Rule states that “[a] covered entity may disclose protected health information to another covered entity or a health care provider for the payment activities of the entity that receives the information.” 45 C.F.R. § 164.506(c)(3). This is further confirmed with regard to device manufacturers in the FAQ which states that “[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.” *See FAQ.*

Accordingly, Zimmer Biomet is considered a health care provider for purposes of the Privacy Rule when it receives protected health information in connection with the ordering and development of personalized patient-specific products or when Zimmer Biomet provides guidance or support regarding the proper use of its products for a specific patient (either in the operating room or otherwise). The Privacy Rule and the FAQ make clear that disclosures of protected health information to Zimmer Biomet for these purposes are permissible treatment disclosures specifically exempt from the business associate requirements. Covered entities also are permitted, without a business associate agreement, to disclose protected health information to Zimmer Biomet as necessary for Zimmer Biomet to obtain payment for the services it provides.

If, after consulting with your counsel or any other person, you have any questions, comments or would simply like to discuss this matter, please do not hesitate to contact me.

Very truly yours,



Peggy L. Bodin, Esq.
Global Privacy Officer