

THE NEW HIPAA RULES AND WHAT THEY MEAN FOR MEDICAL DEVICE DISTRIBUTORS

Barbara Kramer, Esq.
bkramer@kramerandkramer.com

Mitchell A. Kramer, Esq.
mkramer@kramerandkramer.com

On January 25, 2013, the U.S. Department of Health & Human Services (“HHS”) published its final rule regarding revisions to HIPAA.¹ The new HIPAA rules have implications for distributors, especially distributors that are already parties to business associate agreements; distributors using independent or sub-contractors to perform services on behalf of a health care providers; and distributors that otherwise receive, maintain, or transmit protected health information (PHI).

As discussed below, most distributors will still not be considered “business associates” under the new rules. However, the rules expand the situations where distributors could be considered a business associate. And for those businesses that are already parties to business associate agreements, the new regulations impose additional requirements when sub-contracting.

The new HIPAA regulations clarify that when disclosing information to a “health care provider” about the treatment of an individual, the healthcare provider is not regarded as a business associate of the covered entity. Because companies that furnish, bill, or are paid for “health care” are actually considered health care providers, for purposes of HIPAA, they are generally exempt from the HIPAA requirements concerning business associate agreements.

Generally, HIPAA allows a covered health care provider, without an individual’s authorization, to disclose PHI to a medical device company representative for the covered provider’s own treatment, payment, or health care operation purposes, or for the treatment or payment purposes of a company that is also a health care provider.

A company acts as a “health care provider” if it furnishes, bills, or is paid for “health care” in the normal course of business. Medical device manufactures are considered health care providers under HIPAA if they need PHI to counsel a doctor or determine the proper type or size of device needed for a patient or assist the doctor in adjusting a device

¹ The final rule is entitled *Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act* [“HITECH”] and the *Genetic Information Nondiscrimination Act* [“GINA”]; *Other Modifications to HIPAA Rules*. The final rule as published in the Federal Register may be accessed here: <http://www.gpo.gov/fdsys/pkg/FR-2013-01-25/pdf/2013-01073.pdf> .

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for a particular patient. In this type of scenario “a business associate agreement would not be needed for disclosures between health care providers for the treatment of the individual.”

In 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. In this instance, a business associate agreement would be required for the disclosure of any PHI. Likewise, 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.

Obligations of Business Associates

Business associates have the following responsibilities:

- Enter into contracts with subcontractors that comply with the Privacy and Security Rules;
- Keep records and submit compliance reports to HHS, when HHS requires disclosures to investigate the business associates’ compliance with HIPAA, and to cooperate with complaint investigations and compliance reviews;
- Make reasonable efforts to limit the use and disclosure of PHI;
- Notify a covered entity of any breaches of unsecured PHI;
- Disclose PHI as needed by a covered entity to comply with an individual’s request for an electronic copy of the PHI; and
- Provide accountings of disclosures of individuals’ PHI.

Existing Business Associate Agreements

The final rule adopts new transition provisions to allow covered entities and business associates (and business associates and business associate subcontractors) to continue to operate under certain existing contracts for up to one year beyond the compliance date of the final rule. In other words, existing agreements are grandfathered in for a period of one year after the compliance date, which is September 23, 2013, to permit amendments to comply with the final regulations.

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800-451-7466

WWW.KRAMERANDKRAMER.COM

Contacts

Please contact Barbara Kramer or Mitchell Kramer if you have questions or would like additional information.

Barbara Kramer

(734) 821-1055

bkramer@kramerandkramer.com

Mitchell A. Kramer

(215) 887-9030

mkramer@kramerandkramer.com

800-451-7466

www.kramerandkramer.com

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