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Date

Name

Title

Facility

Address

Address

Dear (Mr. Ms.)(Name):

On behalf of DJO, LLC ("DJO"), I am writing in response to your letter requesting that DJO enter into a business associate agreement with [name of customer ("SHORT NAME")] for purposes of compliance with the HIPAA Privacy and Security Rules issued by the Department of Health and Human Services pursuant to the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health ("HITECH") Act (Division A, Title XIII and Division B, Title IV of Pub. L. 111-5) (collectively, "HIPAA").

As described below (as well as in the enclosed Question and Answer document from the Department of Health and Human Services' Health Information Privacy website), it is not necessary for DJO, a medical device company, and [short name of customer], a covered health care provider, to enter into a business associate agreement prior to exchanging PHI.

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 [Privacy] 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.

– U.S. Department of Health & Human Services

DJO is considered a health care provider under the Privacy Rule in that it furnishes, bills and is paid for its "service" (i.e., medical devices). DJO is also a HIPAA Covered Entity, and, as such, complies with the HIPAA regulations, and maintains and enforces the privacy and security policies required under HIPAA. Notwithstanding the fact that DJO is itself a Covered Entity, the Privacy Rule permits a Covered Entity such as [short name of customer] to disclose PHI *without* a business associate agreement, even to a non-Covered Entity, in furtherance of providing treatment to, or seeking payment from, a mutual patient.

Treatment Related Disclosures

The Privacy Rule and the enclosed HHS guidance make clear that disclosures of PHI to DJO representatives who are providing support and guidance involving the use of a DJO

DJO, LLC
1430 Decision Street
Vista, CA 92081-8533

760.727.1280
800.321.9549 toll free
www.djortho.com



product are treatment-related disclosures that do not require patient authorization. Covered entities, such as [short name of hospital/customer], can continue to have DJO representatives perform these functions without predicating such participation on the execution of a business associate agreement.

A covered provider may allow a representative of a medical device manufacturer to view protected health information [without the individual's authorization]...to provide consultation, advice or assistance...[to] assist with a particular patient's treatment.

– U.S. Department of Health & Human Services

Payment Related Disclosures

Furthermore, [short name of customer] may share PHI with a medical device company, such as DJO, as necessary for the device company to receive payment for the health care it provides.

A covered provider may share protected health information with a medical device company as necessary for the device company to received payment for the health care it provides.

– U.S. Department of Health & Human Services

We value your business and hope that this information demonstrates to your satisfaction that there is no need for DJO and [short name of customer] to have a business associate agreement in order to commence or continue with our business relationship. Should you have any questions or concerns, please do not hesitate to contact me at (760) 734-5641. For your information, enclosed is a copy of our notice of privacy practices, which is also located on our website at www.djoglobal.com.

Sincerely,

Kristina Cocita, CP
Compliance Paralegal

Encl (2): U.S. Department of Health & Human Services FAQ's
Notice of Privacy Practices

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U.S. Department of Health & Human Services

Improving the health, safety, and well-being of America

Health Information Privacy

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.

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U.S. Department of Health & Human Services • 200 Independence Avenue, S.W. • Washington, D.C. 20201

NOTICE OF PRIVACY PRACTICES For DJO, LLC

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

If you have any questions about this Notice please contact our Privacy Officer: Dale Hammer (800) 551-6911 Ext. 4742

DJO is committed to protecting your privacy and understands the importance of safeguarding your medical information. We are required by federal law to maintain the privacy of health information that identifies you or that could be used to identify you (known as "Protected Health Information" or "PHI"). We also are required to provide you with this Notice of Privacy Practices, which explains our legal duties and privacy practices, as well as your rights, with respect to PHI that we collect and maintain. DJO is required by federal law to abide by this Notice. However, we reserve the right to change the privacy practices described in this Notice and make the new practices effective for all PHI that we maintain. Should we make such a change, you may obtain a revised Notice by calling our office and requesting a revised copy be sent in the mail, or accessing our website at www.djortho.com.

USES AND DISCLOSURES OF PROTECTED HEALTH INFORMATION

A. Routine Uses and Disclosures of Protected Health Information

We are permitted under federal law to use and disclose PHI, without your written authorization, for certain routine uses and disclosures, such as those made for treatment, payment, and the operation of our business. The following are examples of the types of routine uses and disclosures of PHI that we are permitted to make. While this list is not exhaustive, it should give you an idea of the routine uses and disclosures we are permitted to make.

For Treatment: We will use and disclose your PHI to provide, coordinate, or manage your treatment. For example, we will disclose your PHI, as necessary, to the physician that referred you to us.

For Payment: Your PHI will be used, as needed, to obtain payment for the health care services we provide you. For example, we may tell your health plan about an orthotic device you will receive to determine whether your plan will cover the device.

For Health Care Operations: We may use or disclose your PHI in order to support the business activities of this facility. These activities include, but are not limited to, quality assessment, employee review, legal services, licensing, and conducting or arranging for other business activities.

Treatment Alternatives: We may use or disclose your PHI or contact you to provide you with information about treatment alternatives or other health-related benefits and services that may be of interest to you.

Sale of the Business: If we decide to sell, transfer or merge all or part of our business to or with another entity, we may share your PHI with the new owners.

B. Uses and Disclosures That May Be Made Without Your Authorization or Opportunity to Object

We may use or disclose your PHI in the following situations without your authorization or providing you the opportunity to object.

Required by the Secretary of Health and Human Services: We may be required to disclose your PHI to the Secretary of Health and Human Services to investigate or determine our compliance with the requirements of the final rule on Standards for Privacy of Individually Identifiable Health Information.

Required By Law: We may use or disclose your PHI to the extent that the use or disclosure is otherwise required by federal, state or local law.

Public Health: We may disclose your PHI for public health activities, such as disclosures to a public health authority or other government agency that is permitted by law to collect or receive the information (e.g., the Food and Drug Administration).

Health Oversight: We may disclose PHI to a health oversight agency for activities authorized by law, such as audits, investigations, and inspections. Oversight agencies include government agencies that oversee the health care system, government benefit programs, other government regulatory programs and civil rights laws.

Abuse or Neglect: If you have been a victim of abuse, neglect, or domestic violence, we may disclose your PHI to a government agency authorized to receive such information. In addition, we may disclose your PHI to a public health authority that is authorized by law to receive reports of child abuse or neglect.

Judicial and Administrative Proceedings: We may disclose your PHI in response to an order of a court or administrative tribunal (to the extent such disclosure is expressly authorized), and, in certain conditions, in response to a subpoena, discovery request or other lawful process.

Law Enforcement: We may disclose your PHI, so long as applicable legal requirements are met, for law enforcement purposes, such as providing information to the police about the victim of a crime.

Coroners and Funeral Directors: We may disclose your PHI to a coroner, medical examiner, or funeral director if it is needed to perform their legally authorized duties.

Organ Donation: If you are an organ donor, we may disclose your PHI to organ procurement organizations as necessary to facilitate organ donation or transplantation.

Research: Under certain circumstances, we may disclose your PHI to researchers when their research has been approved by an institutional review board that has reviewed the research proposal and established protocols to ensure the privacy of your PHI.

Serious Threat to Health or Safety: We may disclose your PHI if we believe it is necessary to prevent a serious and imminent threat to the public health or safety and it is to someone we reasonably believe is able to prevent or lessen the threat.

Specialized Government Functions: When the appropriate conditions apply, may disclose PHI for purposes related to military or national security concerns, such as for the purpose of

a determination by the Department of Veterans Affairs of your eligibility for benefits.

Workers' Compensation: We may disclose your PHI as necessary to comply with workers' compensation laws and other similar programs.

Inmates: We may use or disclose your PHI if you are an inmate of a correctional facility and we created or received your PHI in the course of providing care to you.

C. Uses and Disclosures That May Be Made Either With Your Agreement or the Opportunity to Object

Unless you object, we may disclose to a member of your family, a relative, a close friend or any other person you identify, orally or in writing, your PHI that directly relates to that person's involvement in your health care. If you are unable to agree or object to such disclosure, we may disclose such information as necessary if we determine that it is in your best interest based on our professional judgment. We may use or disclose your PHI to notify or assist in notifying a family member, personal representative or any other person that is responsible for your care of your location or general condition.

D. Uses and Disclosures of Protected Health Information Based upon Your Written Authorization

Other uses and disclosures of your PHI, not described above, will be made only with your written authorization. You may revoke your authorization, at any time, in writing, except to the extent that we have taken action in reliance on the authorization.

YOUR RIGHTS REGARDING HEALTH INFORMATION ABOUT YOU

You have certain rights regarding your PHI, which are explained below. You may exercise these rights by submitting a request in writing to our Privacy Officer.

A. You have the right to inspect and copy your PHI. If you would like to see or copy your PHI that is contained in a designated record set (e.g., medical and billing records), we are required to provide you access to such PHI for inspection and copying within 30 days after receipt of your request (60 days if the information is stored off-site). We may charge you a reasonable fee to cover duplication, mailing and other costs incurred by us in complying with your request. In addition, there are situations where we may deny your request for access to your PHI. For example, we may deny your request if we believe the disclosure will endanger your life or that of another person. Depending on the circumstances of the denial, you may have a right to have this decision reviewed.

B. You have the right to request a restriction of your PHI. This means you may ask us not to use or disclose any part of your PHI for purposes of treatment, payment or health care operations. You may also request that any part of your PHI not be disclosed to family members or friends who may be involved in your care or for notification purposes as described in this Notice. Your request must state the specific restriction requested and to whom you want the restriction to apply. We are not required to agree to a restriction that you may request. If we agree to the requested restriction, we may not use or disclose your PHI in violation of that restriction unless it is needed to provide emergency treatment.

C. You have the right to request to receive confidential communications from us by alternative means or at an alternative location. We will accommodate reasonable requests. We may also condition this accommodation by asking

you for information as to how payment will be handled or specification of an alternative address or other method of contact.

D. You have the right to amend your PHI. This means you may request an amendment of your PHI in our records that is contained in a designated record set (e.g., medical and billing records) for as long as we maintain the PHI. We will respond to your request within 60 days (with up to a 30-day extension if needed). We may deny your request if, for example, we determine that your PHI is accurate and complete. If we deny your request, we will send you a written explanation and allow you to submit a written statement of disagreement.

E. You have the right to receive an accounting of certain disclosures that we have made of your PHI. You have the right to receive an accounting of certain disclosures we have made, if any, of your PHI. This right only applies to disclosures for purposes other than treatment, payment or health care operations as described in this Notice. It also excludes disclosures we may have made to you, your family members or friends involved in your care. The right to receive this information is subject to certain exceptions, restrictions and limitations. You must specify a time period, which may not be longer than 6 years and cannot include any date before April 14, 2003. You may request a shorter timeframe. You have the right to one free request within any 12-month period, but we may charge you for any additional requests in the same 12-month period. We will notify you about any such charges, and you are free to withdraw or modify your request in writing before any charges are incurred.

D. You have the right to obtain a paper copy of this notice from us.

COMPLAINTS

If you believe that we have violated your privacy rights, you may file a complaint with us by notifying our Privacy Officer in writing at the following address:

DJO, LLC
1430 Decision Street
Vista, CA 92081
Attn: Dale Hammer

We will not retaliate against you in any way for filing a complaint. You may also submit your complaint to the Secretary of Health and Human Services.

This is a revision to a notice that was first published and effective April 14, 2003. This notice is effective on **October 1, 2004.**